IQTIG Institut für Qualitätssicherung und Transparenz im Gesundheitswesen

Versorgung mit implantierten Herzschrittmachern und Defibrillatoren

Weiterentwicklungsstudie

Anhang zum Abschlussbericht

31. März 2023, erstellt im Auftrag des Gemeinsamen Bundesausschusses

Informationen zum Bericht

BERICHTSDATEN

Versorgung mit implantierten Herzschrittmachern und Defibrillatoren. Weiterentwicklungsstudie. Anhang zum Abschlussbericht

Ansprechperson	Dr. Silvia Klein
Datum der Abgabe	31. März 2023

AUFTRAGSDATEN

Auftraggeber	Gemeinsamer Bundesausschuss (G-BA)
Name des Auftrags	Erstellung einer Weiterentwicklungsstudie für ein Qualitätssicherungsverfahren Versorgung mit implantierten Herzschrittmachern und Defibrillatoren
Datum des Auftrags	18. März 2022

Inhaltsverzeichnis

Anhang A: Recherchebericht

Anhang B: Charakteristika der eingeschlossenen Leitlinien

Anhang B.1: Charakteristika der eingeschlossenen Leitlinien

Anhang B.2: Evidenz- und Empfehlungsgrade der eingeschlossenen Leitlinien

Anhang B.3: Literaturextraktion

Anhang B.4: Orientierende Recherche

Anhang C: Experteninterviews

Anhang C.1: Leitfaden für Experteninterviews

Anhang C.2: Kurzbeschreibung Interviewpartnerinnen und -partner

Anhang D: GOP- und OPS-Kodes

Anhang D.1: Zuordnung der OPS-Kodes zu den GOP

Anhang D.2: Zuordnung der OPS-Kodes 5-377.** zu den Devices

Anhang D.3: Zuordnung der OPS-Kodes 5-378.** zu den Folgeeingriffen

Anhang A: Recherchebericht

Inhaltsverzeichnis

Tabellenverzeichnis 2
Abbildungsverzeichnis 3
1 Ziel der Literaturrecherche 4
1.1 Zielsetzung der Beauftragung 4
1.2 Präzisierung der Fragestellungen 4
2 Informationsbeschaffung – Leitlinien 6
2.1 Recherche 6
2.2 Eingeschlossene Leitlinien 9
2.2.1 Leitlinienbewertung 10
2.2.2 Datenextraktion 11
2.3 Ausgeschlossene Leitlinien 11
3 Informationsbeschaffung – Versorgungssituation 14
3.1 Recherche 14
3.2 Eingeschlossene Publikationen zum Thema Versorgungssituation 23
3.2.1 Datenextraktion 29
3.3 Ausgeschlossene Publikationen zum Thema Versorgungssituation 29
4 Informationsbeschaffung – patientenrelevante Themen 39
4.1 Recherche 39
4.2 Eingeschlossene Studien zu patientenrelevanten Themen 46
4.3 Datenextraktion 50
4.4 Ausgeschlossene Studien zu patientenrelevanten Themen 51
Literatur 63

Tabellenverzeichnis

Tabelle 1: PICO-Schema 4
Tabelle 2: Einschlusskriterien für Leitlinien 6
Tabelle 3: Eingeschlossene Leitlinien 9
Tabelle 4: AGREE-II-Bewertung der eingeschlossenen Leitlinien 10
Tabelle 5: Einschlusskriterien für Versorgungssituation 14
Tabelle 6: Suchstrategie für MEDLINE via Ovid (Thema Versorgungssituation) 15
Tabelle 7: Suchstrategie für Embase via Elsevier (Thema Versorgungssituation) 17
Tabelle 8: Suchstrategie für CINAHL via EBSCO (Thema Versorgungssituation) 18
Tabelle 9: Suchstrategie für Cochrane via Wiley (Thema Versorgungssituation) 21
Tabelle 10: Eingeschlossene Artikel zum Thema Versorgungssituation 23
Tabelle 11: Einschlusskriterien für Publikationen zu patientenrelevanten Themen 39
Tabelle 12: Suchstrategie für MEDLINE via Ovid (patientenrelevante Themen) 41
Tabelle 13: Suchstrategie für Cochrane via Wiley (patientenrelevante Themen) 42
Tabelle 14: Suchstrategie für Embase via Elsevier (patientenrelevante Themen) 43
Tabelle 15: Suchstrategie für CINAHL via EBSCO (patientenrelevante Themen); Datum der Recherche: 18. Mai 2022 44
Tabelle 16: Eingeschlossene Publikationen zu patientenrelevanten Themen 46

Abbildungsverzeichnis

Abbildung 1: Flussdiagramm der Recherche nach Leitlinien 9
Abbildung 2: Flussdiagramm der Recherche nach systematischen Reviews zum Thema Versorgungssituation 23
Abbildung 3: Flussdiagramm der Recherche nach Studien zu patientenrelevanten Themen 46

1 Ziel der Literaturrecherche

1.1 Zielsetzung der Beauftragung

Der Gemeinsame Bundesausschuss (G-BA) hat in seiner Sitzung am 20. Januar 2022 beschlossen, das IQTIG im Rahmen seiner Aufgaben nach § 137a Abs. 3 SGB V mit der Entwicklung einer Weiterentwicklungsstudie für ein Qualitätssicherungsverfahren (QS-Verfahren) zur Versorgung mit implantierten Herzschrittmachern und Defibrillatoren zu beauftragen. Die Weiterentwicklungsstudie soll als Entscheidungsgrundlage für einen weiteren Entwicklungsauftrag dienen.

1.2 Präzisierung der Fragestellungen

Ausgehend vom Ziel der Literaturrecherche erfolgte zunächst die Operationalisierung in strukturierte, recherchierbare Fragen für die systematische Recherche sowie eine Unterteilung der Informationsbeschaffungen:

1. Informationsbeschaffung – Standards/Leitlinien
   - Welche Kriterien beschreiben die Qualität der Nachsorge von erwachsenen Patientinnen und Patienten (ab 18 Jahre) mit implantierten Herzschrittmachern und Defibrillatoren?
2. Informationsbeschaffung – Versorgungssituation in Deutschland
   - Wie sieht die Versorgungssituation von Patientinnen und Patienten aller Altersgruppen mit implantierten Herzschrittmachern und Defibrillatoren in Deutschland aus? Welche Defizite und Potentiale bestehen bei der Versorgung von Patientinnen und Patienten mit implantierten Herzschrittmachern und Defibrillatoren?
3. Informationsbeschaffung – Patientenperspektive
   - Wie erleben die Patientinnen und Patienten aller Altergruppen mit implantierten Herzschrittmachern und Defibrillatoren die Versorgung?

Tabelle 1: PICO-Schema

P	Patientinnen und Patienten mit Rhythmusimplantaten (cardiac implantable electronic devices): ▪ Herzschrittmacher (pacemaker) ▪ Implantierbare Defibrillatoren (implantable defibrillator cardioverter, ICD, subkutan und substernal) ▪ Geräte zur kardialen Resynchronisationstherapie (cardiac resynchronization therapy, CRT-Devices))
I/C	Ambulante oder stationäre Versorgung oder Notfallversorgung
O	Patientenrelevante und –beurteilbare Themen sowie Hinweise auf Qualitätsdefizite, bzw. Verbesserungsbedarfe, die im Zusammenhang mit der Versorgung von Rhythmusimplantaten stehen.

Passend zur Art der geplanten Evidenzaufbereitung wurden vorab für alle Fragestellungen

- die inhaltlichen Ein- und Ausschlusskriterien (z. B. Population, Indikation, Intervention, Endpunkte),
- die methodisch-formalen Ein- und Ausschlusskriterien (z. B. Studien- bzw. Leitlinientyp) sowie
- die Datenquellen (z. B. bibliographische Datenbanken wie MEDLINE/Embase, Leitliniendatenbanken)

definiert.

2 Informationsbeschaffung – Leitlinien

Um die aktuell empfohlenen Standards für die Nachsorge von erwachsenen Patientinnen und Patienten (ab 18 Jahre) mit implantierten Herzschrittmachern und Defibrillatoren zu identifizieren, sollte eine Recherche nach deutschen und internationalen Leitlinien durchgeführt werden.

2.1 Recherche

Es erfolgte eine systematische Recherche nach themenspezifischen Leitlinien in den gängigen Leitliniendatenbanken sowie bei fachübergreifenden bzw. fachspezifischen Leitlinienanbietern. In Tabelle 2 sind die a priori definierten Einschlusskriterien, die dem Screening der Leitlinien zugrunde lagen, aufgeführt.

Tabelle 2: Einschlusskriterien für Leitlinien

E1	Die Publikation ist eine Leitlinie und als Vollpublikation verfügbar.
E2	Die Publikationssprache der gesamten Leitlinie ist Deutsch oder Englisch.
E3	Die Leitlinie ist aktuell und gültig (Publikationsdatum bzw. letzte Überprüfung ab 1. April 2017).
E4	Die Referenz ist keine Mehrfachpublikation.
E5	Die Leitlinie gibt eindeutig identifizierbare Empfehlungen und ist evidenzbasiert (mindestens S2e oder äquivalent).
E6	Die Leitlinie ist aus Deutschland oder aus 8 Ländern der OECD. Deutschland, Australien, Kanada, Neuseeland, USA, Vereinigtes Königreich, Schweiz und Österreich
E7	Die Leitlinie enthält evidenzbasierte Empfehlungen von erwachsenen Patientinnen und Patienten (ab 18 Jahre) mit Rhythmusimplantaten (cardiac implantable electronic devices) bzw. bei denen ein Rhythmusimplantat eingesetzt wird: ▪ Herzschrittmacher (pacemaker) ▪ Implantierbare Defibrillatoren (implantable defibrillator cardioverter, ICD, subkutan und substernal) ▪ Geräte zur kardialen Resynchronisationstherapie (cardiac resynchronization therapy, CRT-Devices) Ausgeschlossen: ▪ Publikation adressiert ausschließlich Patienten mit CCM-Devices ▪ Publikation adressiert ausschließlich Patienten mit implantierten Ereignisrekordern ▪ Publikation adressiert ausschließlich Patienten mit temporären Schrittmachern
E8	Die Leitlinie enthält Empfehlungen zum Prozess der Nachsorge der implantierten Rhythmusimplantate. Die Implantatkontrolle beinhaltet z. B. ▪ Überprüfung der Funktionsfähigkeit des Systems

	▪ Individuelle Optimierung der programmierbaren Parameter ▪ Anpassung der zur Verfügung stehenden Diagnostik- und Therapieoptionen des Rhythmusimplantats an die klinische Situation ▪ Erkennen und Beheben von Fehlfunktionen ▪ Erkennen von Komplikationen ▪ Entscheidung über erforderliche Anpassung eines Rhythmusimplantats an die klinische Situation (Ein- bzw. Zweikammer-, CRT-System, Defibrillator) ▪ Festlegung des optimalen Austauschzeitpunktes eines Systems ▪ Optimierung der Device-Laufzeit

* Als Grundlage für die Entscheidung, welche internationalen Leitlinien eingeschlossen werden sollen, wurden die Mitgliedsstaaten der Organisation for Economic Co-operation and Development (OECD) herangezogen (OECD 2021: 23). Nur Leitlinien aus Industrienationen, die wie Deutschland zu den Mitgliedstaaten der OECD gehören, wurden berücksichtigt.

Die Recherche wurde national und international bei folgenden Leitliniendatenbanken bzw. fachübergreifenden und fachspezifischen Leitlinienanbietern durchgeführt.

Dabei wurden internationale Leitlinienquellen, die bereits in TRIP integriert sind, nicht erneut gesondert durchsucht.

Deutschland

- Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V. (AWMF): http://www.awmf.org/leitlinien/leitlinien-suche.html
- Nationale VersorgungsLeitlinien (NVL): http://www.leitlinien.de/nvl/
- Die Bundesärztekammer (BÄK): https://www.bundesaerztekammer.de/richtlinien/leitlinien/
- Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin (DEGAM): http://www.degam.de/leitlinien.html
- Zentrum für Qualität in der Pflege (Stiftung ZQP): https://lls.zqp.de/leitlinien.php
- Deutsches Netzwerk für Qualitätsentwicklung in der Pflege (DNQP): https://www.dnqp.de/expertenstandards-und-auditinstrumente/
- Deutschen Gesellschaft für Kardiologie – Herz- und Kreislaufforschung e.V (DGK): https://leitlinien.dgk.org/leitlinien/leitlinie/

International

- Turning Research Into Practice (Trip) Medical Database: https://www.tripdatabase.com/
- Bundesministerium Soziales, Gesundheit, Pflege und Konsumentenschutz (BMSGPK): https://www.sozialministerium.at/Themen/Gesundheit/Gesundheitssystem/Gesundheitssystem-und-Qualitaetssicherung/Qualitaetsstandards.html
- The Medical Journal of Australia (MJA) : https://www.mja.com.au/journal/guidelines
- World Health Organization (WHO): https://www.who.int/publications/i?publishingoffices=c09761c0-ab8e-4cfa-9744-99509c4d306b

- Canadian Medical Association (CMA): https://www.cma.ca/En/Pages/clinical-practice-guidelines.aspx
- Guideline Central: https://www.guidelinecentral.com/guidelines/specialty/cardiology/#
- National Institute for Health and Care Excellence (NICE): https://www.nice.org.uk/Guidance
- Scottish Intercollegiate Guidelines Network (SIGN): https://www.sign.ac.uk/our-guidelines/
- Ministry of Health (New Zealand): https://www.health.govt.nz/publications
- American College of Cardiology (ACC): https://www.acc.org/Guidelines
- American Heart Association (AHA): https://professional.heart.org/en/guidelines-and-statements/guidelines-and-statements-search
- British Cardiac Society (BCS): https://www.britishcardiovascularsociety.org/resources/publications-reports
- Canada Heart Rhythm Society (CHRS): https://www.chrsonline.ca/resources-publications/guidelines-clinical-updates
- European Association for Cardio-Thoraic Surgery (EACTS): https://www.eacts.org/resources/clinical-guidelines/
- European Society of Cardiology (ESC): https://www.escardio.org/Guidelines

Die einzelnen Suchstrategien wurden dem Aufbau der jeweiligen Website angepasst. So bieten sowohl Leitliniendatenbanken als auch einige fachübergreifende und fachspezifische Leitlinienanbieter die Möglichkeit der Suche nach Schlagwörtern bzw. eine Freitextsuche an. Bei Anbietern, bei denen keine Schlagwort- bzw. Freitextsuche möglich war, erfolgte die Identifizierung von Leitlinien über die Navigation, die Sitemap oder durch eine Suche nach „Leitlinie" bzw. „guideline" über die Suchfunktion der Website. Somit wurde in der Regel die gesamte Liste der veröffentlichten Leitlinien durchgesehen.

Folgende Suchstrategien wurden für die Leitliniendatenbanken verwendet:

- AWMF: alle aktuellen S2e- und S3-Leitlinien
- Trip Database: *cardiology*
- Canadian Medical Association (CMA): *cardio**
- Guideline Central: *Speciality: Cardiology*
- American Heart Association (AHA): *Anywhere in article-: defibrillator/pacemaker*

Die Recherchen wurde vom 12.–19. April 2022 durchgeführt.

Vom 30. August bis 5. September 2022 erfolgte eine Update-Recherche der Leitlinien. Dabei wurde bei den Webseiten bzw. Leitliniendatenbanken nach Leitlinien recherchiert, die in dem Jahr 2022 publiziert wurden. Es wurden die identischen Suchbegriffe und Kategorien ausgewählt, die bei der Leitlinienrecherche im April durchsucht wurden.

Die Titel der Leitlinien wurden von zwei Personen unabhängig voneinander hinsichtlich ihrer inhaltlichen Relevanz bezogen auf die a priori festgelegte Frage überprüft und ausgewählt. Uneinheitliche Bewertungen einer Leitlinie wurden diskutiert und für den Fall einer fehlenden Einigung wurde die Leitlinie für das Volltext-Screening eingeschlossen.

Die Volltexte der ausgewählten Leitlinien wurden von zwei Personen unabhängig voneinander dahingehend überprüft, ob die a priori festgelegten Einschlusskriterien (siehe Tabelle 2) zutreffen. Uneinheitliche Bewertungen wurden diskutiert und eine Einigung herbeigeführt. Es erfolgte eine Dokumentation des Volltext-Screenings und der Ausschlussgründe für alle ausgeschlossenen Leitlinien (siehe Abschnitt 2.3).

Eine Übersicht über die Recherche und die eingeschlossenen Leitlinien bietet das nachfolgende Flussdiagramm (Abbildung 1).

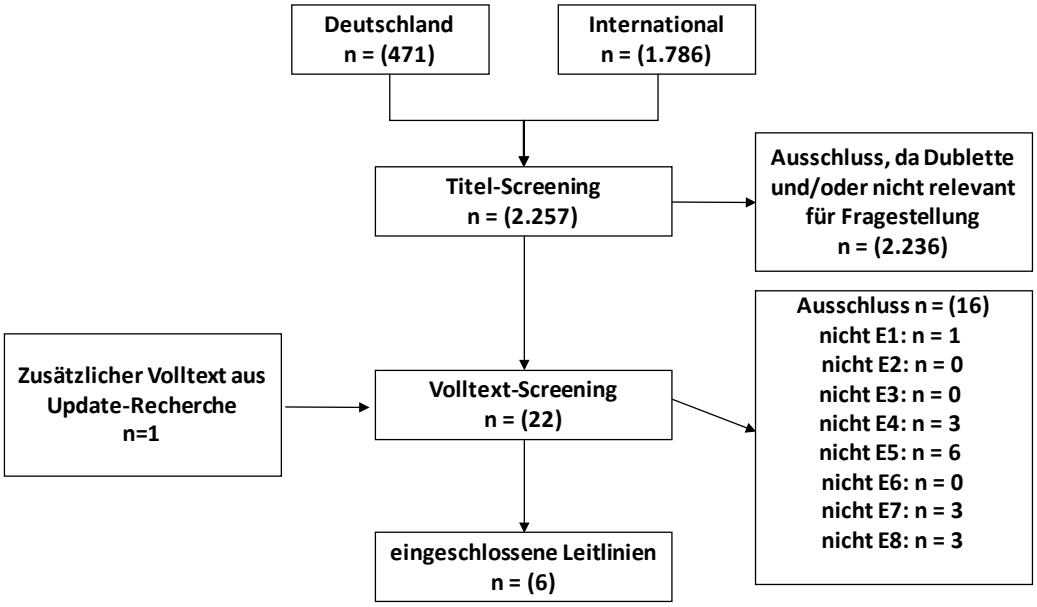

Abbildung 1: Flussdiagramm der Recherche nach Leitlinien

2.2 Eingeschlossene Leitlinien

Nach dem Volltext-Screening wurden 6 Leitlinien eingeschlossen (siehe Tabelle 3).

Tabelle 3: Eingeschlossene Leitlinien

	Leitlinie	Referenz
1	2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death	Al-Khatib et al. (2018)
2	AWMF-Registernummer nvl-006. Nationale VersorgungsLeitlinie: Chronische Herzinsuffizienz	BÄK et al. (2019)
3	2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) With the special contribution of the European Heart Rhythm Association (EHRA)	Glikson et al. (2021)

	Leitlinie	Referenz
4	2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay	Kusumoto et al. (2019)
5	2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure	McDonagh et al. (2021)
6	2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death	Zeppenfeld et al. (2022)

2.2.1 Leitlinienbewertung

Für eine kritische Bewertung der eingeschlossenen Leitlinien wurde das AGREE-II-Instrument verwendet (AGREE Next Steps Consortium 2017). Es besteht aus 23 Items, die sechs Domänen zugeordnet sind; welche die Qualität einer Leitlinie bestimmen:

- Domäne 1: Scope and Purpose
- Domäne 2: Stakeholder Involvement
- Domäne 3: Rigour of Development
- Domäne 4: Clarity of Presentation
- Domäne 5: Applicability
- Domäne 6: Editorial Independence

Daran angelehnt wurden die Leitlinien von zwei Personen unabhängig voneinander bewertet und auf die Domänen 2, 3 und 6 begrenzt. Die entsprechenden Items wurden auf einer Punkteskala von 1 (Strongly Disagree) bis 7 (Strongly Agree) bewertet. Bei Unstimmigkeiten von mehr als zwei Punkten wurde das Item von den bewertenden Personen diskutiert und ein finaler Konsens herbeigeführt. Daraus wird ein standardisierter Wert je Domäne errechnet, der dem prozentualen Anteil an der maximal erreichbaren Punktzahl je Domäne darstellt.

Damit deuten hohe standardisierte Domänenwerte auf eine hohe Qualität der Leitlinie hin und niedrige standardisierte Domänenwerte weisen auf eine geringe Qualität der Leitlinie hin. Die standardisierten Domänenwerte ermöglichen es, die verschiedenen Leitlinien hinsichtlich ihrer methodischen Qualität untereinander zu vergleichen.

Tabelle 4 stellt die AGREE-II-Bewertung der eingeschlossenen Leitlinien für die drei ausgewählten Domänen in Form der standardisierten Domänenwerte dar.

Tabelle 4: AGREE-II-Bewertung der eingeschlossenen Leitlinien

Leitlinie	Domäne 2	Domäne 3	Domäne 6
Al-Khatib et al. (2018)	36 %	58 %	75 %
BÄK et al. (2019)	94 %	90 %	96 %
Glikson et al. (2021)	28 %	28 %	67 %
Kusumoto et al. (2019)	44 %	48 %	71 %

Leitlinie	Domäne 2	Domäne 3	Domäne 6
McDonagh et al. (2021)	28 %	21 %	63 %
Zeppenfeld et al. (2022)	39 %	31 %	54 %

2.2.2 Datenextraktion

Die Datenextraktion der eingeschlossenen Leitlinien wurde von einer Person durchgeführt. Die Datenextraktion umfasst zum einen Leitliniencharakteristika wie Titel, Autorin/Autor, Publikationsjahr, Adressat sowie die Zielpopulation der Leitlinie (siehe Anhang B) und zum anderen die relevanten Empfehlungen mit ihren Evidenz- und Empfehlungsstärken.

2.3 Ausgeschlossene Leitlinien

Folgende im Volltext überprüfte Leitlinien wurden ausgeschlossen (für die Ausschlussgründe vgl. Tabelle 2):

Nicht E1

1. [ASA [American Society of Anesthesiologists] Task Force] (2020): Practice Advisory for the Perioperative Management of Patients with Cardiac Implantable Electronic Devices: Pacemakers and Implantable Cardioverter–Defibrillators 2020. An Updated Report by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Implantable Electronic Devices. Anesthesiology 132(2): 225-252. DOI: 10.1097/ALN.0000000000002821.

Nicht E2

Keine

Nicht E3

Keine

Nicht E4

1. Al-Khatib, SM; Stevenson, WG; Ackerman, MJ; Bryant, WJ; Callans, DJ; Curtis, AB; et al. (2018): 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death [Clinical Practice Guideline]. Circulation 138(13): e272-e391. DOI: 10.1161/CIR.0000000000000549.

2. Heidenreich, PA; Bozkurt, B; Aguilar, D; Allen, LA; Byun, JJ; Colvin, MM; et al. (2022): 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation, Epub 01.04.2022. DOI: 10.1161/CIR.0000000000001063.

3. Kusumoto, FM; Schoenfeld, MH; Barrett, C; Edgerton, JR; Ellenbogen, KA; Gold, M, R.; et al. (2019): 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With

Bradycardia and Cardiac Conduction Delay: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society [Clinical Practice Guideline]. Circulation 140(8): e382-e482. DOI: 10.1161/CIR.0000000000000628.

Nicht E5

1. AIM Specialty Health (2021): Appropriate Use Criteria: Cardiac Resynchronization Therapy [Clinical Appropriateness Guideline]. Reviewed: 11.05.2019; last revised: 26.05.2021; effective: 07.11.2021. Chicago, US-IL: AIM Specialty Health. CAR05-1121.2. URL: https://aimspecialtyhealth.com/wp-con-tent/uploads/2021/09/CAR_CardiacResynchronizationTherapy.pdf (abgerufen am: 29.04.2022).
2. AIM Specialty Health (2021): Appropriate Use Criteria: Implantable Cardioverter Defibrillators [Clinical Appropriateness Guideline]. Reviewed: 28.11.2018; last revised: 26.05.2021; effective: 07.11.2021. Chicago, US-IL: AIM Specialty Health. CAR06-1121.2. URL: https://aimspecialtyhealth.com/wp-content/uploads/2021/09/Implantable-Cardioverter-Defibrillators.pdf (abgerufen am: 29.04.2022).
3. Ertl, G; Angermann, CE; Bekeredjian, R; Beyersdorf, F; Güder, G; Gummert, J; et al. (2016): Aufbau und Organisation von Herzinsuffizienz-Netzwerken (HF-NETs) und Herzinsuffizienz-Einheiten („Heart Failure Units", HFUs) zur Optimierung der Behandlung der akuten und chronischen Herzinsuffizienz. Gemeinsame Empfehlungen der DGK und der DGTHG zur Behandlung der Herzinsuffizienz. Der Kardiologe 10(4): 222-235. DOI: 10.1007/s12181-016-0072-6.
4. Ezekowitz, JA; O'Meara, E; McDonald, MA; Abrams, H; Chan, M; Ducharme, A; et al. (2017): 2017 Comprehensive Update of the Canadian Cardiovascular Society Guidelines for the Management of Heart Failure. Canadian Journal of Cardiology 33(11): 1342-1433. DOI: 10.1016/j.cjca.2017.08.022.
5. Kusumoto, FM; Schoenfeld, MH; Wilkoff, BL; Berul, CI; Birgersdotter-Green, UM; Carrillo, R; et al. (2017): 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 14(12): e503-e551. DOI: 10.1016/j.hrthm.2017.09.001.
6. Stiles, MK; Fauchier, L; Morillo, CA; Wilkoff, BL (2020): 2019 HRS/EHRA/APHRS/LAHRS focused update to 2015 expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing. Heart Rhythm 17(1): e220-e228. DOI: 10.1016/j.hrthm.2019.02.034.

Nicht E6

Keine

Nicht E7

1. Atherton, JJ; Sindone, A; De Pasquale, CG; Driscoll, A; MacDonald, PS; Hopper, I; et al. (2018): National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand:

Guidelines for the Prevention, Detection, and Management of Heart Failure in Australia 2018. Heart, Lung and Circulation 27(10): 1123-1208. DOI: 10.1016/j.hlc.2018.06.1042.

2. DGPR [Deutsche Gesellschaft für Prävention und Rehabilitation von Herz-Kreislauferkrankungen] (2020): AWMF-Registernummer 133-001. S3-Leitlinie zur kardiologischen Rehabilitation (LL-KardReha) im deutschsprachigen Raum Europas Deutschland, Österreich, Schweiz (D-A-CH) [Gesamtversion-Langfassung]. Version 1.1. [Stand:] 10.12.2020. Koblenz: DGPR [u. a.]. URL: https://www.awmf.org/uploads/tx_szleitlinien/133-001l_S3-Kardiologische-Rehabilitation-in-D-A-CH_2020-12.pdf (abgerufen am: 28.04.2022).
3. UMich [University of Michigan] (2019): Ambulatory Adult Heart Failure - Systolic Dysfunction Guideline. Origination: August 1999; last revised: June 2019; © 2022. [Ann Arbor, US-MI] Michigan Medicine Public. URL: https://michmed-public.policystat.com/policy/7109459/latest/ (abgerufen am: 29.04.2022).

Nicht E8

1. Brugada, J; Katritsis, DG; Arbelo, E; Arribas, F; Bax, JJ; Blomström-Lundqvist, C; et al. (2020): 2019 ESC Guidelines for the management of patients with supraventricular tachycardiaThe Task Force for the management of patients with supraventricular tachycardia of the European Society of Cardiology (ESC): Developed in collaboration with the Association for European Paediatric and Congenital Cardiology (AEPC). European Heart Journal 41(5): 655-720. DOI: 10.1093/eurheartj/ehz467.
2. Gorenek, B; Bax, J; Boriani, G; Chen, SA; Dagres, N; Glotzer, TV; et al. (2017): Device-detected subclinical atrial tachyarrhythmias: definition, implications and management—an European Heart Rhythm Association (EHRA) consensus document, endorsed by Heart Rhythm Society (HRS), Asia Pacific Heart Rhythm Society (APHRS) and Sociedad Latinoamericana de Estimulación Cardíaca y Electrofisiología (SOLEACE) [EHRA Consensus Document]. Europace 19(9): 1556-1578. DOI: 10.1093/europace/eux163.
3. Heidenreich, PA; Bozkurt, B; Aguilar, D; Allen, LA; Byun, JJ; Colvin, MM; et al. (2022): 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure [Clinical Practice Guideline]. JACC – Journal of the American College of Cardiology 79(17): e263-e421. DOI: 10.1016/j.jacc.2021.12.012.

3 Informationsbeschaffung – Versorgungssituation

Um für die Generierung der Qualitätsaspekte ein möglichst umfassendes Bild zum Thema Versorgungssituation von Patientinnen und Patienten aller Altersgruppen mit implantierten Herzschrittmachern und Defibrillatoren zu erhalten, sollten Studien systematisch recherchiert werden, die die aktuelle Versorgung in Deutschland abbilden. Diese Ergebnisse können dazu dienen, u.a. im Abgleich mit aktuellen Standards, Versorgungsdefizite und Verbesserungspotentiale zu erkennen.

3.1 Recherche

In Tabelle 5 sind die definierten Einschlusskriterien, die der Recherche und dem Screening der Publikationen zum Thema Versorgungssituation zugrunde lagen, aufgeführt.

Tabelle 5: Einschlusskriterien für Versorgungssituation

E1	Volltext erhältlich
E2	Volltext in deutscher oder englischer Sprache
E3	Publikationsdatum ab 01.04.2017
E4	▪ Systematische Übersichtsarbeiten (von Beobachtungsstudien) ▪ Prospektive und retrospektive Kohortenstudien ▪ qualitative Studien oder Mixed-Methods-Studien (aus ExpertInnensicht/MitarbeiterInnen aus Gesundheitsfachberufen) ▪ Sekundärdatenanalysen
E5	Die Publikation adressiert die ambulante oder stationäre Versorgung oder Notfallversorgung von Patientinnen und Patienten in Deutschland, sofern diese einen Hinweis auf ein Qualitätsdefizit gibt oder die Versorgung beschreibt.
E6	Die Publikation adressiert Patientinnen und Patienten aller Altersgruppen mit Rhythmusimplantaten (cardiac implantable electronic devices): ▪ Herzschrittmacher (pacemaker) ▪ Implantierbare Defibrillatoren (implantable defibrillator cardioverter, ICD, subkutan und substernal) ▪ Geräte zur kardialen Resynchronisationstherapie (cardiac resynchronization therapy, CRT-Devices)) Ausgeschlossen: ▪ Publikation adressiert ausschließlich Patienten mit CCM-Devices ▪ Publikation adressiert ausschließlich Patienten mit implantierten Ereignisrekordern ▪ Publikation adressiert ausschließlich Patienten mit temporären Schrittmachern

E7	In den Publikationen werden direkte oder indirekte Hinweise auf Qualitätsdefizite, bzw. Verbesserungsbedarfe die im Zusammenhang mit den genannten Interventionen bestehen, benannt. z. B. ▪ Sterblichkeit ▪ Komplikationen ▪ Fehlfunktionen des Gerätes

Die Literaturrecherche nach systematischen Reviews zum Thema Versorgungssituation wurde in den folgenden bibliografischen Datenbanken durchgeführt:

- Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions(R) 1946 to May 02, 2022
- Embase via Elsevier
- CINAHL via EBSCO
- Cochrane via Wiley

Ausgehend vom PICO-Schema wurden die geeigneten Suchbegriffe abgeleitet. Für die Recherche wurde zunächst eine Strategie für die Literaturdatenbank MEDLINE entwickelt und dann entsprechend an die anderen Datenbanken angepasst. Die Suchstrategie bestand aus zwei Blöcken: Ein Rechercheblock für die Population und Intervention (Patientinnen und Patienten mit Rhythmusimplantaten) und ein Rechercheblock, der die Recherche auf Publikationen aus Deutschland (bzw. auf eine deutsche Studienpopulation) einschränkt. Dieser Rechercheblock basiert auf dem Deutschland-Filter von Pieper et al. (2015) und wurde für die jeweilige Suchoberfläche angepasst.

Folgende Limitationen wurden, falls in der jeweiligen Datenbank möglich, bei der Suchstrategie berücksichtigt:

- Publikationen ab 2017
- nur „human"
- nur englische und deutsche Publikationen
- keine Kongressabstracts, Fallberichte, Kommentare, Editorials oder Letter

Die Limitationen finden sich eingebettet in den jeweiligen Suchstrategien der einzelnen Datenbanken (Tabelle 6 bis Tabelle 9Tabelle 7).

Die Recherche erfolgte in allen Datenbanken am 3. Mai 2022.

Suchstrategie für MEDLINE via Ovid

Tabelle 6: Suchstrategie für MEDLINE via Ovid (Thema Versorgungssituation); Datum der Recherche: 3. Mai 2022

#	Searches
1	exp Defibrillators/
2	Electrodes, Implanted/

#	Searches
3	exp Pacemaker, Artificial/
4	exp Cardiac Pacing, Artificial/
5	(''Cardioverter-Defibrillator?'' or ''Implantable Cardioverter Defibrillator?'' or ''Implantable Cardioverter-Defibrillator?'' or ICD or ''Implantable Defibrillator?'' or ''Implantable Electrode?'' or ''Implanted Stimulation Electrode?'' or ''Cardiac Stimulator?'' or cardioverter* or pacesetter? or pacemaker? or ''sinoatrial node'' or ''SA node'' or pacer or ''mechanical heart'' or (cardi* adj3 (defibrillat* or implant*))).ti,ab.
6	1 or 2 or 3 or 4 or 5
7	exp Germany/
8	(germany or deutschland).ot,ti,ab,in.
9	(german or deutsch*).ot,ti,ab.
10	(berlin or hamburg or munchen or muenchen or munich or koln or koeln or cologne or frankfurt or stuttgart or dusseldorf or duesseldorf or dortmund or essen or bremen or dresden or leipzig or hannover or nuernberg or nurnberg or aachen or augsburg or bamberg or bayreuth or benediktbeuern or bochum or braunschweig or chemnitz or clausthal or cottbus or darmstadt or detmold or eichstatt or eichstaett or eltville or ingolstadt or erfurt or erlangen or flensburg or freiberg or freiburg or friedrichshafen or fulda or giesen or giessen or greifswald or gottingen or goettingen or hagen or halle or heidelberg or hildesheim or ilmenau or jena or kaiserslautern or karlsruhe or kassel or kiel or koblenz or konstanz or luebeck or lubeck or ludwigsburg or lueneburg or luneburg or leverkusen or mainz or marburg or munster or muenster or neuendettelsau or neubrandenburg or oestrich-winkel or oldenburg or osnabrueck or osnabruck or paderborn or passau or potsdam or regensburg or rostock or saar or augustin or schwabisch or gmund or schwaebisch or gmuend or siegen or speyer or trier or trossingen or tuebingen or tubingen or ulm or vallendar or vechta or weimar or weingarten or witten or wuppertal or wuerzburg or wurzburg or zittau or duisburg or bonn or bielefeld or mannheim or 'north rhine-westphalia' or nrw or 'nordrhein westfalen' or 'rhine ruhr' or rhein or ruhr or 'schleswig holstein' or 'mecklenburg vorpommern' or 'mecklenburg-western pomerania' or brandenburg or sachsen or saxony or 'saxony anhalt' or 'sachsen anhalt' or thuringia or thuringen or thueringen or niedersachsen or 'lower saxony' or hesse or hessia or hessen or 'rhineland palatinate' or rheinland or pfalz or saarland or baden or wurttemberg or wuerttemberg or bavaria or bayern).ot,ti,ab,in.
11	7 or 8 or 9 or 10
12	6 and 11
13	limit 12 to (congress or case reports or comment or editorial or letter)
14	12 not 13
15	exp animals/ not (exp animals/ and exp humans/)
16	14 not 15
17	limit 16 to (english or german)
18	limit 17 to yr="2017 -Current"

Suchstrategie für Embase via Elsevier

Tabelle 7: Suchstrategie für Embase via Elsevier (Thema Versorgungssituation); Datum der Recherche: 3. Mai 2022

No.	Query
#1	'artificial heart pacemaker'/exp
#2	'cardiac implantable electronic device'/exp
#3	'defibrillator'/exp
#4	'pacemaker accessory'/exp
#5	'heart pacing'/exp OR 'cardiac rhythm management device'/de
#6	'cardioverter-defibrillator$':ti,ab OR 'implantable cardioverter defibrillator$':ti,ab OR 'implantable cardioverter-defibrillator$':ti,ab OR icd:ti,ab OR 'implantable defibrillator$':ti,ab OR 'implantable electrode$':ti,ab OR 'implanted stimulation electrode$':ti,ab OR 'cardiac stimulator$':ti,ab OR cardioverter*:ti,ab OR pacesetter$:ti,ab OR pacemaker$:ti,ab OR 'sinoatrial node':ti,ab OR 'sa node':ti,ab OR pacer:ti,ab OR 'mechanical heart':ti,ab OR ((cardi* NEAR/3 (defibrillat* OR implant*)):ti,ab)
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	'germany'/exp
#9	germany:ca,ad,ab,ti OR deutschland:ca,ad,ab,ti
#10	german:ab,ti OR deutsch*:ab,ti
#11	berlin:ca,ad,ab,ti OR hamburg:ca,ad,ab,ti OR münchen:ca,ad,ab,ti OR muenchen:ca,ad,ab,ti OR munchen:ca,ad,ab,ti OR munich:ca,ad,ab,ti OR köln:ca,ad,ab,ti OR koeln:ca,ad,ab,ti OR koln:ca,ad,ab,ti OR cologne:ca,ad,ab,ti OR frankfurt:ca,ad,ab,ti OR stuttgart:ca,ad,ab,ti OR düsseldorf:ca,ad,ab,ti OR duesseldorf:ca,ad,ab,ti OR dusseldorf:ca,ad,ab,ti OR dortmund:ca,ad,ab,ti OR essen:ca,ad,ab,ti OR bremen:ca,ad,ab,ti OR dresden:ca,ad,ab,ti OR leipzig:ca,ad,ab,ti OR hannover:ca,ad,ab,ti OR nürnberg:ca,ad,ab,ti OR nuernberg:ca,ad,ab,ti OR nurnberg:ca,ad,ab,ti OR aachen:ca,ad,ab,ti OR augsburg:ca,ad,ab,ti OR bamberg:ca,ad,ab,ti OR bayreuth:ca,ad,ab,ti OR benediktbeuern:ca,ad,ab,ti OR bochum:ca,ad,ab,ti OR braunschweig:ca,ad,ab,ti OR chemnitz:ca,ad,ab,ti OR clausthal:ca,ad,ab,ti OR cottbus:ca,ad,ab,ti OR darmstadt:ca,ad,ab,ti OR detmold:ca,ad,ab,ti OR eichstätt:ca,ad,ab,ti OR eichstatt:ca,ad,ab,ti OR eichstaett:ca,ad,ab,ti OR eltville:ca,ad,ab,ti OR ingolstadt:ca,ad,ab,ti OR erfurt:ca,ad,ab,ti OR erlangen:ca,ad,ab,ti OR flensburg:ca,ad,ab,ti OR freiberg:ca,ad,ab,ti OR freiburg:ca,ad,ab,ti OR friedrichshafen:ca,ad,ab,ti OR fulda:ca,ad,ab,ti OR gießen:ca,ad,ab,ti OR giessen:ca,ad,ab,ti OR giesen:ca,ad,ab,ti OR greifswald:ca,ad,ab,ti OR göttingen:ca,ad,ab,ti OR goettingen:ca,ad,ab,ti OR gottingen:ca,ad,ab,ti OR hagen:ca,ad,ab,ti OR halle:ca,ad,ab,ti OR heidelberg:ca,ad,ab,ti OR hildesheim:ca,ad,ab,ti OR ilmenau:ca,ad,ab,ti OR jena:ca,ad,ab,ti OR kaiserslautern:ca,ad,ab,ti OR karlsruhe:ca,ad,ab,ti OR kassel:ca,ad,ab,ti OR kiel:ca,ad,ab,ti OR koblenz:ca,ad,ab,ti OR konstanz:ca,ad,ab,ti OR luebeck:ca,ad,ab,ti OR lübeck:ca,ad,ab,ti OR lubeck:ca,ad,ab,ti OR ludwigsburg:ca,ad,ab,ti OR lueneburg:ca,ad,ab,ti OR lüneburg:ca,ad,ab,ti OR luneburg:ca,ad,ab,ti OR leverkusen:ca,ad,ab,ti OR mainz:ca,ad,ab,ti OR marburg:ca,ad,ab,ti OR münster:ca,ad,ab,ti OR munster:ca,ad,ab,ti OR muenster:ca,ad,ab,ti OR neuendettelsau:ca,ad,ab,ti OR neubrandenburg:ca,ad,ab,ti OR 'oestrich win-

No.	Query
	kel':ca,ad,ab,ti OR oldenburg:ca,ad,ab,ti OR osnabrueck:ca,ad,ab,ti OR osnabrück:ca,ad,ab,ti OR osnabruck:ca,ad,ab,ti OR paderborn:ca,ad,ab,ti OR passau:ca,ad,ab,ti OR potsdam:ca,ad,ab,ti OR regensburg:ca,ad,ab,ti OR rostock:ca,ad,ab,ti OR saar:ca,ad,ab,ti OR augustin:ca,ad,ab,ti OR schwäbisch:ca,ad,ab,ti OR gmünd:ca,ad,ab,ti OR schwabisch:ca,ad,ab,ti OR gmund:ca,ad,ab,ti OR schwaebisch:ca,ad,ab,ti OR gmuend:ca,ad,ab,ti OR siegen:ca,ad,ab,ti OR speyer:ca,ad,ab,ti OR trier:ca,ad,ab,ti OR trossingen:ca,ad,ab,ti OR tuebingen:ca,ad,ab,ti OR tübingen:ca,ad,ab,ti OR tubingen:ca,ad,ab,ti OR ulm:ca,ad,ab,ti OR vallendar:ca,ad,ab,ti OR vechta:ca,ad,ab,ti OR weimar:ca,ad,ab,ti OR weingarten:ca,ad,ab,ti OR witten:ca,ad,ab,ti OR wuppertal:ca,ad,ab,ti OR wuerzburg:ca,ad,ab,ti OR würzburg:ca,ad,ab,ti OR wurzburg:ca,ad,ab,ti OR zittau:ca,ad,ab,ti OR duisburg:ca,ad,ab,ti OR bonn:ca,ad,ab,ti OR bielefeld:ca,ad,ab,ti OR mannheim:ca,ad,ab,ti OR 'north rhine-westphalia':ca,ad,ab,ti OR nrw:ca,ad,ab,ti OR 'nordrhein westfalen':ca,ad,ab,ti OR 'rhine ruhr':ca,ad,ab,ti OR rhein:ca,ad,ab,ti OR ruhr:ca,ad,ab,ti OR 'schleswig holstein':ca,ad,ab,ti OR 'mecklenburg vorpommern':ca,ad,ab,ti OR 'mecklenburg-western pomerania':ca,ad,ab,ti OR brandenburg:ca,ad,ab,ti OR sachsen:ca,ad,ab,ti OR saxony:ca,ad,ab,ti OR 'saxony anhalt':ca,ad,ab,ti OR 'sachsen anhalt':ca,ad,ab,ti OR thuringia:ca,ad,ab,ti OR thüringen:ca,ad,ab,ti OR thuringen:ca,ad,ab,ti OR thueringen:ca,ad,ab,ti OR niedersachsen:ca,ad,ab,ti OR 'lower saxony':ca,ad,ab,ti OR hesse:ca,ad,ab,ti OR hessia:ca,ad,ab,ti OR hessen:ca,ad,ab,ti OR 'rhineland palatinate':ca,ad,ab,ti OR rheinland:ca,ad,ab,ti OR pfalz:ca,ad,ab,ti OR saarland:ca,ad,ab,ti OR baden:ca,ad,ab,ti OR württemberg:ca,ad,ab,ti OR wurttemberg:ca,ad,ab,ti OR wuerttemberg:ca,ad,ab,ti OR bavaria:ca,ad,ab,ti OR bayern:ca,ad,ab,ti
#12	#8 OR #9 OR #10 OR #11
#13	#7 AND #12
#14	'case report'/de OR [conference abstract]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR [preprint]/lim OR comment:ti
#15	#13 NOT #14
#16	'animal'/exp NOT ('animal'/exp AND 'human'/exp)
#17	#15 NOT #16
#18	#17 AND ([english]/lim OR [german]/lim)
#19	#18 AND [2017-2022]/py

Suchstrategie für CINAHL via EBSCO

Tabelle 8: Suchstrategie für CINAHL via EBSCO (Thema Versorgungssituation); Datum der Recherche: 3. Mai 2022

#	Query
S1	MM defibrillators, implantable
S2	MM Electrodes, Implanted
S3	MM Pacemaker, Artificial
S4	(MH "Cardiac Pacing, Artificial+")

#	Query
S5	TI (''Cardioverter-Defibrillator*'' or ''Implantable Cardioverter Defibrillator*'' or ''Implantable Cardioverter-Defibrillator*'' or ICD or ''Implantable Defibrillator*'' or ''Implantable Electrode*'' or ''Implanted Stimulation Electrode*'' or ''Cardiac Stimulator*'' or cardioverter* or pacesetter* or pacemaker* or ''sinoatrial node'' or ''SA node'' or pacer or ''mechanical heart'' or (cardi* N3 (defibrillat* or implant*)))
S6	AB (''Cardioverter-Defibrillator*'' or ''Implantable Cardioverter Defibrillator*'' or ''Implantable Cardioverter-Defibrillator*'' or ICD or ''Implantable Defibrillator*'' or ''Implantable Electrode*'' or ''Implanted Stimulation Electrode*'' or ''Cardiac Stimulator*'' or cardioverter* or pacesetter* or pacemaker* or ''sinoatrial node'' or ''SA node'' or pacer or ''mechanical heart'' or (cardi* N3 (defibrillat* or implant*)))
S7	S1 OR S2 OR S3 OR S4 OR S5 OR S6
S8	(MH "Germany+")
S9	((AB germany OR TI germany OR AF germany) OR (AB german OR TI german) OR (AB deutschland OR TI deutschland OR AF deutschland) OR (AB deutsch* OR TI deutsch*) OR (AB berlin OR TI berlin OR AF berlin) OR (AB hamburg OR TI hamburg OR AF hamburg) OR (AB münchen OR TI münchen OR AF münchen) OR (AB muenchen OR TI muenchen OR AF muenchen) OR (AB munchen OR TI munchen OR AF munchen) OR (AB munich OR TI munich OR AF munich) OR (AB köln OR TI köln OR AF köln) OR (TI koeln OR AB koeln OR AF koeln) OR (TI koln OR AB koln OR AF koln) OR (AB cologne OR TI cologne OR AF cologne) OR (AB frankfurt OR TI frankfurt or AF frankfurt) OR (AB stuttgart OR TI stuttgart OR AF stuttgart) OR (AB dusseldorf OR TI dusseldorf OR AF dusseldorf) OR (AB düsseldorf OR TI düsseldorf OR AF düsseldorf) OR (AB duesseldorf OR TI duesseldorf OR AF duesseldorf) OR (AB dortmund OR TI dortmund OR AF dortmund) OR (AB essen OR TI essen OR AF essen) OR (AB bremen OR TI bremen OR AF bremen) OR (AB dresden OR TI dresden OR AF dresden) OR (AB leipzig OR TI leipzig OR AF leipzig) OR (AB hannover OR TI hannover OR AF hannover) OR (AB nürnberg OR TI nürnberg OR AF nürnberg) OR (AB nurnberg OR TI nurnberg OR AF nurnberg) OR (AB nuernberg OR TI nuernberg OR AF nuernberg) OR (AB aachen OR TI aachen OR AF aachen) OR (AB augsburg OR TI augsburg OR AF augsburg) OR (AB bamberg OR TI bamberg OR AF bamberg) OR (AB bayreuth OR TI bayreuth OR AF bayreuth) OR (AB benediktbeuern OR TI benediktbeuern OR AF benediktbeuern) OR (AB bochum OR TI bochum OR AF bochum) OR (AB braunschweig OR TI braunschweig OR AF braunschweig) OR (AB chemnitz OR TI chemnitz OR AF chemnitz) OR (AB clausthal OR TI clausthal OR AF clausthal) OR (TI cottbus OR AB cottbus OR AF cottbus) OR (AB darmstadt OR TI darmstadt OR AF darmstadt) OR (AB detmold OR TI detmold OR AF detmold) OR (TI eichstätt OR AB eichstätt OR AF eichstätt) OR (TI eichstaett OR AB eichstaett OR AF eichstaett) OR (TI eichstatt OR AB eichstatt OR AF eichstatt) OR (TI eltville OR AB eltville OR AF eltville) OR (AB ingolstadt OR TI ingolstadt OR AF ingolstadt) OR (AB erfurt OR TI erfurt OR AF erfurt) OR (AB erlangen OR TI erlangen OR AF erlangen) OR (TI flensburg OR AB flensburg OR AF flensburg) OR (AB freiberg OR TI freiberg OR AF freiberg) OR (AB freiburg OR TI freiburg OR AF freiburg) OR (AB friedrichshafen OR TI friedrichshafen OR AF friedrichshafen) OR (AB fulda OR TI fulda OR AF fulda) OR (TI gießen OR AB gießen OR AF gießen) OR (AB giessen OR TI giessen OR AF giessen) OR (TI giesen OR AB giesen OR AF giesen) OR (AB greifswald OR TI greifswald OR AF greifswald) OR (AB göttingen OR TI göttingen OR AF göttingen) OR (AB gottingen OR TI gottingen OR AF gottingen) OR (AB goettingen OR TI goettingen OR AF goettingen) OR (AB hagen OR TI hagen OR AF hagen) OR (AB halle OR TI halle OR AF halle) OR (AB heidelberg OR TI heidelberg OR AF heidelberg) OR (AB hildesheim OR TI hildesheim OR AF hildesheim) OR (AB ilmenau OR TI ilmenau OR AF ilmenau) OR (TI jena OR AB jena OR AF jena) OR (AB kaiserslautern OR TI kaiserslautern OR AF kaiserslautern) OR (AB karlsruhe OR TI karlsruhe OR AF karlsruhe) OR (AB kassel OR TI kassel OR AF kassel) OR (AB kiel OR TI kiel OR AF kiel) OR (AB koblenz OR TI koblenz OR AF koblenz) OR (AB konstanz OR TI konstanz OR AF konstanz) OR (AB lübeck OR TI lübeck OR AF lübeck) OR (AB

#	Query
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S10	S8 or S9

#	Query
S11	S7 and S10
S12	(MH "Animals+") NOT ((MH "Animals+") AND (MH "Human+"))
S13	S11 not S12
S14	S11 not S12 Limiters - Publication Type: Abstract, Case Study, Clinical Trial, Commentary, Doctoral Dissertation, Editorial, Letter, Masters Thesis, Proceedings, Protocol, Randomized Controlled Trial
S15	S13 NOT S14 Limiters - Published Date: 20170401-20220431; Language: English, German

Suchstrategie für Cochrane via Wiley

Tabelle 9: Suchstrategie für Cochrane via Wiley (Thema Versorgungssituation); Datum der Recherche: 3. Mai 2022

ID	Search
#1	MeSH descriptor: [Defibrillators] explode all trees
#2	MeSH descriptor: [Electrodes, Implanted] this term only
#3	MeSH descriptor: [Pacemaker, Artificial] explode all trees
#4	MeSH descriptor: [Cardiac Pacing, Artificial] explode all trees
#5	(''Cardioverter-Defibrillator*'' or ''Implantable Cardioverter Defibrillator*'' or ''Implantable Cardioverter-Defibrillator*'' or ICD or ''Implantable Defibrillator*'' or ''Implantable Electrode*'' or ''Implanted Stimulation Electrode*'' or ''Cardiac Stimulator*'' or cardioverter* or pacesetter* or pacemaker* or ''sinoatrial node'' or ''SA node'' or pacer or ''mechanical heart'' or (cardi* NEAR/3 (defibrillat* or implant*))):ti,ab
#6	#1 or #2 or #3 or #4 or #5
#7	MeSH descriptor: [Germany] explode all trees
#8	german*:ti,ab
#9	deutsch*:ti,ab
#10	(berlin or hamburg or munchen or muenchen or munich or koln or koeln or cologne or frankfurt or stuttgart or dusseldorf or duesseldorf or dortmund or essen or bremen or dresden or leipzig or hannover or nuernberg or nurnberg or aachen or augsburg or bamberg or bayreuth or benediktbeuern or bochum or braunschweig or chemnitz or clausthal or cottbus or darmstadt or detmold or eichstatt or Eichstaett or eltville or Ingolstadt or Erfurt or Erlangen or flensburg or freiberg or freiburg or friedrichshafen or fulda or giesen or giessen or Greifswald or gottingen or goettingen or Hagen or Halle or heidelberg or Hildesheim or Ilmenau or Jena or kaiserslautern or karlsruhe or kassel or kiel or koblenz or konstanz or luebeck or lubeck or ludwigsburg or lueneburg or luneburg or leverkusen or mainz or marburg or munster or muenster or neuendettelsau or neubrandenburg or oestrich-winkel or oldenburg or osnabrueck or osnabruck or paderborn or passau or potsdam or regensburg or rostock or saar or augustin or schwabisch or gmund or schwaebisch or gmuend or siegen or speyer or trier or trossingen or tuebingen or

ID	Search
	tubingen or ulm or vallendar or vechta or weimar or weingarten or witten or wuppertal or wuerzburg or wurzburg or zittau or duisburg or bonn or bielefeld or mannheim or 'north rhine-westphalia' or nrw or 'nordrhein westfalen' or 'rhine ruhr' or rhein or ruhr or 'schleswig holstein' or 'mecklenburg vorpommern' or 'mecklenburg-western pomerania' or brandenburg or sachsen or saxony or 'saxony anhalt' or 'sachsen anhalt' or thuringia or thuringen or thueringen or niedersachsen or 'lower saxony' or hesse or hessia or hessen or 'rhineland palatinate' or rheinland or pfalz or saarland or baden or wurttemberg or wuerttemberg or bavaria or bayern):ti,ab
#11	#7 or #8 or #9 or #10
#12	#6 and #11 with Cochrane Library publication date Between Apr 2017 and May 2022, in Cochrane Reviews

Die Titel und Abstracts der recherchierten Publikationen wurden von zwei Personen unabhängig voneinander hinsichtlich ihrer inhaltlichen Relevanz bezogen auf die a priori festgelegte Frage überprüft und ausgewählt. Uneinheitliche Bewertungen wurden diskutiert und im Fall einer fehlenden Einigung wurden die Publikationen für ein Volltext-Screening einbezogen.

Die Volltexte der ausgewählten Publikationen wurden von zwei Personen unabhängig voneinander dahingehend überprüft, ob die a priori festgelegten Einschlusskriterien (siehe Tabelle 5) zutreffen. Uneinheitliche Bewertungen wurden diskutiert und eine Einigung herbeigeführt. Es erfolgte eine Dokumentation des Volltext-Screenings und der Ausschlussgründe für alle ausgeschlossenen Publikationen (siehe Abschnitt 3.3).

Eine Gesamtübersicht über die Recherche nach systematischen Reviews in bibliographischen Datenbanken bietet das nachfolgende Flussdiagramm (Abbildung 2).

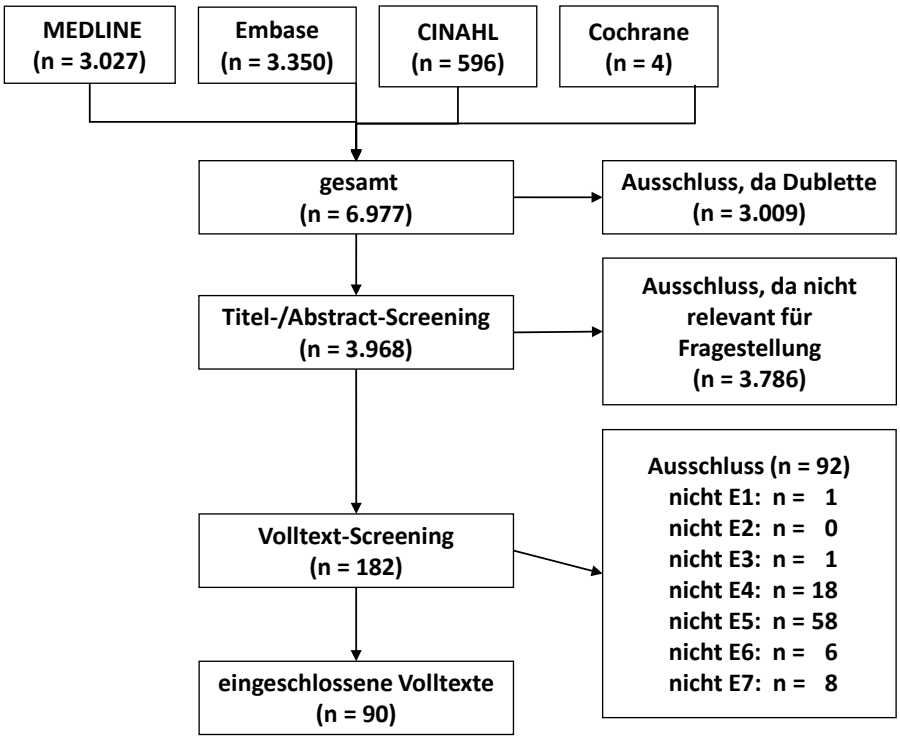

Abbildung 2: Flussdiagramm der Recherche nach systematischen Reviews zum Thema Versorgungssituation

3.2 Eingeschlossene Publikationen zum Thema Versorgungssituation

Nach dem Volltext-Screening wurden 90 Artikel eingeschlossen (siehe Tabelle 10).

Tabelle 10: Eingeschlossene Artikel zum Thema Versorgungssituation

	Titel	Referenz
1	Incidence and predictors of pacemaker induced cardiomyopathy: A single-center experience	Abdin et al. (2019)
2	Cardiac device implantations in obese patients: Success rates and complications	Attanasio et al. (2017)
3	Long-Term Experience With the Subcutaneous Implantable Cardioverter-Defibrillator in Teenagers and Young Adults	Bettin et al. (2017)
4	Change of sensing vector in the subcutaneous ICD during follow-up and after device replacement	Bettin et al. (2018)
5	Follow-up of the first patients with a totally subcutaneous ICD in Germany from implantation till battery depletion	Bettin et al. (2019)
6	Single chamber implantable cardioverter defibrillator compared to dual chamber implantable cardioverter defibrillator: less is more! Data from the German Device Registry	Bogossian et al. (2020)
7	Peripoperative Mortalität nach ICD-Implantation	Bogossian et al. (2021)

	Titel	Referenz
8	Performance and outcome of the subcutaneous implantable cardioverter-defibrillator after transvenous lead extraction	Chung et al. (2021)
9	Activation of remote monitoring for cardiac implantable electronic devices: small dog for tall weeds	D'Ancona et al. (2017)
10	Use of Implantable Cardioverter-Defibrillators in Congenital Heart Disease and Pediatric Patients: Results from the German National Registry for Congenital Heart Defects	Dicks et al. (2020)
11	Cardiac resynchronization therapy in the ageing population – With or without an implantable defibrillator?	Döring et al. (2018)
12	Extraction of infected cardiac implantable electronic devices and the need for subsequent re-implantation	Döring et al. (2020a)
13	Transvenous revision of leads with cardiac perforation following device implantation—Safety, outcome, and complications	Döring et al. (2020b)
14	Defibrillator generator replacements in patients with left ventricular assist device support: The risks of hematoma and infection	Eulert-Grehn et al. (2022)
15	Cardiac resynchronization therapy in congenital heart disease: Results from the German National Register for Congenital Heart Defects	Flügge et al. (2018)
16	Can we rely on Danish? Real-world data on patients with nonischemic cardiomyopathy from the German Device Registry	Frommeyer et al. (2019)
17	Long-term single-center experience of defibrillator therapy in children and adolescents	Frommeyer et al. (2018)
18	Implantable cardioverter defibrillators in patients with electrical heart disease and hypertrophic cardiomyopathy: data from the German device registry	Frommeyer et al. (2020)
19	Potential of remote monitoring to prevent sensing and detection failures in implantable cardioverter defibrillators	Götz et al. (2022)
20	Survival of patients undergoing cardiac resynchronization therapy with or without defibrillator: the RESET-CRT project	Hadwiger et al. (2022b)
21	Device runtime and costs of cardiac resynchronization therapy pacemakers - a health claims data analysis	Hadwiger et al. (2022a)
22	Transvenous lead extraction after heart transplantation: How to avoid abandoned lead fragments	Hahnel et al. (2020)
22	Transvenous lead extraction after heart transplantation: How to avoid abandoned lead fragments	Hahnel et al. (2020)
23	Perioperative complications after pacemaker implantation: higher complication rates with subclavian vein puncture than with cephalic vein cutdown	Hasan et al. (2022)

	Titel	Referenz
24	Secondary prevention implantable cardioverter-defibrillator (ICD) therapy: value in octogenarians	Hauck et al. (2022)
25	Thrombocytopenia and end stage renal disease are key predictors of survival in patients with cardiac implantable electronic device infections	Herrmann et al. (2020)
26	Image noise reduction technology allows significant reduction of radiation dosage in cardiac device implantation procedures	Hoffmann et al. (2017)
27	Implantable cardioverter defibrillator therapy in grown-up patients with transposition of the great arteries—role of anti-tachycardia pacing	Hohmann et al. (2018)
28	Long-term incidence of upper extremity venous obstruction in implantable cardioverter defibrillator patients	Horlbeck et al. (2021)
29	Cardioverter–defibrillator does not improve short-term survival among patients with non-ischemic cardiomyopathy and reduced left ventricular ejection fraction	Jilek et al. (2020)
30	Distribution and impact of age in patients with implantable cardioverter-defibrillators regarding early complications and 1-year clinical outcome: results from the German Device Registry	Kaya et al. (2021)
31	Feasibility and safety of using local anaesthesia with conscious sedation during complex cardiac implantable electronic device procedures	Kaya et al. (2018)
32	Assessment of Association Between Venous Occlusion and Infection of Cardiac Implantable Electronic Devices	Keyser et al. (2022)
33	Long-term performance and lead failure analysis of the Durata defibrillation lead compared to its previous model, the recalled Riata defibrillation lead	Kleemann et al. (2019b)
34	Contemporary benefit-harm profile over two decades in primary prophylactic ICD-therapy	Kleemann et al. (2019a)
35	Prognostic relevance of new onset arrhythmia and ICD shocks in primary prophylactic ICD patients	Kleemann et al. (2020)
36	Complications and 1-year benefit of cardiac resynchronization therapy in patients over 75 years of age – Insights from the German Device Registry	Köbe et al. (2017a)
37	Selection and outcome of implantable cardioverter-defibrillator patients with and without cardiac resynchronization therapy: Comparison of 4384 patients from the German Device Registry to randomized controlled trials	Köbe et al. (2022)
38	Outcome in patients undergoing upgrade to cardiac resynchronization therapy: predictors of outcome after upgrade to CRT	Kosiuk et al. (2020)
39	Transvenous and non-transvenous implantable cardioverter-defibrillators in children, adolescents, and adults with congenital	Krause et al. (2019)

	Titel	Referenz
	heart disease: who is at risk for appropriate and inappropriate shocks?	
40	Avoiding inappropriate therapy of single-lead implantable cardioverter-defibrillator by using atrial-sensing electrodes	Kurt et al. (2018)
41	Comparison of transvenous vs subcutaneous defibrillator therapy in patients with cardiac arrhythmia syndromes and genetic cardiomyopathies	Kuschyk et al. (2021)
42	The effect of iron deficiency on cardiac resynchronization therapy: results from the RIDE-CRT Study	Lacour et al. (2020)
43	Device updates successfully reduce T-wave oversensing and inappropriate shocks in subcutaneous ICD patients	Larbig et al. (2018a)
44	Postoperative ergometry-guided programming does not prevent T-wave oversensing and inappropriate shocks in S-ICD patients	Larbig et al. (2018b)
45	Very Long-Term Follow-Up in Cardiac Resynchronization Therapy: Wider Paced QRS EqualsWorse Prognosis	Leitz et al. (2021)
46	Incidence and costs of cardiac device infections: retrospective analysis using German health claims data	Ludwig et al. (2018)
47	Complications and associated healthcare costs of transvenous cardiac pacemakers in Germany	Ludwig et al. (2019)
48	Electrical cardioversion of patients with implanted pacemaker or cardioverter–defibrillator: results of a survey of german centers and systematic review of the literature	Lüker et al. (2018)
49	Efficacy and safety of non-transvenous cardioverter defibrillators in infants and young children	Müller et al. (2019)
50	Analysis of causes of death in patients with implanted defibrillators	Nägele et al. (2021)
51	Predictors of rhythm outcomes after cardiac resynchronization therapy in atrial fibrillation patients: When should we use an atrial lead?	Nedios et al. (2021)
52	Is mortality a useful parameter for public reporting in pacemaker implantation? Results of an obligatory external quality control programme	Nowak et al. (2017)
53	Very early discharge after cardiac implantable electronic device implantations: is this the future?	Ohlow et al. (2021)
54	Home monitoring after ambulatory implanted primary cardiac implantable electronic devices: The home ambulance pilot study	Parahuleva et al. (2017)
55	Laser lead extraction allows for safe and effective removal of single- and dual-coil implantable cardioverter defibrillator leads: A single-centre experience over 12 years	Pecha et al. (2017)

	Titel	Referenz
56	Safety and efficacy of transvenous lead extraction of very old leads	Pecha et al. (2021)
57	Upgrading patients with pacemakers to resynchronization pacing: Predictors of success	Rafla et al. (2018)
58	Risk factors and survival of patients with permanent pacemaker implantation after heart transplantation	Rivinius et al. (2019)
59	Low Prevalence of Inappropriate Shocks in Patients With Inherited Arrhythmia Syndromes With the Subcutaneous Implantable Defibrillator Single Center Experience and Long-Term Follow-Up	Rudic et al. (2017)
60	Defibrillation failure in patients undergoing replacement of subcutaneous defibrillator pulse generator	Rudic et al. (2020a)
61	Incidence, mechanisms, and clinical impact of inappropriate shocks in patients with a subcutaneous defibrillator	Rudic et al. (2020b)
62	Impact of Left Ventricular Ejection Fraction on Recurrent Ventricular Tachyarrhythmias in Recipients of Implantable Cardioverter Defibrillators	Rusnak et al. (2020)
63	Determinants of inappropriate implantable cardioverter-defibrillator shocks: the German Device Registry perspective	Safak et al. (2019a)
64	New generation cardioverter-defibrillator lead with a floating atrial sensing dipole: Long-term performance	Safak et al. (2018)
65	Pacing-induced cardiomyopathy in chronic right ventricular apical pacing: a midterm follow-up study	Safak et al. (2019b)
66	ICD therapy in the elderly: a retrospective single-center analysis of mortality	Scheurlen et al. (2021)
67	Improvement of electrical synchrony in cardiac resynchronization therapy using dynamic atrioventricular delay programming and multipoint pacing	Schiedat et al. (2021)
68	Novel Implantable Cardioverter Defibrillator Programming With High Rate Cut-Off, Long Detection Intervals and Multiple Anti-Tachycardia Pacing Reduces Mortality	Schober et al. (2021)
69	Prognostic impact of recurrences of ventricular tachyarrhythmias and appropriate ICD therapies in a high-risk ICD population	Schupp et al. (2019)
70	Clinical Course of Dual-Chamber Implantable Cardioverter-Defibrillator Recipients followed by Cardiac Remote Monitoring: Insights from the LION Registry	Schwab et al. (2018)
71	Prevalence of left ventricular systolic dysfunction in a typical outpatient pacemaker cohort	Schwerg et al. (2020)
72	T-wave loop area from a pre-implant 12-lead ECG is associated with appropriate ICD shocks	Seegers et al. (2017)

	Titel	**Referenz**
73	Prognosis associated with redo cardiac resynchronization therapy following complete device and lead extraction due to device-related infection	Seifert et al. (2018)
74	Long-term outcomes after event-free cardioverter defibrillator implantation: comparison between patients discharged within 24 h and routinely hospitalized patients in the German DEVICE registry	Spitzer et al. (2017)
75	Neonates and infants requiring life-long cardiac pacing: How reliable are epicardial leads through childhood?	Stanner et al. (2019)
76	Managing large lead vegetations in transvenous lead extractions using a percutaneous aspiration technique	Starck et al. (2018)
77	Fully digital data processing during cardiovascular implantable electronic device follow-up in a high-volume tertiary center	Staudacher et al. (2017)
78	Deactivation of cardiovascular implantable electronic devices in patients nearing end of life. Reality or only recommendation?	Tischer et al. (2020a)
79	Individual programming of current multiprogrammable pacemakers. Still unsatisfactory?	Tischer et al. (2020b)
80	Electrical remodelling and response following cardiac resynchronization therapy: A novel analysis of intracardiac electrogram using a quadripolar lead	Toner et al. (2018)
81	Triple lead cephalic versus subclavian vein approach in cardiac resynchronization therapy device implantation	Vogler et al. (2018)
82	Impact of chronic kidney disease on recurrent ventricular tachyarrhythmias in ICD recipients	Weidner et al. (2019a)
83	Increasing age is associated with recurrent ventricular tachyarrhythmias and appropriate ICD therapies secondary to documented index ventricular tachyarrhythmias	Weidner et al. (2019b)
84	Outcome differences and device performance of the subcutaneous ICD in patients with and without structural heart disease	Willy et al. (2020a)
85	The entirely subcutaneous ICDTM system in patients with congenital heart disease: experience from a large single-centre analysis	Willy et al. (2019)
86	Performance of the entirely subcutaneous ICD in borderline indications	Willy et al. (2020b)
87	Pitfalls of the S-ICD therapy: experiences from a large tertiary centre	Willy et al. (2021)
88	Telemonitoring with Electronic Devices in Patients with a Single Ventricle Anatomy	Zartner et al. (2021b)
89	Performance of epimyocardial leads in patients with a single ventricle circulation	Zartner et al. (2021a)

	Titel	Referenz
90	Probability of sinus rhythm conversion and maintenance in cardiac resynchronization therapy patients with atrial fibrillation during 5-year follow-up	Ziegelhoeffer et al. (2020)

3.2.1 Datenextraktion

Die Datenextraktion der eingeschlossenen Artikel zum Thema Versorgungssituation wurde von einer Person durchgeführt. Die Datenextraktion schloss relevante Informationen wie Autorin/Autor, Publikationsjahr, Titel, Studienpopulation, Fragestellung der Studie sowie zentrale Ergebnisse der Studie ein. Die extrahierten Daten der eingeschlossenen Publikationen sind in Anhang B dokumentiert.

3.3 Ausgeschlossene Publikationen zum Thema Versorgungssituation

Folgende im Volltext überprüfte Artikel zum Thema Versorgungssituation wurden ausgeschlossen (für die Ausschlussgründe vgl. Tabelle 5):

Nicht E1

1. Bastian, D; Ebrahim, IO; Chen, JY; Chen, MC; Huang, D; Huang, JL; et al. (2018): Real-world geographic variations in the use of cardiac implantable electronic devices-The PANORAMA 2 observational cohort study. PACE – Pacing and Clinical Electrophysiology 13: 13.

Nicht E2

keine

Nicht E3

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Nicht E7

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3. Eichenlaub, M; Astheimer, K; Minners, J; Blum, T; Restle, C; Maring, C; et al. (2020): Evaluation of a new ultralow-dose radiation protocol for electrophysiological device implantation: A near-zero fluoroscopy approach for device implantation. Heart Rhythm 17(1): 90-97. DOI: 10.1016/j.hrthm.2019.07.031.
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6. Grimm, W; Grimm, K; Greene, B; Parahuleva, M (2021): Predictors of pacing-dependency in patients with cardiovascular implantable electronic devices. Cardiology Journal 28(3): 423-430. DOI: 10.5603/CJ.a2019.0088
7. Kaya, E; Senges, J; Hochadel, M; Eckardt, L; Andresen, D; Ince, H; et al. (2020): Impact of diabetes on clinical outcome of patients with heart failure undergoing ICD and CRT procedures: results from the German Device Registry. ESC Heart Failure 7(3): 984-995. DOI: 10.1002/ehf2.12613.
8. Paech, C; Ebel, V; Wagner, F; Stadelmann, S; Klein, AM; Döhnert, M; et al. (2020): Quality of life and psychological co-morbidities in children and adolescents with cardiac pacemakers and implanted defibrillators: a cohort study in Eastern Germany. Cardiology in the Young 30(4): 549-559. DOI: 10.1017/S104795112000061X.

Nicht E8

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4 Informationsbeschaffung – patientenrelevante Themen

Um für die Generierung der Qualitätsaspekte ein möglichst umfassendes Bild zur Patientenperspektive bzw. zu patientenrelevanten und -beurteilbaren Themen zu erhalten, sollten sowohl systematische Übersichtsarbeiten als auch Primärliteratur systematisch recherchiert werden.

4.1 Recherche

In Tabelle 11 sind die definierten Einschlusskriterien, die der Recherche und dem Screening der Publikationen zu patientenrelevanten Themen zugrunde lagen, aufgeführt.

Tabelle 11: Einschlusskriterien für Publikationen zu patientenrelevanten Themen

	Einschluss
E1	Der Volltext der Publikation ist erhältlich.
E2	Die Publikationssprache ist Deutsch oder Englisch.
E3	Die Publikation wurde ab dem 01. April 2017 publiziert.
E4	Die Referenz ist keine Mehrfachpublikation.
E5	▪ Systematische Übersichtsarbeiten ▪ Qualitative Studien oder Mixed-Methods-Studien
E6	Die Publikation adressiert die ambulante oder stationäre Versorgung oder Notfallversorgung von Patientinnen und Patienten aus 8 Ländern der OECD: ▪ Deutschland, Australien, Kanada, Neuseeland, USA, Vereinigtes Königreich, Schweiz und Österreich Dabei muss die Mehrheit (>=80%) der eingeschlossenen Patientinnen und Patienten in den genannten Ländern versorgt werden.
E7	Die Publikation adressiert Patientinnen und Patienten aller Altersgruppen mit Rhythmusimplantaten (cardiac implantable electronic devices): ▪ Herzschrittmacher (pacemaker) ▪ Implantierbare Defibrillatoren (implantable defibrillator cardioverter, ICD, subkutan und substernal) ▪ Geräte zur kardialen Resynchronisationstherapie (cardiac resynchronization therapy, CRT-Devices)) Dabei soll die Mehrheit (≥ 80%) der eingeschlossenen Patientinnen und Patienten ein oben genanntes Rhythmusimplantat tragen. Ausgeschlossen: ▪ Publikation adressiert ausschließlich Patienten mit CCM-Devices ▪ Publikation adressiert ausschließlich Patienten mit implantierten Ereignisrekordern

	Einschluss
	Publikation adressiert ausschließlich Patienten mit temporären Schrittmachern
E8	Fokus der Publikation liegt auf patientenrelevanten und potentiell patientenbeurteilbaren Themen, die im Zusammenhang mit der Versorgung von Rhythmusimplantaten stehen. Spezifische Aspekte wie z. B.: ▪ gemeinsame Entscheidungsfindung ▪ Patienteninformation und Informationsübermittlung ▪ Kommunikation inkl. telemedizinischer Überwachung/Nachkontrolle ▪ gesundheitsbezogene Lebensqualität, ink. Schockerleben ▪ Berücksichtigung von Präferenzen und Behandlungsoptionen ▪ Psychische Erkrankungen: v.a. Angst und Depression Kontinuität und Einbindung weiterer ärztlicher/medizinischer Berufe

Die Literaturrecherche nach Publikationen zu patientenrelevanten Themen wurde in den folgenden bibliografischen Datenbanken durchgeführt:

- MEDLINE via Ovid
- Embase via Elsevier
- CINAHL via EBSCO
- Cochrane via Wiley

Für die Recherche wurde zunächst eine Strategie für die Literaturdatenbank MEDLINE entwickelt und dann entsprechend an die anderen Datenbanken angepasst. Die Suchstrategie bestand aus zwei Blöcken: ein Rechercheblock für die Population und Intervention (Patientinnen und Patienten mit Rhythmusimplantaten) sowie ein Rechercheblock für die Patientenperspektive.

Folgende Limitationen wurden, falls in der jeweiligen Datenbank möglich, bei der Suchstrategie berücksichtigt:

- Publikationen ab 2017
- nur „human“
- nur englische und deutsche Publikationen
- keine Kongressabstracts, Fallberichte, Kommentare, Editorials oder Letter

Die Limitationen finden sich eingebettet in den jeweiligen Suchstrategien der einzelnen Datenbanken (Tabelle 12, Tabelle 13, Tabelle 14 und Tabelle 15).

Die Recherche erfolgte in allen Datenbanken am 18. Mai 2022.

Suchstrategie für MEDLINE via Ovid

Tabelle 12: Suchstrategie für MEDLINE via Ovid (patientenrelevante Themen); Datum der Recherche: 18. Mai 2022

#	Searches
1	exp Defibrillators/
2	Electrodes, Implanted/
3	exp Pacemaker, Artificial/
4	exp Cardiac Pacing, Artificial/
5	(''Cardioverter-Defibrillator?'' or ''Implantable Cardioverter Defibrillator?'' or ''Implantable Cardioverter-Defibrillator?'' or ''Implantable Defibrillator?'' or ''Implantable Electrode?'' or ''Implanted Stimulation Electrode?'' or ''Cardiac Resynchronization Therap*'' or ''Cardiac Stimulator?'' or cardioverter* or pacesetter? or pacemaker? or ''sinoatrial node?'' or ''SA node?'' or pacer or ''mechanical heart?'' or (cardi* adj3 (defibrillat* or implant*))).ti,ab.
6	1 or 2 or 3 or 4 or 5
7	exp Patient Satisfaction/ or Patient Participation/
8	Patient Education as Topic/ or Health Knowledge, Attitudes, Practice/ or Attitude to Health/
9	Quality of Life/ or Patient Reported Outcome Measures/ or Needs Assessment/
10	Focus Groups/ or narration/ or exp Qualitative Research/ or Interviews as Topic/
11	exp "Surveys and Questionnaires"/
12	((("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide) adj3 (interview* or discussion* or questionnaire*)) or (focus group* or qualitative or ethnograph* or fieldwork or "field work" or "key informant")).ti,ab.
13	(patient? adj3 (experienc* or view? or opinion? or percept* or perceive? or perspect* or attitude? or belief? or believ* or prefer* or oriented or particip* or satisf* or desire* or wish* or involv* or report* or respon* or monitor* or track* or outcome?)).ti,ab.
14	7 or 8 or 9 or 10 or 11 or 12 or 13
15	6 and 14
16	limit 15 to (congress or case reports or comment or editorial or letter)
17	15 not 16
18	exp animals/ not (exp animals/ and exp humans/)
19	17 not 18
20	limit 19 to (english or german)
21	limit 20 to yr="2017 -Current"

Suchstrategie für Cochrane via Wiley

Tabelle 13: Suchstrategie für Cochrane via Wiley (patientenrelevante Themen); Datum der Recherche: 18. Mai 2022

#	Searches
#1	MeSH descriptor: [Defibrillators] explode all trees
#2	MeSH descriptor: [Electrodes, Implanted] this term only
#3	MeSH descriptor: [Pacemaker, Artificial] explode all trees
#4	MeSH descriptor: [Cardiac Pacing, Artificial] explode all trees
#5	(''Cardioverter-Defibrillator*'' or ''Implantable Cardioverter Defibrillator*'' or ''Implantable Cardioverter-Defibrillator*'' or ''Implantable Defibrillator*'' or ''Implantable Electrode*'' or ''Implanted Stimulation Electrode*'' or ''Cardiac Resynchronization Therap*'' or ''Cardiac Stimulator*'' or cardioverter* or pacesetter* or pacemaker* or ''sinoatrial node*'' or ''SA node*'' or pacer* or ''mechanical heart*'' or (cardi* NEAR/3 (defibrillat* or implant*))):ti,ab
#6	#1 or #2 or #3 or #4 or #5
#7	MeSH descriptor: [Patient Satisfaction] explode all trees
#8	MeSH descriptor: [Patient Participation] this term only
#9	MeSH descriptor: [Patient Education as Topic] this term only
#10	MeSH descriptor: [Health Knowledge, Attitudes, Practice] this term only
#11	MeSH descriptor: [Attitude to Health] this term only
#12	MeSH descriptor: [Quality of Life] this term only
#13	MeSH descriptor: [Patient Reported Outcome Measures] this term only
#14	MeSH descriptor: [Needs Assessment] this term only
#15	MeSH descriptor: [Focus Groups] this term only
#16	MeSH descriptor: [Narration] this term only
#17	MeSH descriptor: [Qualitative Research] explode all trees
#18	MeSH descriptor: [Interviews as Topic] this term only
#19	MeSH descriptor: [Surveys and Questionnaires] explode all trees
#20	(("semi-structured" or semistructured or unstructured or informal or "in-depth" or indepth or "face-to-face" or structured or guide) near/3 (interview* or discussion* or questionnaire*)):ti,ab
#21	("focus group" or "focus groups" or qualitative or ethnograph* or fieldwork or "field work" or "key informant"):ti,ab
#22	(patient* NEAR/3 (experienc* or view* or opinion* or percept* or perceive* or perspect* or attitude* or belief* or believ* or prefer* or oriented or particip* or satisf* or desire* or wish* or involv* or report* or respon* or monitor* or track* or outcome?)):ti,ab

#	Searches
#23	#7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22
#24	#6 and #23
#25	#24 with Cochrane Library publication date Between Jan 2017 and Apr 2022, in Cochrane Reviews
#26	#24 with Publication Year from 2017 to 2022, in Trials
#27	#25 or #26

Suchstrategie für Embase via Elsevier

Tabelle 14: Suchstrategie für Embase via Elsevier (patientenrelevante Themen); Datum der Recherche: 18. Mai 2022

No.	Searches
#1	'artificial heart pacemaker'/exp
#2	'cardiac implantable electronic device'/exp
#3	'defibrillator'/exp
#4	'pacemaker accessory'/exp
#5	'heart pacing'/exp OR 'cardiac rhythm management device'/de
#6	'cardioverter-defibrillator$':ti,ab OR 'implantable cardioverter defibrillator$':ti,ab OR 'implantable cardioverter-defibrillator$':ti,ab OR 'implantable defibrillator$':ti,ab OR 'implantable electrode$':ti,ab OR 'implanted stimulation electrode$':ti,ab OR 'cardiac resynchronization therap*':ti,ab OR 'cardiac stimulator$':ti,ab OR cardioverter$:ti,ab OR pacesetter$:ti,ab OR pacemaker$:ti,ab OR 'sinoatrial node$':ti,ab OR 'sa node$':ti,ab OR pacer$:ti,ab OR 'mechanical heart$':ti,ab OR ((cardi* NEAR/3 (defibrillat* OR implant*)):ti,ab)
#7	#1 OR #2 OR #3 OR #4 OR #5 OR #6
#8	'patient satisfaction'/de OR 'patient participation'/de OR 'patient preference'/de OR 'patient attitude'/de
#9	'quality of life'/de OR 'patient-reported outcome'/de OR 'self report'/de OR 'needs assessment'/de
#10	'patient education'/de OR 'attitude to health'/de
#11	'interview'/exp OR 'narrative'/de OR 'qualitative research'/exp
#12	((('semi-structured' OR semistructured OR unstructured OR informal OR 'in-depth' OR indepth OR 'face-to-face' OR structured OR guide) NEAR/3 (interview* OR discussion* OR questionnaire*)):ab,ti) OR 'focus group*':ab,ti OR qualitative:ab,ti OR ethnograph*:ab,ti OR fieldwork:ab,ti OR 'field work':ab,ti OR 'key informant':ab,ti
#13	(patient$ NEAR/3 (experienc* OR view$ OR opinion$ OR percept* OR perceive$ OR perspect* OR attitude$ OR belief$ OR believ* OR prefer* OR oriented OR particip* OR satisf* OR desire$ OR wish* OR involv* OR report* OR respon* OR monitor* OR track* OR outcome$)):ti,ab

No.	Searches
#14	#8 OR #9 OR #10 OR #11 OR #12 OR #13
#15	#7 AND #14
#16	'case report'/de OR [conference abstract]/lim OR [conference review]/lim OR [editorial]/lim OR [letter]/lim OR [preprint]/lim OR comment:ti
#17	#15 NOT #16
#18	'animal'/exp NOT ('animal'/exp AND 'human'/exp)
#19	#17 NOT #18
#20	#19 AND ([english]/lim OR [german]/lim)
#21	#20 AND [2017-2022]/py

Suchstrategie für CINAHL via EBSCO

Tabelle 15: Suchstrategie für CINAHL via EBSCO (patientenrelevante Themen); Datum der Recherche: 18. Mai 2022

No.	Searches
S1	(MH "Defibrillators, Implantable")
S2	(MH "Electrodes, Implanted")
S3	(MH "Pacemaker, Artificial")
S4	(MH "Cardiac Pacing, Artificial+")
S5	TI ((''Cardioverter-Defibrillator#'' or ''Implantable Cardioverter Defibrillator#'' or ''Implantable Cardioverter-Defibrillator#'' or ''Implantable Defibrillator#'' or ''Implantable Electrode#'' or ''Implanted Stimulation Electrode#'' or ''Cardiac Resynchronization Therap*'' or ''Cardiac Stimulator#'' or cardioverter# or pacesetter# or pacemaker# or ''sinoatrial node#'' or ''SA node#'' or pacer# or ''mechanical heart#'' or (cardi* N3 (defibrillat* or implant*)))) OR AB ((''Cardioverter-Defibrillator#'' or ''Implantable Cardioverter Defibrillator#'' or ''Implantable Cardioverter-Defibrillator#'' or ''Implantable Defibrillator#'' or ''Implantable Electrode#'' or ''Implanted Stimulation Electrode#'' or ''Cardiac Resynchronization Therap*'' or ''Cardiac Stimulator#'' or cardioverter# or pacesetter# or pacemaker# or ''sinoatrial node#'' or ''SA node#'' or pacer# or ''mechanical heart#'' or (cardi* N3 (defibrillat* or implant*))))
S6	S1 or S2 or S3 or S4 or S5
S7	(MH "Patient Satisfaction+") OR (MH "Consumer Participation")
S8	(MH "Patient Education") OR (MH "Health Knowledge") OR (MH "Attitude to Health")
S9	(MH "Quality of Life") OR (MH "Self Report") OR (MH "Patient-Reported Outcomes") OR (MH "Needs Assessment")
S10	(MH "Questionnaires+") OR (MH "Qualitative Studies+")
S11	(MH "Focus Groups") OR (MH "Narratives") OR (MH "Interviews+") OR (MH "Surveys")

No.	Searches
S12	((AB "focus groups*" OR TI "focus groups*") OR (AB qualitative OR TI qualitative) OR (AB ethnograph* OR TI ethnograph*) OR (AB fieldwork OR TI fieldwork) OR (AB "field work" OR "field work") OR (AB "key informant" OR TI "key informant"))
S13	((AB semi-structured OR TI semi-structured) OR (AB semistructured OR TI semistructured) OR (AB unstructured OR TI unstructured) OR (AB informal OR TI informal) OR (AB in-depth OR TI in-depth) OR (AB indepth OR TI indepth) OR (AB face-to-face OR TI face-to-face) OR (AB structured OR TI structured) OR (AB guide OR TI guide)) N3 ((AB interview* OR TI interview*) OR (AB discussion* OR TI discussion*) OR (AB questionnaire* OR TI questionnaire*))
S14	TI ((patient# N3 (experienc* or view# or opinion# or percept* or perceive# or perspect* or attitude# or belief# or believ* or prefer* or oriented or particip* or satisf* or desire# or wish* or involv* or report* or respon* or monitor* or track* or outcome#))) OR AB ((patient# N3 (experienc* or view# or opinion# or percept* or perceive# or perspect* or attitude# or belief# or believ* or prefer* or oriented or particip* or satisf* or desire# or wish* or involv* or report* or respon* or monitor* or track* or outcome#)))
S15	S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S16	S6 AND S15
S17	S16 Limiters - Publication Type: Abstract, Case Study, Commentary, Editorial, Letter, Proceedings
S18	S16 NOT S17
S19	(MH "Animals+") NOT ((MH "Animals+") AND (MH "Human+"))
S20	S18 NOT S19
S21	S20 Limiters - Published Date: 20170401-20220431; Language: English, German

Die Titel und Abstracts der recherchierten Publikationen wurden von zwei Personen unabhängig voneinander hinsichtlich ihrer inhaltlichen Relevanz bezogen auf die a priori festgelegte Frage überprüft und ausgewählt. Uneinheitliche Bewertungen wurden diskutiert und im Fall einer fehlenden Einigung wurden die Publikationen für ein Volltext-Screening einbezogen.

Die Volltexte der ausgewählten Publikationen wurden von zwei Personen unabhängig voneinander dahingehend überprüft, ob die a priori festgelegten Einschlusskriterien (siehe Tabelle 11) zutreffen. Uneinheitliche Bewertungen wurden diskutiert und eine Einigung herbeigeführt. Es erfolgte eine Dokumentation des Volltext-Screenings und der Ausschlussgründe für alle ausgeschlossenen Publikationen (siehe Abschnitt 4.4).

Eine Gesamtübersicht über die Recherche in bibliographischen Datenbanken bietet das nachfolgende Flussdiagramm (Abbildung 3).

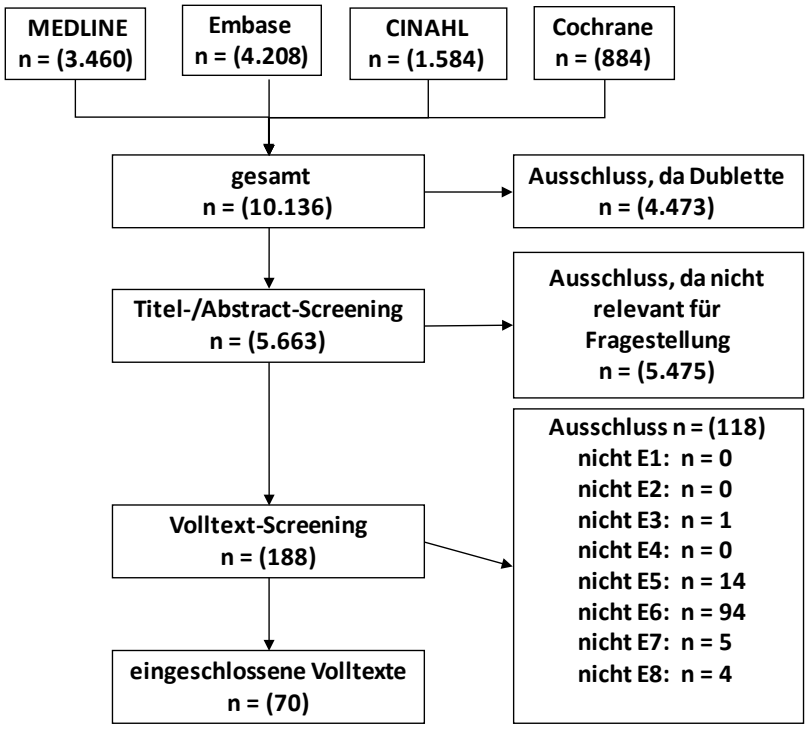

Abbildung 3: Flussdiagramm der Recherche nach Studien zu patientenrelevanten Themen

4.2 Eingeschlossene Studien zu patientenrelevanten Themen

Nach dem Volltext-Screening wurden 70 Artikel eingeschlossen (siehe Tabelle 16).

Tabelle 16: Eingeschlossene Publikationen zu patientenrelevanten Themen

	Titel	Referenz
1	Social cognitive intervention following an initial implantable cardioverter defibrillator: Better treatment response for secondary versus primary prevention	Auld et al. (2020)
2	The experience of patients with an implantable cardioverter-defibrillator: a systematic review and meta-synthesis of qualitative studies	Barisone et al. (2022)
3	Patient understanding of disease and the use and outcome of implantable cardioverter defibrillators in hypertrophic cardiomyopathy	Baskar et al. (2018)
4	Predictors of patient satisfaction after cardiac pacemaker implantation or ICD implantation	Bergmann et al. (2020)
5	Implementation, feasibility, and acceptability of quality of life therapy to improve positive emotions among patients with implantable cardioverter defibrillators	Carroll et al. (2020)
6	"I don't know exactly what you're referring to": the challenge of values elicitation in decision making for implantable cardioverter-defibrillators	Carroll et al. (2018)

	Titel	**Referenz**
7	The educational experiences and needs of patients with an internal cardiac defibrillator: An interpretive phenomenological study	Christie et al. (2021)
8	The ethics of unilateral implantable cardioverter defibrillators and cardiac resynchronization therapy with defibrillator deactivation: patient perspectives	Daeschler et al. (2017)
9	Providing Patients with Implantable Cardiac Device Data through a Personal Health Record: A Qualitative Study	Daley et al. (2017)
10	'I'm still here, that's probably the best part'. Lives of those living rurally with an implantable cardioverter defibrillator: a qualitative study	Doolan-Noble et al. (2021)
11	Patient plus partner trial: A randomized controlled trial of 2 interventions to improve outcomes after an initial implantable cardioverter-defibrillator	Dougherty et al. (2019)
12	Evaluation of an Internet-based intervention for ICD patients with elevated symptoms of posttraumatic stress disorder	Ford et al. (2019)
13	Exploring the patients' experiences of living with a subcutaneous implantable cardioverter defibrillator	Forman et al. (2018)
14	"I'm Not Sure We Had A Choice": Decision Quality and The Use of Cardiac Implantable Electronic Devices In Older Adults With Cognitive Impairment	Fowler et al. (2018)
15	Patient and Provider Perspectives on Remote Monitoring of Pacemakers and Implantable Cardioverter-Defibrillators	Fraiche et al. (2021)
16	Cosmetic outcomes and quality of life in children with cardiac implantable electronic devices	Gist et al. (2019)
17	Longitudinal changes in quality of life following ICD implant and the impact of age, gender, and ICD shocks: observations from the INTRINSIC RV trial	Gopinathannair et al. (2017)
18	"Why Would I Choose Death?". A Qualitative Study of Patient Understanding of the Role and Limitations of Cardiac Devices	Hadler et al. (2019)
19	Complex Decision-Making in Heart Failure. A Systematic Review and Thematic Analysis	Hamel et al. (2018)
20	Perceived control and quality of life among recipients of implantable cardioverter defibrillator	Hammash et al. (2019)
21	Deactivation of Implantable Cardioverter-Defibrillators in Heart Failure. A Systematic Review	Herman et al. (2018)
22	Implantable cardioverter defibrillator (ICD) functionality: patient and family information for advanced decision-making	Hill et al. (2019)
23	The Capture Gap: Implantable Cardioverter-Defibrillator Quality of Life	Hopgood et al. (2020)
24	Living with an implantable cardioverter defibrillator: partners' experiences	Humphreys et al. (2018)

	Titel	Referenz
25	Men with implantable cardioverter defibrillators: A qualitative study of gender and age	Jakub (2018)
26	Remote Monitoring of Cardiovascular Implantable Electronic Devices in Canada: Survey of Patients and Device Health Care Professionals	Kelly et al. (2021)
27	Changes in quality of life, depression, general anxiety, and heart-focused anxiety after defibrillator implantation	Kindermann et al. (2021)
28	Posttraumatic stress and quality of life with the totally subcutaneous compared to conventional cardioverter-defibrillator systems	Köbe et al. (2017b)
29	Patients With Implantable Cardioverter Defibrillators on Social Media Report More Shock Anxiety Than Clinic Patients: Results From an Online Survey	Kramer Freeman et al. (2017)
30	Deactivating a Pacemaker in Home Care Hospice: Experiences of the Family Caregivers of a Terminally Ill Patient	Kutcher und Srokoa (2020)
31	Decision-Making of Patients With Implantable Cardioverter-Defibrillators at End of Life: Family Members' Experiences	Lee et al. (2017)
32	The INFluence of Remote monitoring on Anxiety/depRession, quality of lifE, and Device acceptance in ICD patients: a prospective, randomized, controlled, single-center trial	Leppert et al. (2021)
33	Lead extraction for reduction of chronic pain related to cardiovascular implantable electronic device	Lewis et al. (2019)
34	User-centered Development of a Decision Aid for Patients Facing Implantable Cardioverter-Defibrillator Replacement. A Mixed-Methods Study	Lewis et al. (2018)
35	Effectiveness of cognitive behavioral therapy on mood symptoms in patients with implantable cardioverter defibrillator: A systematic review and meta-analysis	Li et al. (2022)
36	Health-Related Quality of Life in the Spironolactone to Reduce ICD Therapy (SPIRIT) Trial	Liberato et al. (2022)
37	Intervention mediating effects of self-efficacy on patient physical and psychological health following ICD implantation	Liberato et al. (2021)
38	Restoring Normalcy: The Experiences of Five Women Living with an Implantable Cardioverter Defibrillator	Manuel und Colbourne (2018)
39	Evidence of Cognitive Bias in Decision Making Around Implantable-Cardioverter Defibrillators: A Qualitative Framework Analysis	Matlock et al. (2017)
40	Implantable cardioverter defibrillator knowledge and end-of-life device deactivation: A cross-sectional survey	McEvedy et al. (2018)
41	Prospective evaluation of health status, quality of life and clinical outcomes following implantable defibrillator generator exchange	Merchant et al. (2021)

	Titel	Referenz
42	Missed opportunities! End of life decision making and discussions in implantable cardioverter defibrillator recipients	Miller et al. (2019)
43	Delivering remote monitoring data to patients with implantable cardioverter-defibrillators: Does medium matter?	Mirro et al. (2018)
44	Delivering an efficient and effective support group for patients with implantable cardioverter-defibrillators (ICDs): patient perspectives of key concerns and predictors of inclination to attend	Murray et al. (2021)
45	Quality of life predicting long-term outcomes in cardiac resynchronization therapy patients	Nagy et al. (2019)
46	Post-operative pain following cardiac implantable electronic device implantation: Insights from the BRUISE CONTROL trials	Nair et al. (2021)
47	Age, Sex, and Remote Monitoring Differences in Device Acceptance for Patients With Implanted Cardioverter Defibrillators in Canada	Ng et al. (2020)
48	Quality of life and psychological co-morbidities in children and adolescents with cardiac pacemakers and implanted defibrillators: a cohort study in Eastern Germany	Paech et al. (2020)
49	The gap between what patients know and desire to learn about their cardiac implantable electronic devices	Patel et al. (2020)
50	Day-case device implantation-A prospective single-center experience including patient satisfaction data	Peplow et al. (2018)
51	Experiences of adults living with an implantable cardioverter defibrillator for cardiovascular disease: a systematic review of qualitative evidence	Pike et al. (2020)
52	Health-Related Quality of Life and Psychological Adjustment of Children and Adolescents with Pacemakers and Implantable Cardioverter Defibrillators: A Systematic Review	Pyngottu et al. (2019)
53	Digging Deeper: Understanding Trajectories and Experiences of Shared Decision-Making for Primary Prevention ICD Implantation	Rao et al. (2022a)
54	The impact of government-mandated shared decision-making for implantable defibrillators: A natural experiment	Rao et al. (2022b)
55	Using cardiac implantable electronic device data to facilitate health decision making: A design study	Rohani Ghahari et al. (2018)
56	Remote-only monitoring for patients with cardiac implantable electronic devices: a before-and-after pilot study	Sapp et al. (2021)
57	An exploratory assessment of pediatric patient and parent needs after implantable cardioverter defibrillator implant	Schneider et al. (2020)
58	Efficacy of a web-based intervention for improving psychosocial well-being in patients with implantable cardioverter-defibrillators: the randomized controlled ICD-FORUM trial	Schulz et al. (2020)

	Titel	Referenz
59	Evaluation and acceptance of mobile-electrocardiogram use in implantable cardioverter defibrillator patients – Can I see my ECG?	Sears et al. (2020)
60	Die Lebensqualität von Patienten mit implantierbarem Kardioverter-Defibrillator aus salutogenetischer Sicht. Eine qualitative Studie der kardiologischen	Senn et al. (2020)
61	Long-term outcomes after event-free cardioverter defibrillator implantation: comparison between patients discharged within 24 h and routinely hospitalized patients in the German DEVICE registry	Spitzer et al. (2017)
62	Patient Perception of the Remote Versus Clinic Visits for Interrogation of Implantable Cardioverter Defibrillators	Srivatsa et al. (2020)
63	'You can't start a car when there's no petrol left': a qualitative study of patient, family and clinician perspectives on implantable cardioverter defibrillator deactivation	Standing et al. (2021)
64	The incidence and impact of implantable cardioverter defibrillator shocks in the last phase of life: An integrated review	Stoevelaar et al. (2018)
65	Patient and Partner Sexual Concerns During the First Year After an Implantable Cardioverter Defibrillator: A Secondary Analysis of the P+P Randomized Clinical Trial	Streur et al. (2020)
66	Impact of the implantable cardioverter defibrillator on confidence to undertake physical activity in inherited heart disease: A cross-sectional study	Sweeting et al. (2017)
67	A prospective longitudinal study of health-related quality of life and psychological wellbeing after an implantable cardioverter-defibrillator in patients with genetic heart diseases	van den Heuvel et al. (2022)
68	Phantom shocks in implantable cardioverter-defibrillator recipients: impact of education level, anxiety, and depression	Varghese et al. (2019)
79	Decision regret in implantable cardioverter-defibrillator recipients. A cross-sectional analysis on patients that regret their decision after ICD implantation	Varghese et al. (2020)
70	Patient perspectives on the need for implanted device information: Implications for a post-procedural communication framework	Wilson et al. (2021)

4.3 Datenextraktion

Die Datenextraktion der eingeschlossenen Studien zu patientenrelevanten Themen wurde von einer Person durchgeführt. Die Datenextraktion schloss relevante Informationen wie u. a. Autorin/Autor, Publikationsjahr, Titel, Studiendesign, Studienpopulation und Fragestellung ein. Die extrahierten Daten der eingeschlossenen Studien sind in Anhang B dokumentiert.

4.4 Ausgeschlossene Studien zu patientenrelevanten Themen

Folgende im Volltext überprüfte Artikel zum patientenrelevanten Themen wurden ausgeschlossen (für die Ausschlussgründe vgl. Tabelle 11):

Nicht E1

Keine

Nicht E2

Keine

Nicht E3

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Nicht E4

Keine

Nicht E5

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Anhang B: Charakteristika der eingeschlossenen Leitlinien

Anhang B.1: Charakteristika der eingeschlossenen Leitlinien

Referenz	Titel	Herausgeber, Herkunftsland	Ziel der Leitlinie	Zielpopulation	Adressatinnen und Adressaten
Al-Khatib et al. (2018)	2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death	American College of Cardiology Foundation, the American Heart Association, Inc., and the Heart Rhythm Society USA	The purpose of this AHA/ACC/HRS document is to provide a contemporary guideline for the management of adults who have VA or who are at risk for SCD, including diseases and syndromes associated with a risk of SCD from VA.	adults who have VA or who are at risk for SCD, including diseases and syndromes associated with a risk of SCD from VA	healthcare professionals
BÄK et al. (2019)	AWMF-Registernummer nvl-006. Nationale VersorgungsLeitlinie: Chronische Herzinsuffizienz	Bundesärztekammer (BÄK) Arbeitsgemeinschaft der Deutschen Ärztekammern Kassenärztliche Bundesvereinigung (KBV) Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF)	Die NVL Chronische Herzinsuffizienz soll die sektorenübergreifende Versorgung von Patienten mit chronischer Herzinsuffizienz verbessern. Die Empfehlungen betreffen daher sowohl die Versorgung im gesamten ambulanten Bereich, als auch in Teilaspekten des stationären Bereichs (Behandlung der akuten Dekompensation, invasive Therapien). Außerdem definiert die NVL die Übergänge zwischen primärärztlicher und spezialfachärztlicher Versorgung sowie zwischen ambulanter und stationärer Versorgung. Die NVL Chronische Herzinsuffizienz soll dazu beitragen, folgende Ziele zu erreichen: ▪ stärker auf die Bedürfnisse der Patienten ausgerichtete Versorgung: verbesserte Arzt-Patienten-	Patienten mit Links- und Globalherzinsuffizienz inklusive akuter Dekompensationen	▪ Ärztinnen und Ärzte, die in den von der NVL angesprochenen Versorgungsbereichen tätig sind ▪ nicht-ärztliche Fachberufe, die in den angesprochenen Versorgungsbereichen als Kooperationspartner der Ärzteschaft tätig sind (Pflegekräfte, Apotheker) ▪ die betroffenen Patienten und ihr persönliches Umfeld

Referenz	Titel	Herausgeber, Herkunftsland	Ziel der Leitlinie	Zielpopulation	Adressatinnen und Adressaten
			Kommunikation, gemeinsame Vereinbarung von Therapiezielen, Förderung der Therapieadhärenz, Behandlung am Lebensende gemäß den individuellen Bedürfnissen und Präferenzen des Patienten; ▪ adäquate Therapie der Grunderkrankungen zur Prävention des Entstehens oder der Progression einer chronischen Herzinsuffizienz; ▪ Einbindung wiederholter edukativer Elemente zur Verbesserung des Selbstmanagements und der Adhärenz der Patienten in der Langzeitbetreuung; ▪ Optimierung der Therapie zur Vermeidung von Dekompensationen und Krankenhauseinweisungen; ▪ verbesserte Koordination aller an der Versorgung Beteiligten (interdisziplinäre Versorgung, Palliativversorgung, sektorenübergreifende Versorgung).		▪ Vertragsverantwortliche von Strukturierten Behandlungsprogrammen und Integrierter Versorgung ▪ medizinisch wissenschaftliche Fachgesellschaften und andere Herausgeber von Leitlinien ▪ Kostenträger im Gesundheitssystem ▪ Einrichtungen der ärztlichen Aus-, Fort- und Weiterbildung und an Qualitätsmanagementsysteme ▪ breite Öffentlichkeit zur Information über gute medizinische Vorgehensweise
Glikson et al. (2021)	2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy.	European Society of Cardiology (ESC) Europe	assisting health professionals in proposing the best management strategies for an individual patient with a given condition	cardiac pacing and cardiac resynchronization therapy	health professionals
Kusomoto et al. (2019)	2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia	American College of Cardiology Foundation, the American Heart Association, Inc., and the Heart Rhythm Society	to provide guidance to clinicians for the management of patients with bradycardia, or symptoms thought to be associated with bradycardia or cardiac conduction system disorders	adult population (>18 years of age) with bradycardia and cardiac conduction delay	general internists, family physicians, emergency physicians, anesthesiologists, surgeons, cardiologists, and arrhythmia specialists

Referenz	Titel	Herausgeber, Herkunftsland	Ziel der Leitlinie	Zielpopulation	Adressatinnen und Adressaten
	and Cardiac Conduction Delay	USA			
McDonagh et al. (2021)	2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure	European Society of Cardiology (ESC) Europe	to help health professionals manage people with heart failure according to the best available evidence, to provide practical, evidence-based recommendations	patients with acute and chronic heart failure	health professionals
Zeppenfeld et al. (2022)	2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death	European Society of Cardiology (ESC) Europe	to assist health professionals in proposing the best management strategies for an individual patient, to facilitate decision making of health professionals in their daily practice	patients with ventricular arrhythmias	health professionals

Anhang B.2: Evidenz- und Empfehlungsgrade der eingeschlossenen Leitlinien

2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death

Evidenzgraduierung

Tabelle 1: Class (Strength) of recommendations, Seite e96

Class I (Strong) Benefit >>> Risk	Suggested phrases for writing recommendations: ▪ Is recommended ▪ Is indicated/useful/effective/beneficial ▪ Should be performed/administered/other ▪ Comparative-Effectiveness Phrases ▫ Treatment/strategy A is recommended/indicated in preference to treatment B ▫ Treatment A should be chosen over treatment B
Class IIa (Moderate) Benefit >> Risk	Suggested phrases for writing recommendations: ▪ Is reasonable ▪ Can be useful/effective/beneficial ▪ Comparative-Effectiveness Phrases ▫ Treatment/Strategy A is probably recommended/indicated in preference to treatment B ▫ It is reasonable to choose treatment A over treatment B
Class IIb (Weak) Benefit ≥ Risk	Suggested phrases for writing recommendations: ▪ May/might be reasonable

	▪ May/might be considered ▪ Usefulness/effectiveness is unknown/unclear/uncertain or not well established
Class III: No Benefit (Moderate) Benefit = Risk	Suggested phrases for writing recommendations: ▪ Is not recommended ▪ Is not indicated/useful/effective/beneficial ▪ Should not be performed/administered/other
Class III: Harm Risk > Benefit	Suggested phrases for writing recommendations: ▪ Potentially harmful ▪ Causes harm ▪ Associated with excess morbidity/mortality ▪ Should not be performed/administrated/other

Evidenzstärke

Tabelle 2: Level (Quality) of Evidence, Seite e96

Level A	▪ High-quality evidence from more than 1 RCT ▪ Meta-analysis of high-quality RCTs ▪ One or more RCTs corroborated by high-quality registry studies
Level B-R (Randomized)	▪ Moderate-quality evidence from 1 or more RCTs ▪ Meta-analyses of moderate-quality RCTs
Level B-NR (Non-randomized)	▪ Moderate-quality evidence from 1 or more well designed, well-executed nonrandomized studies, observational studies, or registry studies ▪ Meta-analyses of such studies
Level C-LD	▪ Randomized or nonrandomized observational or registry studies with limitations of designs or execution

(Limited Data)	▪ Meta-analyses of such studies ▪ Physiological or mechanistic studies in human subjects
Level C-EO (Expert Opinion)	Consensus of expert opinion based on clinical experience

AWMF-Registernummer nvl-006. Nationale VersorgungsLeitlinie: Chronische Herzinsuffizienz

Evidenzgraduierung

Die Evidenzgraduierung („Level of Evidence") der einzelnen Quellen folgte dem Schema des Oxford Centre for Evidence-Based Medicine (OCEBM 2011, www.cebm.net). (vgl. Rechercheberichts: BÄK et al. 2019: 13)

Tabelle 3: Einstufung von Leitlinien-Empfehlungen in Empfehlungsgrade (Grades of Recommendation), Seite 11

Empfehlungsgrad	Beschreibung	Formulierung	Symbol
A	Starke Positiv-Empfehlung	soll	⇑⇑
B	Abgeschwächte Positiv-Empfehlung	sollte	⇑
0	Offene Empfehlung	kann	⇔
B	Abgeschwächte Negativ-Empfehlung	sollte nicht	⇓
A	Starke Negativ-Empfehlung	soll nicht	⇓⇓

2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

Evidenzgraduierung

The recommendations for formulating and issuing ESC Guidelines can be found on the ESC website (https://www.escardio.org/Guidelines).

Tabelle 1: Classes of recommendations, Seite 7

Class	Definition	Wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended or is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Evidenzstärke

Tabelle 2: Levels of evidence, Seite 7

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay

Evidenzgraduierung

Tabelle 3: Class (Strength) of recommedations, Seite e58

Class I (Strong) Benefit >>> Risk	Suggested phrases for writing recommendations: ▪ Is recommended ▪ Is indicated/useful/effective/beneficial ▪ Should be performed/administered/other ▪ Comparative-Effectiveness Phrases ▫ Treatment/strategy A is recommended/indicated in preference to treatment B ▫ Treatment A should be chosen over treatment B
Class IIa (Moderate) Benefit >> Risk	Suggested phrases for writing recommendations: ▪ Is reasonable ▪ Can be useful/effective/beneficial ▪ Comparative-Effectiveness Phrases ▫ Treatment/Strategy A is probably recommended/indicated in preference to treatment B ▫ It is reeasonable to choose treatment A over treatment B
Class IIb (Weak) Benefit ≥ Risk	Suggested phrases for writing recommendations: ▪ May/might be reasonable ▪ May/might be considered ▪ Usefulness/effectiveness is unknown/unclear/uncertain or not well established
Class III: No Benefit (Moderate) Benefit = Risk	Suggested phrases for writing recommendations: ▪ Is not recommended

	▪ Is not indicated/useful/effective/beneficial ▪ Should not be performed/administered/other
Class III: Harm Risk > Benefit	Suggested phrases for writing recommendations: ▪ Potentially harmful ▪ Causes harm ▪ Associated with excess morbidity/mortality ▪ Should not be performed/administrated/other

Evidenzstärke

Tabelle 4: Level (Quality) of Evidence, Seite e58

Level A	▪ High-quality evidence from more than 1 RCT ▪ Meta-analysis of high-quality RCTs ▪ One or more RCTs corroborated by high-quality registry studies
Level B-R (Randomized)	▪ Moderate-quality evidence from 1 or more RCTs ▪ Meta-analyses of moderate-quality RCTs
Level B-NR (Nonrandomized)	▪ Moderate-quality evidence from 1 or more well designed, well-executed nonrandomized studies, observational studies, or registry studies ▪ Meta-analyses of such studies
Level C-LD (Limited Data)	▪ Randomized or nonrandomized observational or registry studies with limitations of designs or execution ▪ Meta-analyses of such studies ▪ Physiological or mechanistic studies in human subjects
Level C-EO (Expert Opinion)	Consensus of expert opinion based on clinical experience

2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

Evidenzgraduierung

Tabelle 5: Classes of recommendations, Seite 10

Class	Definition	Wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended or is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Evidenzstärke

Tabelle 6: Levels of Evidence, Seite 10

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

2022 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death

Evidenzgraduierung

Tabelle 7: Classes of recommendations, Seite 7

Class	Definition	Wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended or is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
Class IIa	Weight of evidence/opinion is in favour of usefulness/efficacy.	Should be considered
Class IIb	Usefulness/efficacy is less well established by evidence/opinion.	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Evidenzstärke

Tabelle 8: Levels of Evidence, Seite 8

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

Anhang B.3: Literaturextraktion

Anhang B.3.1 Versorgungssituation in Deutschland

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
Abdin (2019)	Retrospective single center study + Follow-up (FUP) Secondary data analysis	Total: n=173 Subgroups: ▪ PICM: n=26 ▫ Sex: 23 (88.4 %) male ▫ Mean Age: 71.85 (standard deviation (SD)=12.1) years ▪ No PICM: n=147 ▫ Sex: 82 (55.7 %) male ▫ Mean Age: 75.49 (SD=11.2) years	Identify the incidence and predictors of pacemaker induced cardiomyopathy (PICM)	<u>PICM development:</u> No association between RV pacing percentage and left-ventricular ejection fraction (LVEF) deterioration. Patients in the PICM group had a lower rate of hypertension (16/26 vs 121/147, p=.016), were likely to be men (23/26 vs 82/147, p=.002) and had a wider paced QRS duration (QRSd) (148.2 ± 15.5 ms vs 134.7 ± 19.4 ms, p=.001). Male sex and wider paced QRS are independent predictors of PICM. <u>FUP:</u> RV pacing percentage was similar between both groups (76.5 ± 11.2 vs 76.2 ± 9.8 %, p=.65). <u>Multi variable regression analyses:</u> Male sex (hazard ratio (HR) 6.45, 0.95 CI 1.9–21.86, p=.003) and paced QRSd (HR 1.04, 0.95 CI 1.02–1.07, p<.001) solely remained as independent predictors of PICM occurrence. In receiver operating characteristic curve analysis, paced QRSd ≥ 140 ms had the best sensitivity (84.5 %) and specificity (62.6 %) for development of PICM (area under curve=.768)
Attanasio (2017)	Retrospective chart review Secondary data analysis	Total: n=965 Sex: 649 (67.3 %) male Mean Age: 69.2 (SD=13.0) years Subgroups: ▪ Obese Patients: n=249 ▫ Sex: 171 (68.7 %) male	Evaluate the safety and efficacy of various cardiac device implantations in obese patients compare procedural success, complications,	<u>Complications:</u> The number of major complications was significantly lower in obese than nonobese patients (11 [4.4 %] vs 62 [8.7 %], p<.05; odds ratio (OR): 2.2, 95 % confidence interval (CI): 1.1–4.4). Further analysis according to the type of complications showed a significantly lower rate of major bleedings (1 [0.4 %] vs 24 [3.4 %], p<.05; OR: 10.4, 95 % CI: 1.3–80.2) and pneumothoraces (0 [0 %] vs 13 [1.8 %]; p<.05) in obese patients. <u>Radiation exposure:</u>

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
		▫ Mean Age: 67 (SD=10.8) years ▪ Nonobese Patients: n=716 ▫ Sex: 478 (66.8 %) male ▫ Mean Age: 69.9 (SD=13.6) years	and total radiation dose needed for the implantation.	Significantly higher dose-area product (DAP) in obese patients compared with nonobese patients, whereas procedural duration and fluoroscopy time were not statistically different
Bettin (2017)	Retrospective cohort study Quantitative, primary data	Total: n=31 Sex: 19 (61.3 %) male Mean Age: 20.1 (SD=4.0) years Subgroups: ▪ teenagers (age <20) with subcutaneous implantable cardioverter-defibrillator (S-ICD): n=13 ▫ Sex: 8 (61.5 %) male ▫ Mean Age: 16.1 (SD=2.3) ▪ young adults (age 20–26) with S-ICD: n=18 ▫ Sex: 11 (61.1 %) male ▫ Mean Age: 22.9 (SD=1.8) years ▪ Control group (CG): n=31 patients (matched)	To examine the use of the S-ICD in teenagers and young adults.	<u>Shocks:</u> The teenagers with S-ICD systems experienced significantly more shocks than the young adults with S-ICD. <u>Inappropriate shocks (IAS):</u> there was a difference in the time to the first IAS (log-rank test; p=.005) The leading cause of IAS was T-wave oversensing (TWOS) in 3 cases (9.6 %). Younger age at the time of insertion was found to be an independent predictor of IAS (HR: 0.56; 95 % CI: 0.34 to 0.92; p<.05).

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
Bettin (2018)	Retrospective single center study + FUP Quantitative, primary data	Total: n=216 Sex: 153 (71 %) male Mean Age: 43.6 (SD=15.7) years	To determine reasons and frequency of vector change in the S-ICD, especially after device replacement.	Vector change: Compared to patients without vector change in the postoperative device setup or during FUP, in patients with vector change the secondary and alternate vector were chosen more frequently. IAS: Main mechanism of IAS deliveries was TWOS (66.7 %). In all patients with shock delivery due to TWOS, the sensing vector was changed manually. TWOS was only seen in the primary and secondary vector (7 patients with primary vector, 5 patients with secondary vector). After reprogramming the sensing vector, 3 patients had recurrent TWOS.
Bettin (2019)	Retrospective analysis + FUP Quantitative, primary data	Total: n=28 Sex: 21 (75 %) male mean age: 41.9 (SD=12.6)	Analyzed the longtime FUP of our first S-ICD patients from the initial implantation till battery depletion.	Mortality: No deaths were observed during the FUP. Appropriate therapy/IAS: During FUP 2 patients experienced an appropriate therapy delivery. In total, 3 IAS in 3 patients. IAS occurred earlier in FUP than appropriate therapies. 18 therapies in 10 patients were withheld. No further inappropriate therapies were seen till battery depletion of the device. The IAS rate in the initial cases was 0.017 per patient-year. Device replacement: Only one patient had premature ERI after 32.1 months. No peri- or postoperative complications after device replacement Estimated battery longevity or S-ICD of about 5 years was reached in all but one patient. Replacement of the S-ICD seems to be a safe and uncomplicated procedure.
Bogossian (2020)	Multicenter prospective registry	Total: n=2240 Subgroups: ▪ DDD ICD: n=611 ▫ Sex: 491 (80.4 %) male	To analyze in the German prospective Device Registry whether advantages for the DDD-ICD could be defined	In-hospital complications: higher in the DDD-ICD group with higher revision/device complication rates 3 % vs. 1.2 %; p=.003/n=27 from 604 patients vs. 41 from 1623 patients higher mortality rate in patients with DDD-ICD systems 1 % vs. 0 % p<.001; n=6 from 611 patients vs. 0 from 1629 patients

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
	Secondary data analysis	▫ Mean Age: 66 (SD=12) years ▫ < 80 years: 8.7 % ▪ VVI ICD: n=1629 ▫ Sex: 1358 (83.4 %) ▫ Mean Age: 63 (SD=13) years ▫ < 80 years: 5.6 % years	or if the additional lead is the reason for higher complication and mortality rates in DDD-ICD recipients p.912	<u>One year FUP:</u> DDD-ICD patients presented an increased incidence for device revision, rehospitalization and mortality <u>Revision:</u> 8.8 % vs. 6.7 %, p=.13/43 from 491 patients vs. 81 from 1214 patients <u>Rehospitalization:</u> 33.7 % vs. 30.1 %, p=.14/165 from 489 patients vs. 366 from 1215 patients <u>Mortality:</u> 7.6 % vs. 5.9 %, p=ns/60 from 592 patients vs. 190 from 1574 patients <u>Logistic regression:</u> In-hospital device revision DDD-ICD vs. VVI-ICD OR2.54(1.28–5.03), p=.008 non-fatal- in-hospital complications DDD-ICD vs. VVI-ICD OR1.66(0.99–2.78), p=.054 <u>Cox-regression for 1-year-mortality:</u> DDD-ICD vs. VVI-ICD Adjusted HR 1.13(0.78–1.65), p=.515
Bogossian (2021)	Retrospective design Secondary data analysis	Total: n=18.625 Geschlecht: 14.508 (77,9 %) männlich Alter: ≤ 60 Jahre: 5212 61–80 Jahre: 12.020 > 80 Jahre: 1393	Aus den Datensätzen der Qualitätssicherung Nordrhein-Westfalen sollen die Baseline- und Implantationsparameter identifiziert werden, die mit einer erhöhten perioperativen Mortalität nach implantier-	<u>Vergleich Altersgruppen (≤60 Jahre, 61–80 Jahre, >80 Jahre):</u> Die Überlebenswahrscheinlichkeit zwischen den ersten beiden Altersgruppen zeigte keinen signifikanten Unterschied (p=0,0748). Die Patienten der dritten Altersgruppe hatten gegenüber den beiden jüngeren Gruppen eine signifikant höhere Mortalität (jeweils p<0,001) <u>American Society of Anesthesiologists (ASA)-Klasse:</u> Die Mortalität war bei Patienten mit höherer ASA-Klasse gegenüber Patienten mit niedriger ASA-Klasse signifikant höher. <u>New York Heart Association (NYHA)-Klasse:</u> Die Mortalität bei Patienten höherer NYHA-Klassen war signifikant höher als bei Patienten niedriger NYHA-Klassen. <u>Komorbiditäten:</u>

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
			barem kardioverter Defibrillator (ICD)-Implantation assoziiert sind.	Die dialysepflichtige Niereninsuffizienz war gegenüber Patienten ohne Niereninsuffizienz und gegenüber nicht dialysepflichtigen niereninsuffizienten Patienten mit einer signifikant höheren Mortalität assoziiert. Prozedurbedingte Mortalität: 4 Patienten (0,033 %) unmittelbar perioperativ verstorben
Chung (2021)	Retrospective design Secondary data analysis	Total: n=144 Subgroups: ▪ S-ICD after transvenous lead extraction (TLE): n=31 ▫ Sex: 28 (90.3 %) male ▫ Mean Age: 54.3 (SD=15.7) years ▪ de-novo S-ICD: n=113 ▫ Sex: 85 (75.2 %) male ▫ Mean Age: 46.7 (SD=14.4) years	To evaluate device performance, postoperative outcome, and safety in patients who received a S-ICD after TLE compared to patients who underwent de-novo S-ICD implantation	TLE procedural data: Leading cause for TLE: systemic infection with 38.8 % (n=12), pocket infection with 25.8 % (n=8), lead dysfunction (25.8 %). Complete procedural success rate of 93.5 %. Total clinical success rate: 100 %. Intraoperative complication rate: 6.5 %, Intraoperative and procedure-related postoperativemortality after TLE: 0 % S-ICD procedural data: Primary prevention: TLE group: CIED-related infection (50 % vs.6.3 %); p<.0001 and vascular issues (13.2 % vs. 2.4 %); p=.017; de-novo S-ICD: "young patient age" (31.6 % vs. 74.6 %); p<.0001. FUP: Most common complication: inappropriate S-ICD therapy (12.9 % in TLE group), (13.3 % in de-novo S-ICD group); p=1 Leading cause for IAT: cardiac oversensing with 6.4 % vs. 6.2 % of patients receiving IAT due to TWOS and 6.4 % vs. 2.7 % of patients due to supraventricular tachycardia (SVT) or atrial fibrillation (AF)
D'Ancona (2017)	Retrospective design Secondary data analysis:	Total: n=1223 Subgroups: ▪ RM: n=720 ▫ Sex: 20 % female ▫ Median Age: 68 (interquartile range (IQR)=58–75)	Investigated RM within the premises of a multicenter, prospective, real-world registry Focus on:	RM capabilities: 720 (58.8 %) implanted with RM-capable devices (in 11 centers; Biotronik 41.6 %, St. Jude Medical 23.1 %; Medtronic 18.l %, Guidant 16.8 %, Others 0.4 %) 503 (41.1 %) with devices that had no RM features RM activation: At discharge, RM feature was activated in only 91 patients, corresponding to 12.6 % of the total number of patients implanted with RM-capable CIEDs (91/720). FUP:

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
	German Device-II registry	▪ no RM: n=503 ▫ Sex: 21.5 % female ▫ Median Age: 67 (IQR=57–75) years	(1) cardiac implantable electric devices (CIEDs) with RM capabilities implantation rate (2) actual rate of RM features activation.	completed in 95 % of the total cohort (1167/1223 patients). In 13.8 % of the surviving patients implanted with RM-capable CIEDs the RM feature remained activated at FUP One-year estimated mortality is 9 % in patients with activated RM, 5.6 % in those with not activated RM, and 7.7 % in those without RM capability
Dicks (2020)	Retrospective design Secondary data analysis: German National Register for Congenital Heart Defects (NRCHD)	Total: n=109 Sex: 68 (62 %) male Median Age: 35.5 (IQR 23.75–46.99) years n=13 < 18 years	To identify indications for ICD implantation, incidence and type of related complications and appropriate therapies as a surrogate for benefit from ICD therapy	<u>Indication:</u> Secondary prevention (n=84, 78 %). Reason: Ventricular tachycardia (VT) (n=53 (65 %)); ventricular fibrillation (VF) (n=21 (26 %)). Primary prevention: (n=24 (22 %)) <u>Complexity of disease:</u> Simple heart defect: (n=23 (21 %)) - ICD for primary prevention (n=4 (17 %)). Congenital heart defect of moderate complexity: (n=39 (36 %)) - ICD for primary prevention (n=11 (28 %)) Defect of severe complexity: (n=47 (43 %) - ICD for primary prevention (n=8 (17 %)) <u>Complication:</u> device related complication: n=23 (15 %), most frequent complication: lead dysfunction (n=11, 48 %), Infection: n=2 (9 %), revision of the ICD system for battery depletion or system-related complications: n=30 <u>Mortality:</u> In none of these patients there was a definitive documented causal relationship between death and a complication or malfunctioning of the ICD device

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
Döring (2018)	Retrospective observational study Quantitative, primary data	Total: n=177 Subgroups: ▪ cardiac resynchronization therapy pacemaker (CRT-P): n=80 ▫ Sex: 45 (56.3 %) male ▫ Mean Age: 82.6 (SD=4.5) years ▪ cardiac resynchronization therapy defibrillator (CRT-D): n=97 ▫ Sex: 74 (75.5 %) male ▫ Mean Age: 77.8 (SD=1) years	to evaluate the effect of an additional ICD on all-cause mortality in elderly patients undergoing cardiac resynchronization therapy (CRT) device implantation.	<u>Procedural data and adverse events:</u> Procedure-related adverse events occurred in 13 of 177 study patients (7 %). Lead dislodgement requiring a revision procedure was the most common major complication. 3 % of the CRT-O patients experienced device-related infections with the need of system removal during FUP. <u>Death from any cause:</u> During a mean FUP of 26 ± 19 months, 62 (35 %) of the 177 study patients died, 28 (35 %) in the CRT-P and 34 (35.1 %) in the CRT-D group (HR: 1.16; 95 % CI: 0.70 to 1.92; p=.563) <u>Arrhythmic events and ICD interventions:</u> During FUP, 9 of the 97 patients in the CRT-D group (9.3 %) experienced ICD interventions. Five patients (5.2 %) had appropriate therapies (appropriate shocks (AS) in 3 and ATP in 2 patients), and 4 patients (4.1 %) had inappropriate interventions (IAS in 3 and ATP in 1 patient) due to misclassification of a supraventricular arrhythmia. One patient in the CRT-P group (1 %) experienced sustained VT and was upgraded to CRT-D.
Döring (2020a)	Retrospective analysis + FUP Registry study	Total: n=302 Sex: 236 (78 %) male Mean Age: 71 (SD=12) years Subgroups: ▪ Re-CIED+: n=191 ▫ Sex: 159 (83.2 %) male ▫ Mean Age: 70 (SD=11) years ▪ Re-CIED-: n=111 ▫ Sex: 77 (69.4 %) male	To assess the frequency of patients who do not meet indications for re-implantation after TLE; to analyze acute and long-term complications and mortality after TLE in patients with and	<u>Patient population:</u> Re-CIED+ patients were of younger age (70 ± 11 vs. 73 ± 13 years; p=.004) and more often male (83 vs. 69 %; p=.006) than re-CIED patients. Left-ventricular ejection fraction was significantly lower in patients who received a new device (44 ± 15 % vs. 48 ± 14 %; p=.02). <u>Initial indications for CIED:</u> In comparison to re-CIED- patients, an initial complete heart block was most common in re-CIED+ patients (28 vs. 7 %; p<.001). The prevalence of sick sinus syndrome (SSS; 43 vs. 19 %; p<.001) and AF with slow conduction (6 vs. 2 %; p=.041) was significantly higher among re-CIED-patients. At baseline, a single-chamber PM was more often present in re-CIED- patients (9 % vs. 3 %; p=.035), and CRT-D was more often explanted in re-CIED+ patients (30 % vs. 15 %; p=.005) <u>Re-implantation:</u>

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
		▫ Mean Age: 73 (SD=13) years	without indication for re-implantation.	Of the 191 re-implanted patients, 123 (64 %) received the same CIED system and 68 (36 %) underwent either a downgrade (36/68 (53 %1), upgrade (22/68 (32 %1), or change to a S-ICD (10/68 [15 %1). Compared to all included patients, only 41 % received their originally implanted system. FUP: The survival rate was significantly lower among re-CIED- patients (67 vs. 71 %; p=.023), In multivariate analysis only age (HR 1.041; 95 % CI 1.017–1.064; p=.001), CRP-value (HR 1.004; 95 % CI 1.001–1.007; p=.003) and implantation of a pacemaker (PM) (instead of ICD) (HR 0.56; 95 % CI 0.32–0.97; p=.038) remained as significant predictors of mortality.
Döring (2020b)	Retrospective analysis + FUP Registry study	Total: n=56 Sex: 24 (43 %) male Mean Age: 75 (SD=10) years Subgroups: ▪ Early perforation: n=34 ▫ Sex: 14 (41 %) male ▫ Mean Age: 74 (SD=12) years ▪ Late perforation: n=22 ▫ Sex: 10 (46 %) male ▫ Mean Age: 77 (SD=7) years	To evaluate the clinical course, outcome, and complications in patients undergoing transvenous revision of leads with cardiac perforation.	Patient characteristics: Patients with late perforation had significantly more pericardial effusions requiring puncture (9, 41 % vs 4, 12 %; p=.041) and were more likely to present with shortness of breath as the leading symptom (10, 46 % vs 3, 9 %; p=.003). Diagnosis of cardiac perforation: Majority of patients (93 %) showed electrical abnormalities during device interrogation. 45 patients (80 %) had an increase in pacing threshold or exit block of the perforated lead, 40 patients (71 %) showed a significant decrease in sensing values and 29 patients (52 %) in lead impedance. While all patients received chest X-ray, transthoracic echocardiography, and device interrogation, only 21 patients (38 %) with suspicion of cardiac perforation underwent a cardiac CT-scan. The crucial diagnostic tools to confirm cardiac perforationwere chest X-ray in 30 patients (54 %), cardiac CT-scan in 21 patients (38 %), device-interrogation in four patients (7 %), and echocardiography in one patient (2 %). Site of perforation and complications: The most frequent perforation site was the RV apex in 42 patients (75 %), followed by the RV free wall in nine patients (16 %) and the right atrial appendage in five patients (9 %). In patients with need for pericardiocentesis, the RV free wall and the right atrial appendage were significantly more often the sites of perforation compared with patients without relevant pericardial effusion (31 vs12 %and 23 vs 5 %, respectively, p=.019). Outcome and FUP:

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				In patients presenting with tamponade requiring pericardiocentesis, hospitalizationwas significantly prolonged (10 ± 8 days vs 5 ± 3 days, p=.001).
Eulert-Grehn (2022)	Retrospective, single-center study Quantitative, primary data	Total: n=251 Subgroups: ▪ Non-left ventricular assist device (LVAD): n=190 ▫ Sex: 31 (16.3 %) female ▫ Mean Age: 67.19 (SD=12.04) years ▪ LVAD: n=61 ▫ Sex: 3 (4.9 %) female ▫ Mean Age: 60.20 (SD=9.28) years	to analyze the outcomes after ICD generator exchange (GE) in LVAD patients with a primary focus on pocket-related complications.	<u>Pocket hematomas and pocket infections:</u> Primary combined end-point had an event rate of 39.14 per 100 patient-years in LVAD patients, compared to 11.07 in non-LVAD patients (p=.008). The primary endpoint occurred 3.5 times more often in LVAD patients than in non-LVAD patients. The cumulative incidence function shows that the events occurred in the first two postoperative months, with all events in the non-LVAD group occurring in the first 2 weeks. <u>Pocket hematomas:</u> With an event rate of 21.35 per 100 patient-years in LVAD patients and 9.96 per 100 patient-years in non-LVAD patients (p=.244). The number of patients with clinically significant pocket hematomas undergoing revision was 3.8 times higher in the LVAD group and statistically significant (p=.042). <u>Pocket infections:</u> Pocket infections in the first 6 months post-GE had an event rate of 17.79 per 100 patient-years in LVAD patients, compared to 1.10 per 100 patient-years in non-LVAD patients (p=.007). Pocket infections and/or cardiac device infections (CDI) occurred in 8.2 % of LVAD patients and 0.5 % of non-LVAD patients (p=.002). 60 % of patients with a CDI in the LVAD group had clinically significant pocket hematomas. <u>Pocket revisions:</u> Pocket revisions due to pocket infection and/or hematoma were necessary for 13.1 % of LVAD patients, compared to 3.2 % of non-LVAD patients (p=.025). Pocket revisions in the first 6 months post-GE in the non-LVAD group had a more than 4-fold higher event rate per 100 patient years (p=.015; non-LVAD EPPY 6.54 vs LVAD 28.47). <u>Infection-hematoma ratio:</u> With a ratio of 0.833, the infection-to-hematoma ratio was 7.6 times higher in LVAD patients and statistically significant (p<.001), compared to 0.11 in non-LVAD patients.
Flügge (2018)	Retrospective study	Total: n=55 Sex: 41 (63.1 %) male	Based on a nationwide dataset from the German	<u>Patient characteristics:</u> ▪ Conventional antibradycardia pacing or ICD indications (n=48, 87.3 %):

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	+ FUP Secondary data analysis: German National Register for Congenital Heart Defects	Median Age: 21.5 (IQR 8.7–37.7) years	National Register for Congenital Heart Defects (NRCHD) we aimed to describe use of CRT in congenital heart disease (CHD), clarify indications and temporal trends for the use of this device therapy in the community.	▫ upgrade to CRT system to avoid detrimental consequences of longstanding conventional ventricular single-site pacing (n=44) ▫ required an ICD due to heart failure (HF) and a history of malignant VT (n=4) ▪ CHD patients received a CRT system (n=7) <u>Tetralogy of Fallot (n=11, 3 with CRT-D):</u> ▪ co-existing indications for PM therapy/ICD, upgraded to CRT (n=9, upgrade from ODD (n=4), from WI (n=1), from ICD (n=2)) ▪ fitted specifically with CRT system to address symptomatic HF and asynchrony (n=2) <u>Systemic right ventricle patients - congenitally corrected transposition (ccTGA) (n=9):</u> ▪ ccTGA patients received CRT-systems (n=8; 3 CRT-Ds) ▫ pre-existing 3-rd degree AV-block and upgrade from a two-chamber device to CRT (n=6) ▫ CRT device implantation primarily for refractory HF symptoms and asynchrony (n=2; 1 male, age 50 and 69 years at CRT implantation) <u>Systemic right ventricle patients - Transposition of the great arteries (n=6):</u> ▪ patients with transposition of the great arteries received a CRT system (n=5; median age at implantation 25 years; range 20–41 years; 3 CRT-D systems). ▪ All patients were fitted with epicardial right ventricular (RV) leads ▪ upgrade from a pre-existing DDD-system to CRT for severe RV dysfunction and HF symptoms (n=3) ▪ no pre-existing PM systems (n=2) ▪ relative conventional PM indication was present due to a history of symptomatic bradycardias (n=1). ▪ device solely for CRT (n=1) <u>Univentricular hearts (Fontan) (n=2):</u> Two patients after Fontan palliation (one with extracardiac tunnel and one with fenestrated lateral tunnel) received a CRT system (age at implantation 10 and 39 years, respectively). Underlying diagnoses included pulmonary atresia with intact ventricular septum and unbalanced atrioventricular (AV) and ventriculoarterial discordance with hypoplastic right ventricle. One patient was fitted the epicardial CRT system

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				during conversion from a classical atria-pulmonary Fontan circulation to total cavo-pulmonal connection (age 39 years), while the other patient was given an epicardial CRT system due to higher degree AV-block. Adverse events: ▪ Pacing system failure requiring revision (n=20), mainly related to lead dysfunction/dislocation: ▫ pacing threshold increase (n=3), electrode breakages (n=4), revision of the PM lead connection (n=1), electrode dislocations (n=3), other unspecified PM related problems (n=11) ▪ pocket site infections requiring therapy (n=5) ▪ death (n=8), from refractory HF (n=3, 1, 2 and 5 years after implantation)
Frommeyer (2018)	Single-center analysis + FUP Secondary data analysis: single-center registry data	Total: n=58 Sex: 33 (56.9 %) male Mean Age: 14 (SD=3.3) years	To assess outcome, complications and success of ICD therapy in a single-center pediatric population	FUP: 3 patients (5.2 %) died during their observation period. AS was observed in 32 patients (55.2 %). The majority of these events occurred within the first year after implantation. Inappropriate therapies and device complications: IAS: 17 patients (29.3 %); Cause: SVT (n=9, 52.9 %), TWOS (n=3, 17.6 %), lead failure 5 patients (29.4 %) Timing of IAS: within the first 2 years after ICD implantations (n=10 patients 58.8 %), 5 years after ICD implantation or later (n=3, 17.6 %). In 11 patients (18.9 %) inappropriate delivery of anti-tachycardia pacing (ATP) was recorded. All episodes were the result of inappropriate detection of SVT. During FUP lead failure was reported in 15 patients (25.9 %) leading to surgical revision. System infection occurred in 2 patients (2.5 %). During the observation period the pulse GE was due to reach of the elective replacement indicator in 39 patients (67.2 %).
Frommeyer (2019)	Retrospective analysis + FUP Secondary data analysis:	Total: n=1335 Subgroups: ▪ DEVICE registry: n=779 ▫ Sex: 75.6 % male ▫ Median Age: 66 (IQR=57–73) years	Data from a multi-center real-world registry on patients with non-ischemic cardiomyopathy (NICM) are discussed in	FUP: 706 patients (90.7 %) were alive at their last contact, while 72 patients (9.3 %) had died during their observation period (34 patients (47.2 %) unknown cause, 25 (34.7 %) cardiovascular deaths, 13 (18.1 %) non-cardiovascular deaths) Estimated 1-year overall mortality was 5.4 %. The rate of major adverse cardiac and cerebrovascular events (MACCE; including death, myocardial infarction and stroke) was 6 % (n=45) after 1 year. 77 patients (10.9 %) experienced shock deliveries of the implanted ICD. Role of age at implantation:

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
	German Device Registry	▪ DANISH trial (ICD group): n=556 ▫ Sex: 73 % male ▫ Median Age: 64 (IQR=56–72) years	the light of the DANISH trial.	Younger patients were significantly more often implanted with VVI ICD systems (< 59 years: 42.1 %; 59 to < 68 years: 38 %) than patients of 68 years or older (24.8 %, p<.001). The rate of CRT-I CD implantations was significantly higher in patients older than 68 years (66.2 %) as compared with younger patients(< 59 years: 47.5 %; 59 to< 68 years: 46.5 %, p<.001). Overall mortality 1 year after implantation was significantly higher in patients of 68 years and older (7.9 %) as compared with the other study groups (59 to <68 years: 2.5 %; < 59 years: 3.8 %; p<.015). In accordance, MACCE occurred more frequently in older patients (9 % vs. 3 % and 3.8 %, p<.005).
Frommeyer (2020)	Prospective registry analysis + FUP Secondary data analysis: German Device Registry (DEVICE)	Total: n=5450 Subgroups: ▪ hypertrophic cardiomyopathy (HCM): n=174 ▫ Sex: 128 (73.6 %) male ▫ Age: 59 (47; 69) years ▪ Electrical heart disease (EHD): n=112 ▫ Sex: 61 (54.5 %) male ▫ Age: 52 (41; 69) years ▪ CG: n=5164 ▫ Sex: 4209 (81.5 %) male ▫ Age: 68 (59; 74) years	to analyze data from a multicenter real-world registry and patients with EHD and HCM were compared with patients with structural heart disease.	Patients' characteristics/demographics: Patients with HCM or EHD were significantly younger than patients in the CG. Defibrillator systems for CRT were implanted more frequently in the CG. Of note, the majority of patients with EHD received an ICD for secondary prevention while in patients with HCM and in the CG, primary prevention represented the major indication for ICD implantation Implantation procedure: Regarding severe peri-interventional complications pericardial effusion (2.7 % vs. 0.6 % in HCM patients and 0.7 % in the CG, p=.046) and pneumothorax (2.6 % vs. 0 % in HCM patients and 0.4 % in the CG, p=.002) was observed more often in patients with EHD. FUP: One-year mortality was 1.8 % in the HCM group, 6.6 % in patients with EHD and 7.3 % in the CG.
Gotz (2022)	Prospective design Secondary data analysis:	Total: n=664 Subgroups: ▪ Without AF: n=535 ▫ Sex: 434 (81.1 %) male	To analyze the amount, nature, and distribution of sensing errors in current im-	Device classified AF: Of the 664 IN-TIME patients, 129 presented with verified AF episodes. R-wave oversensing was by far the most frequent reason (55.9 %), followed by oversensing caused by myopotentials, suspected conductor defect, and insulation defect (42.4 %). Device classified ventricular tachyarrhythmias:

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
	IN-TIME-study	▫ Mean Age: 65.1 (SD=9.6) years ▪ With AF: n=129 ▫ Sex: 102 (79.1 %) male ▫ Mean Age: 67.5 (SD=8.6) years	plantable cardioverter-defibrillator (ICD) and CRT-D technology by using remote monitoring (RM) data for the device-detected tachyarrhythmic episodes.	558 out of 664 patients had no VF or VT events after exclusion of all induced and false-positive VT/VF episodes. 106 patients had 1001 verified VT/VF episodes, more commonly verified VT (74 pts, 875 episodes) than verified VF. (48 pts, 126 episodes). The result of the manual assessment of the 300 false-positive VT/VF episodes revealed that SVT in 155 events (51.7 %), AF in 64 events (21.3 %), and TWOS in 63 events (21 %) were the most frequent reasons for missensing. False-positive events in the VF zone triggered shock delivery in 11 patients, with 10 of these patients (90.9 %) experiencing AF. 4 patients received shocks due to false-positive detection either in the VT-1 zone (n=2, caused by AF) or in the VT-2 zone (n=2, 1 SVT other than AF and 1 TWOS). In total, 15 IAS episodes occurred during a cumulative FUP time of 601 years corresponds to a rate of ≈ 2.5 IAS per 100 patient-years.
Hadwiger (2022a)	Retrospective design Secondary data analysis: BARMER database	Total: n=17,826 Subgroups: ▪ CRT-D: n=14,092 ▫ Sex: 3858 (27 %) female ▫ Mean Age: 70.4 (SD=9.82) ▪ CRT-P: n=3734 ▫ Sex: 1447 (39 %) female ▫ Mean Age: 76.8 (SD=10.1) years	to evaluate the runtime and costs of CRT devices from implantation to replacement for any reason, using health claims data of a major German statutory health insurance provider	7826 patients had a CRT implantation or upgrade (2006 to 2019). These patients caused 18,246 device implantations or upgrades, 4043 GE, and 371 device removals. Of these 22,660 cases, 18,404 were CRT-D devices and 4256 were CRT-P devices. 4725 complete runtimes were observed. Of these, 4296 were CRT-D runtimes and 429 were CRT-P runtimes. The median device runtime was 6.04 years for CRT-D devices and 8.16 years for CRT-P devices. <u>Sensitive Analysis:</u> First analysis (cases from 2010 or later): median runtime of 6.29 years for CRT-D and 8 years for CRT-P. Second analysis (excluding observations with runtime >10 years): median runtime of 6.01 years for CRT-D devices and 7.96 years or CRT-P devices. Third analysis (one runtime observation per patient): median runtime of 6.08 years for CRT-D devices and 8.27 years for CRT-P devices.
Hadwiger (2022b)	Retrospective, non-experimental, population-	Total: n=3569 Subgroups: ▪ CRT-P: n=847 ▫ Sex: 440 (52 %) male	to compare the survival of patients undergoing de novo implantation of a	In the unadjusted Kaplan–Meier time-to-event curves, CRT-P patients had a higher cumulative incidence of all-cause death than CRT-D patients [HR: 1.63, 95 % CI: 1.38–1.92]. Adjusting for age, the HR for all-cause death in Cox regression was 1.13 (95 % CI: 0.95–1.35), and the difference in survival was no longer significant. The HR was independent of age (P for interaction=0.371). No significant difference between

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	based weighted cohort study design Secondary data analysis: BARMER database	▫ Mean Age: 76.7 (SD=8.89) ▪ CRT-D: n=2722 ▫ Sex: 1768 (65 %) male ▫ Mean Age: 69.9 (SD=9.57) years	CRT with defibrillator (CRT-D) option and CRT with pacemaker (CRT-P) in a large health claims database	CRT-D and CRT-P in the cumulative incidence of death was observed in any of the three age groups. The HRs were similar in the three age groups (P for interaction=0.598).
Hahnel (2022)	Retrospective design Quantitative, primary data	Total: n=102 Subgroups: ▪ TLE during heart transplantation (HTX): n=74 ▫ Sex: 64 (86.5 %) male ▫ Mean Age: 50.9 (SD=12.0) years ▪ TLE after HTX: n=28 ▫ Sex: 15 (53.6 %) male ▫ Mean Age: 47.5 (SD=14.4) years	to investigate whether an elective lead extraction approach in a second procedure after cardiac transplantation is a viable concept to achieve complete lead extraction in this patient collective	We found metallic lead fragments in 19 patients, while 13 patients had plastic lead fragments. Leads in the group of patients with unsuccessful lead extraction had numerically longer implant duration but without statistically significant difference. Remaining lead fragments led to complications during the further clinical course in two patients. No major or minor complications occurred during lead extraction procedures. All leads were completely removed and the procedural success rate was 100 %. When comparing the rate of successful lead extraction between the one- and two-step approach, there was a significantly higher rate of procedural success in the two-step approach group (58.1 % vs 100 %; p<.001) There were no major or minor complications in any of the groups.
Hasan (2022)	Retrospective design Secondary data analysis:	Total: n=123,693 Subgroups: ▪ Cephalic vein cut-down (CVC): n=75,251 (60.8 %)	To evaluate/compare the peri-/postoperative complications of first PM	The difference in complication rates of 1.15 % was significant (CVC 2.49 % (n=1879), SP 3.64 % (n=1765), p<.0001). OR of SP in comparison to CVC was 1.47 (95 % CI: 1.38–1.57, p<.001). <u>Complications:</u> Most common: lead dislocation (CVC: 1.62 % vs. SP: 1.78 %), pneumothorax (CVC: 0.15 % vs. SP: 0.85 %) Rare: VF, hemothorax, postoperative wound infection (CVC: 0.009 %; SP: 0.004 %)

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	quality assurance data (NRW) (SGB V § 135 bis § 137)	▫ Sex: 34,912 (46.39 %) female ▫ Mean Age: 77 (SD=7) years ▪ Subclavian puncture (SP): n=48,442 (39.2 %) ▫ Sex: 24,142 (49.83 %) female ▫ Mean Age: 77 (SD=7) years	implantation depending on venous access (CVC vs SP)	Subgroup analysis: Number of PM leads: Two or more PM leads (DDD/CRT-subgroup): 74.2 % in the CVC group and 79.6 % in the SP group; procedures with a single lead: 25.7 % in the CVC group and 20.2 % in the SP group DDD/CRT-subgroup: 1372 (2.45 %) events in 55,858 CVC procedures; 1427 (3.69 %) events in 38,580 SP procedures (p<.0001) single lead group: 505 (2.6 %) events in 19,381 CVC procedures; 333 (3.38 %) events in 9827 SP procedures (p=.0001) When comparing the complication depending on venous access, our study with 1879 events of 75,251 implantations (2.49 %) in the CVC group shows a significantly lower complication rate in the CVC group compared with 1765 events of 48,442 implantations (3.64 %) in the SP group.
Hauck (2021)	Retrospective design Secondary data analysis: local ICD-registry	Total: n=519 Sex: 417 (80.3 %) male Age: 61.2 (± 14.5) years Subgroups: ▪ < 80 years: n=485 ▫ Sex: 390 (80.4 %) male ▫ Age: 59.7 (± 13.8) years ▪ ≥ 80 years: n=34 ▫ Sex: 27 (79.4 %) ▫ Age: 82.6 (± 2.2) years	To investigates the clinical outcome of octogenarians after ICD implantation for secondary prevention with regard to all-cause mortality, appropriate ICD therapy and device-related adverse events requiring surgical intervention	Mortality: The mortality rate in the age group ≥ 80 years was significantly higher than that of patients aged < 80 years. Further analysis showed significantly lower annual mortality rates for patients aged < 70 years than for octogenarians [≤ 59 years (2.4 %; p<.001), 60–64 years (3.5 %; p<.001), 65–69 years (4.9 %; p=.002)]. Predictors of all-cause mortality: age at the time of ICD implantation as well as chronic kidney disease (CKD) were independent predictors of all-cause mortality but not LVEF, diabetes, obesity, CRT therapy, ischemic heart disease and dilated cardiomyopathy (CM). Appropriate ICD therapy due to ventricular arrhythmias: 29.7 % of all patients had received appropriate ICD therapy because of ventricular arrhythmias (annual rate 5.9 %). 19.1 % of patients were treated with both ATP and ICD shock or ICD shock alone and 10.6 % of patients with ATP without ICD shock. 26.5 % of octogenarians received appropriate ICD therapy (annual rate 5.3 %). 20.5 % had ventricular arrhythmias and were treated with ATP and ICD shock or ICD shock alone and 6 % with ATP without ICD shock. Device-related adverse events requiring surgical intervention:

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				Event rates were very low and included lead dislocation (n=9), ICD system infection (n=2), pocket hematoma (n=2) and hemothorax (n=1).
Herrmann (2020)	Retrospective design Quantitative, primary data	Total: n=277 Sex: 79 (28.5 %) female Median Age: 73.8 (IQR 65.7–80.4) Subgroups: ▪ Survival >30 days: n=261 ▫ Sex: 73 (28 %) female ▫ Age: 73.2 (IQR=65.1–80.2) ▪ Death ≤30 days: n=14 ▫ Sex: 4 (28.6 %) female ▫ Age: age: 78.6 (IQR=71.8–81.1) years ▪ Survival >1 year: n=214 ▫ Sex: 57 (26.6 %) female ▫ Age: 71.8 (IQR=64.5–79.7) years ▪ Death ≤1 year: n=52 ▫ Sex: 12 (23.1 %) female ▫ Age: 78.3 (IQR=73–82.7) years	to identify specific predictors which would allow us to detect patients at an increased risk of mortality and identify modifiable factors.	Time point of infection: Median time since last CIED procedure: 0.83 years; Median time since initial CIED implant: 4.79 years. Procedural goals and procedural success: In 230 cases (83 %) the goal of the procedure was removal of the CIED and leads. In 8 cases (2.9 %) the patient was referred to our tertiary care center for lead removal after failed lead removal in a secondary care center. Patient characteristics or the patient's wish dictated that the generator be removed but the leads remain in place in 28 cases (10.1 %) and that local wound debridement or wound revision be performed in 11 cases (4 %). Complete procedural success of lead extraction could be achieved in 207 (87 %) and clinical procedural success of lead extraction could be achieved in 226 cases (95 %). Microbiological features of infection: Bacterial isolates in blood culture (OR: 2.19), Preoperative thrombocytopenia (OR: 2.30) Survival rate (complete cohort): at 30 days: 94.9 %, at 6 month: 86.5 %, at 1 year: 80.9 %, at 5 years: 56.3 % and at 10 years: 41.9 %. Complications and recurrent infections: 3 major complications occurred. One patient was reanimated intraoperatively after developing sinus arrest, one patient required operative treatment of hemopericardium and one patient required operative treatment for a laceration of the brachiocephalic-caval junction. 8 patients in our cohort developed a recurrent IPI of the newly implanted PM. 3 further patients developed a CIED related infective endocarditis of the new CIED after complete removal of the initial device.

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Hoffmann (2017)	Retrospective design Quantitative, primary data	Total: n=279 ▪ Subgroups: ▪ reference patients: n=147 ▫ Sex: 106 (72 %) male ▫ Mean Age: 71 (SD=15.3) ▪ noise reduction patients: n=132 ▫ Sex: 82 (62 %) male ▫ Mean Age: 73.2 (SD=12.4) years	To quantify the reduction in radiation dose by the use of a modern angiography system with the new image noise reduction technology as compared to a mobile C-arm system in a routine clinical setting of device implantation procedures.	Procedure and fluoroscopy times: similar between the groups Radiation dosage: In CRT procedures, there was a reduction of total OAP by 79 % from 7252 ± 6431 centigray-centimetres (cGycm^2) to 1544 ± 834 cGycm^2 (p<.001) using the INRT. This was due to less fluoro OAP (1414 ± 757 cGycm^2 vs 5854 ± 6767 cGycm^2) and less cine OAP (130 ± 106 cGycm^2 vs 1399 ± 1342 cGycm^2). In CRT procedures cine DAP accounted for almost 20 % of total CAP using the C-arm system and for less than 10 % using the IN RT. Considering all device implantation procedures, the mean OAP decreased from 1698 ± 3785 cGycm^2 to 682 ± 698 cGycm,2 which is a reduction by 60 %. Mean DAP using the C-arm system and considering all procedures was 692 ± 1170 cGycm^2 for female patients and 1997 ± 4341 cGycm^2 for male patients. Considering the INRT, the mean OAP was 482 ± 472 cGycm^2 for female patients and 795 ± 783 cGycm^2 for male patients. Reduction in radiation dose was comparable between both genders. Considering different body mass index (BMI) groups, the reduction in radiation dosage tended to be greater with higher BMI. Mean total OAP with the C-arm system was 1189 ± 2359 cGycm^2 in patients with a BMI <25 kg/m^2, 1080 ± 1798 cGycm^2 in patients with a BMI of 25–30 kg/m^2, and 2337 ± 5279 cGycm^2 in patients with a BMI ≥30 kg/m^2. Considering the INRT, mean OAP was 603 ± 734 cGycm^2 in patients with a BMI <25 kg/m^2, 534 ± 437 cGycm^2 in patients with a BMI of 25–30 kg/m^2, and 869 ± 848 cGycm^2 in patients with a BMI ≥30 kg/m^2. Mean DAP reduction was 49 %, 51 %, and 63 % for the three BMI groups, respectively.
Hohmann (2018)	Retrospective and prospective design Secondary data analysis:clinical data from hospital records; FUP	Total: n=14 Sex: 8 (57 %) male Age: mean age at ICD implantation: 31 (SD=15) years	To report our single center longterm experience with ICD therapy in patients with dextro-transposition of the great arteries or ccTGA.	<u>Ventricular tachyarrhythmias:</u> 9 patients (64 %) experienced ventricular tachyarrhythmias during FUP which were treated by the (8 by ICD shocks, 1 by ATP). ATP was successful in 102 episodes (80 % of episodes treated with ATP). 22 of the episodes with unsuccessful ATP were terminated by ICD shock. 6 arrhythmias were not treated successfully by the ICD. Overall 69 (39 %) episodes were treated by high voltage shock, either as first line treatment or after failed ATP. All shocks were successful in terminating the ventricular tachyarrhythmia. <u>IAS:</u> The mean ventricular cycle length was 247±29 ms, significantly shorter (p<.001) than the cycle length of the true ventricular episodes. Mean time to first IAS for SVT was 3578 days (95 % CI, 1182–5974 days). Patients with inappropriate therapies for SVT suffered from 0.75±0.61 IAS per year on average.

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Horlbeck (2021)	Retrospective design Secondary data analysis: institution's prospective ICD registry and the medical records	Total: n=448 Sex: 349 (78 %) male Age: mean age at implant: 58 (SD=13) years	To investigate the long-term incidence and possible predictors of upper venous obstruction in a single center cohort consisting exclusively of ICD patients over 20 years.	Events of venous occlusion: 147 detected during FUP. Kaplan-Meier analysis: almost linear progression of the prevalence of venous obstruction (long-term FUP) Predictors of venous obstruction: Main predictor: the presence of more than two transvenous leads (p<.001, HR 2.01, CI 2–2.022) Significant predictors: advanced age at the time of first implantation (p=.004, HR 1.023 per year, CI 1.022–1.024), Dilated CM (p=.035, HR 1.49, CI 1.47–1.51)
Jilek (2020)	Retrospective design Secondary data analysis: data from the EVITA-HF registry	Total: n=1804 Subgroups: ▪ ICD group: n=331 (18.3 %) ▫ Sex: 256 (77.3 %) years ▫ Mean Age: 66 (SD=12) years ▪ non-ICD group: n=1473 ▫ Sex: 1130 (76.7 %) male ▫ Mean Age: 66 (SD=14) years	To analyse data from the EVITA-HF registry to give an answer from real-world registry data to the DANISH trial (The DANISH trial raised doubts about the effectiveness of primary prevention of sudden cardiac death (SCD) by ICD implanta-	Among the ICD group, 99.7 % of the patients were discharged from hospital alive (100 % with an ICD, 44 % with a left ventricular (LV) lead for CRT). Among the non-ICD group, 98 % of patients left the hospital alive (p=.038). After a median FUP of 12.6 months (12; 14.6) in the ICD group and 12.6 months (12.0; 14.3) in the non-ICD group: 97.6 % (n=322) vs. 93.6 % (n=1357) were available for assessment (p=.005). The overall death rate was significantly lower in the ICD group compared to non-ICD group [7.2 % vs. 14.3 %; HR 0.48 (0.31–0.74)]. Patients with ischemic cardiomyopathy (ICM) showed a survival benefit from ICD therapy [7.9 % vs. 19.4 %; HR 0.37 (0.22–0.62)], whereas patients with NICM did not benefit from ICD [6.3 % vs. 6.9 %; HR 0.92 (0.43–1.97)]. The mortality was higher in the non-ICD group of patients with ICM compared to NICM. In the subgroups of females, males, elderly (≥ 75 years), diabetic and nondiabetic patients, patients without chronic obstructive pulmonary disease as well as patients with and without renal insufficiency ICD therapy was associated with lower mortality. ICD does not improve short term (12 months) survival among patients with NICM and reduced LVEF in contrast to patients with ICM

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
			tion among patients with non-ischemic HF)	
Kaya (2018)	Retrospective design Secondary data analysis: routinely collected data	Total: n=279 Sex: 185 (66.3 %) male Mean Age: 70.8 (SD=13) years Subgroups: ▪ non-complex: n=119 ▫ Mean Age: 74.9 (SD=12) years ▪ complex: n=160 ▫ Mean Age: 68.3 (SD=12.3) years	to summarise our experience employing local anaesthesia with conscious sedation for all non-complex and complex CIED procedures at a single centre.	Women required significantly higher doses of fentanyl for analgesia than did men (61 ± 70.4 µg vs. 42.7 ± 50.2 µg, p=.012). CRT device implantations took longer (107.3 ± 66.8 min vs. 49.2 ± 33.9 min, p<.0001) and required higher cumulative doses of midazolam and propofol (midazolam: 4.8 ± 3.7 mg vs. 2.3 ± 2.3 mg, p=.001; propofol: 34.2 ± 63.2 mg vs. 9.5 ± 30.3 mg, p=.027) than did single- and dual-chamber device implantations. Patients who underwent PM or ICD implantation received lower doses of propofol than did those who underwent CRT device implantation, predominantly because of a longer mean procedural duration. 100 % procedural success The mean procedural duration was longer and the average sedation dosages for fentanyl and midazolam were higher in the complex group than it was in the noncomplex group. The minimum mean arterial pressure during complex procedures was only slightly lower than was that during noncomplex procedures. The ejection fraction (EF) in the complex group was lower than was that in the noncomplex group. In 44 patients (16 %), the mean arterial pressure decreased by 34.6 ± 9.7 mmHg (vs. 17.9 ± 6.7 in the normotensive group) from an initial value of 105.1 ± 18 mmHg. This decrease was primarily managed conservatively by the administration of intravenous saline.
Kaya (2021)	Prospective design Secondary data analysis: German Device Registry	Total: n=3239 Subgroups: ▪ age <58: n=898 ▫ Sex: 712 (79.3 %) male ▫ Mean Age: 47 (SD=9.6) years ▪ age 58–74: n=1617 ▫ Sex: 1367 (84.5 %) male	to evaluate the distribution and impact of age with respect to peri-interventional complications and clinical outcome after I year of FUP.	Peri-procedural events and complications did not differ between the groups despite the huge heterogeneity in baseline characteristics and comorbidities. Still, our analysis revealed a very high 1-year mortality and MACCE rate in the elderly, while on the other side, very low rates were observed in the young compared with the intermediate age reference group, despite all patients being equally protected from sudden cardiac death by an ICD device.

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		▫ Mean Age: 67.1 (SD=4.8) years ▪ age 75–92: n=724 ▫ Sex: 559 (77.2 %) male ▫ Mean Age: 78.9 (SD=3.2) years		
Keyser (2022)	Retrospective design Quantitative, primary data	Total: n=483 Sex: 357 (73.91 %) male Mean Age: 65 (SD=14) years	to assess venous patency and risk factors in patients referred for repeat CIED lead surgery with special emphasis on CIED infection.	Infection: Diagnosis of CIED infection according to the modified Duke lead criteria could be established in 114 patients (24 %) prior to surgery. Only 67 patients (58.8 %; overall, 14.1 %) of these 114 also presented with unmistakable signs of a pocket infection. A lead-associated infective endocarditis was detected in 47 patients (41.2 %; overall, 9.9 %). Venous patency: Patients (n=347) without infection demonstrated patent veins, whereas 14 non-infected patients presented venous occlusion (p<.05). In case of CIED infection, venous occlusion was more frequent (74 patients) compared with venous patency (40 patients) (p<.05). The OR for venous occlusion in patients with CIED infection was 16 (95 % CI: 9.54–26.81) and the relative risk 11.38 (95 % CI 7.03–18.82). The sensitivity for venous occlusion to predict CIED infection was only 64.2 %, whereas specificity was 96.1 %. Risk Factors: In univariate analysis, venous occlusion was significantly associated with CIED infection and non-CIED infections compared with non-infected CIED (each p<.05). Right-sided implantation of CIED leads had a significantly higher rate of venous occlusion compared with left sided implantation (p<.05). Occlusion of the upper veins significantly increased with the number of CIED procedures and number of indwelling leads (p<.05) as well as with a history of malignant disease (p<.05). The major risk factor for CIED infection in multivariate regression was venous occlusion (p<.001; OR: 76.09; 95 % CI: 32.77–176.65). Coronary heart disease and a history of heart surgery were risk factors for venous occlusion, but to a lesser extent (p=.030; OR: 2.30; 95 % CI: 1.08–4.89 and p=.046; OR: 1.99; 95 % CI:

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				1.01–3.95, respectively). Novel oral anticoagulant medications appeared to be protective with regard to venous patency (p=.021, OR: .326, 95 % CI: .13–.85).
Kleemann (2019a)	Prospective design Secondary data analysis: single-center registry data	Total: n=1222 Subgroups: ▪ Group 1 (implant 2010–2017): n=579 ▫ Sex: 20 % female ▫ Mean Age: 64 (SD=11) years ▪ Group 2 (implant 2000–2009): n=643 ▫ Sex: 16 % female ▫ Mean Age: 63 (SD=10) years	To evaluate the contemporary benefit-harm profile in patients undergoing primary prophylactic ICD therapy.	The benefit-harm profile at the end of FUP was as follows: 33 % of patients had benefit from ICD therapy (n=409) and 35 % ICD complications (n=427). Twenty-two percent (n=264) of ICD patients had only harm from ICD without benefit. In a multivariate analysis including the factors age > 70 years, female gender, EF < 30 %, non-ischemic heart disease, diabetes, AF, CRT, Riata ICD lead and implantation decade the only independent predictor for increased incidence of ICD-treated ventricular tachyarrhythmias was AF whereas implantation in 2010s was associated with a lower incidence of appropriate ICD therapy. Independent predictors for ICD complications were AF and NICM whereas low EF < 30 %and implantation in the 2010s were associated with a lower rate of ICD complications. Riata ICD lead was not associated with an increased complication rate. NICM was an independent predictor for ICD complications without benefit from ICD therapy.
Kleemann (2019b)	Prospective design Secondary data analysis: single-center registry data	Total: n=1407 Subgroups: ▪ Durata: n=913 ▫ Sex: 20 % female ▫ Mean Age: 64 (SD=12) years ▪ Riata: n=494 ▫ Sex: 17 % female ▫ Mean Age: 63 (SD=11) years	To analyze the long-term performance of the Durata ICD leads compared to the Riata leads in clinical practice and to evaluate the mechanisms causing lead defects.	Durata leads with a DF-4 connector had a lower incidence of lead defects than Durata leads with a DF-1 connector (p=.005). Durata leads with a single coil had a lower incidence of lead failure compared to Durata leads with a dual coil (p=.003). The leading electrical cause of lead defect was artifact sensing due to insulation failure. The rate of insulation failure was higher in Riata leads compared to Durata leads (83 % vs 56 %, p=.001). Lead fracture was more often present in Durata leads (44 % vs 17 %, p=.001) and affected the P/S cable in 40 % and that of the shock coils in 60 %. One-third of patients in each group had radiologic signs of lead compression in the proximal clavicular region. 3 % in the Riata group showed a lead externalization whereas in Durata leads no externalization could be observed. No visible radiographic defect was present in 70 % in the Durata group and 67 % in the Riata group. In the Durata group 81 of 92 ICD leads (88 %) were revised, in the Riata group 96 of 103 ICD leads (93 %). Extraction of defected leads was performed in 29 Durata and 41 Riata ICD leads. <u>10-year mortality & rate of appropriate ICD therapy:</u>

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				Estimated 10-year mortality rate of patients with Durata leads was 33 % vs 43 % in patients with Riata leads {p=.07). Estimated rate of appropriate ICD therapy after 10 years was lower in Durata group {54 % vs 61 %, p log rank <.001). A reduction was observed with regard to AS as well as adenosine triphosphate therapy. Similarly, rate of IAS after 10 years was significantly lower in Durata group (25 % vs 39 %, p<.001).
Kleemann (2020)	Prospective design Secondary data analysis: single-center registry data	Total: n=622 Subgroups: ▪ New onset arrhythmia or ICD shock: n=366 ▫ Sex: 18 % female ▫ Median Age: 65 (IQR=55–70) years ▪ No arrhythmia/no ICD shock: n=256 ▫ Sex: 19 % female ▫ Median Age: 63 (IQR=54–71) years	To investigate whether the onset of arrhythmia or the ICD shock itself has a negative impact on prognosis in ICD patients with primary prophylactic ICD indication and without history of AF	Patients with arrhythmia and/or ICD shock during FUP less often had an ischemic heart disease or diabetes and they more often underwent an ICD implantation before 2005. During the median FUP time of 6 years, one-third (n=200) of ICD patients developed new AF and 40 % (n=249) of patients new VT/VF. ICD-shocks terminated VT/VF in 166 (27 %) patients. IAS occurred in 113 (18 %) patients due to AF (9 %), lead defect (6 %) or sinus tachycardia (4 %). Patients with new onset arrhythmias had a worse survival than patients without arrhythmias. There was an approximately 10 % increase of 5-year mortality depending on the type of new onset arrhythmia (without arrhythmia 19 %, new AF 28 %, new VT 36 %, with new VF 55 %). The Kaplan-Meier survival curve of patients with new AF compared to patients without arrhythmias started to diverge after 2 years, whereas patients with VT or VF had a prompt decline soon after occurrence of VT or VF. Patients with IAS had a similar outcome as patients without ICD shocks, whereas ICD shocks due to VT or VF had a comparable worse outcome. In a multivariate analysis, new onset of AF, VT and VF was independent predictors for increased mortality. The occurrence of VT shocks or IAS was not associated with a negative prognosis.
Köbe (2017a)	Prospective design Secondary data analysis: German Device Registry	Total: n=1199 Subgroups: ▪ Age > 75 years: n=320 (26.7 %) ▫ Sex: 256 (80 %) male ▪ Age < 75 years: n=879 (73.3 %) ▫ Sex: 686 (78 %) male	Focuses on perioperative complications and outcome after 1 year in patients <75 years of age and patients >75 years	<u>Perioperative complication:</u> A satisfactory CRT electrode function was achieved in the majority of patients irrespective of age (94.8 % >75 years vs. 94.1 % < 75 years, p=.68). In the group of 956 patients receiving a first CRT perioperative revision of the system was necessary in 1.6 % of the older and 3.5 % of the younger patients (p=.14). Reasons for revision were mostly lead-related (sensing or stimulation problems in n=4 patients >75 years vs. n=21 < 75 years, p=.85), or wound revisions (n=1 > 75 years vs. n=4 < 75 years, p=1.0). No patients died in hospital after revision of an existing CRT system. <u>FUP:</u> As expected 1-year mortality was significantly higher in the older patients (11 % vs. 6.4 %, p=.014, age one of the strongest predictors). In terms of a cardiac reason for death groups did just reach statistical signif-

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				icance. Death had a cardiac origin in 60.9 % of patients > 75 years compared to 83.8 % of younger patients (p<.05), and was sudden in 20 % of older patients compared 29.4 % of younger patients (p=.45). Rehospitalisation had more often a non-cardiac origin in the older patients (63.2 % vs. 37.4 %, p<.001) probably reflecting comorbidities. With focus on the patients being alive after 1 year 50.7 % of the older patients had a stable or improved NYHA class compared to 60.1 % of patients <75 years of age (OR 0.68, p<.05). Especially older patients with smaller QRS complexes (120 to 5150 ms QRS width) were less likely to benefit from CRT (OR 0.31, p<.01). CKD as concomitant comorbidity had a significantly higher risk of non-response in the older patients than in patients being younger than 75 years of age.
Köbe (2022)	Prospective design Secondary data analysis: German Device Registry	Total: n=4384 Subgroups: ▪ ICD: n=3100 ▫ Sex: 81.7 % male ▫ Mean Age: 63.9 (SD=13.4) years ▪ CRT-D: n=1284 ▫ Sex: 77.4 % male ▫ Mean Age: 67.6 (SD=11) years	To analyze the differences of baseline characteristics compared to RCTs and on acute perioperative complication rates. Besides, we analyzed the QOL with devices, predictors for 1-year mortality and predictors for ICD shocks in primary prevention indications	<u>Acute outcome:</u> An early revision of the system was necessary in 3 % of CRT-D patients and 1.7 % of ICD patients (p=.038). Reasons for intrahospital revisions were mainly wound revisions (29.7 % of revisions ICD and 18.5 % of revisions CRT-D, p=.39) followed by complications with the LV lead in 14.8 % of CRT revisions and with the atrial lead (18.9 % ICD vs. 14.8 % CRT-D; p=.75). Pocket hematoma was seen significantly more often in the CRT-D group (CRT-D 1.2 % vs. ICD 1 %; p=.52) though more CRT-D patients were on anticoagulation (CRT-D 40.7 % vs. ICD 33 %; p=.01). <u>FUP results:</u> Mean improvement of NYHA class was 0.8 in the CRT-group and less in patients receiving an ICD without resynchronization therapy (ICD –0.2 ± 1 vs. CRT-D –0.8 ± 1.0; p<.001). ICD shocks and syncope occurred more often in the ICD group (shocks 19.2 % vs. 11.60 %, p<.001; syncope 5.4 % vs. 3.8 %, p=.11) probably reflecting the higher amount of secondary prevention indications in this group. <u>Patient perspective/ QOL:</u> 90 % of patients perceived therapy as effective after 1 year. Significantly more patients with a CRT device reported ineffectiveness (2.9 % vs. 1.3 %; p=.029) probably reflecting nonresponse to CRT or progression of HF symptoms. Almost one-third of patients reported fear of ICD shock therapy with a significant higher proportion in ICD group (p<.001) probably due to already experienced ICD shocks. <u>ICD benefit:</u>

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				In terms of 1-year mortality the overall mortality was 9.4 % in the lowest group, 6.3 % in the intermediate and 5.4 % in the highest group (p<.001). A significant difference related to the highest benefit score was seen in VT ablations within one year (1.2 % in the lowest, 6.3 % in the highest benefit group, p=.037).
Kosiuk (2020)	Retrospective design Quantitative, primary data	Total: n=86 Sex: 77 (89 %) male Age: mean age by first ICD implantation: 63 (SD=10) years mean age by implantation of biventricular device: 68 (SD=9) years	to analyze the clinical courses of patients with a history of HF who are upgraded to CRT	Upgrade indication and previous history of HF: QRS complex widening (33 %), worsening of NYHA class (31 %), deterioration of LVEF (6 %), combination of multiple factors (30 %), primary prevention of SCD (67.4 %) Short term response to CRT: In univariate analysis, initial presence of dual chamber system was the only factor associated with NYHA class improvement in short term FUP (OR 8.8; 95 % CI 1.05–74.5, p=.021). Analysis of long term FUP: In 54 % of patients NYHA class after long term FUP of 40 ± 4 months further improved compared to NYHA class assessed at the short term FUP. It worsened in 12 %, while 34 % of patients reported unchanged functional status. Observed mortality and outcome predictors: At mean FUP of 31 ± 26 months 43 patients (50 %) died, mean survival 49 ± 4 months after CRT upgrade: cardiac related cause (n=16, 18.6 %)), non-cardiac reasons (n=8, 9.3 %), unknown cause (n=62, 72 %). In the univariate analysis the glomerular filtration rate (GFR) value (HR 0.97; 95 % CI 0.95–0.98; p=.001) and the LVEF measured at the upgrade procedure (HR 0.94; 95 % CI 0.9–0.99; p=.027) were inversely associated with mortality. Age at CRT upgrade (HR 1.04; 95 % CI 1–1.07; p=.023) influenced patients outcome. Multivariate comparison showed, that the GFR value (HR 0.97; 95 % CI 0.95–0.99; p=.009) and LVEF estimated by upgrade (HR 0.92; 95 % CI 0.87–0.97; p=.002) were the only independent predictors of mortality. Rate of HTX/LVAD implantation: The age of patients at the CRT upgrade implantation (HR 0.92; 95 % CI 0.87–0.98; p=.009), as well as the age at the first implantation (HR 0.91; 95 % CI 0.87–0.96; p=.002) correlated significantly with surgical treatment for advanced HF. Duration of patients' HF history reached statistical significance (HR 1.20; 95 % CI 1.06–1.37; p=.004). In the multivariate analysis, the only independent factor associated with LVAD implantation and HTX was GFR value (HR 1.05; 95 % CI 1–1.11; p=.048).

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Krause (2019)	Retrospective design Secondary data analysis: medical records	Total: n=1407 Sex: 75 (38.5 %) male Mean Age: 23 (SD=14) years	To analyse the rate of AS and IAS with respect to underlying diseases, type of ICD system, and ICD programming in a large group of paediatric and CHD patients	Indications for ICD implantation: Primary prevention indication was more prevalent in patients with CM (n=50/61, 81 %, p<.001) compared to patients with CHD and channelopathies. ICD systems: Multinomial logistic regression showed that implantation of dual chamber systems was significantly more frequent in patients with CHD (p=.001; OR 4.1, CI 1.8–9.4). ICD shocks: Patients with a secondary prevention indication were more likely to experience AS than patients with a primary prevention indication (n=24/66, 36 % vs. n=8/129, 6 %, p<.001). Patients with extracardiac ICD systems experienced significantly more AS compared to patients with transvenous ICD (TV-ICD) systems (n=12/42, 29 % vs. n=20/153, 13 %; p=.02). Time interval from ICD implantation to the first adequate shock was significantly shorter in patients with channelopathies compared with patients with CM and CHD (log rank p=.02). Time to first shock in patients with CHD vs. patients with channelopathies differed only slightly (log rank p=.05). Patients with channelopathies (n=11/40, 28 %) had significantly more AS compared with patients with CHD (n=6/55, 11 %) or CM (n=15/79, 19 %; p<.05, OR 2.5, CI 1.1–5.8). In patients with IAS and activated VT detection zone, VT detection rate was set significantly lower (181± 18 b.p.m., n=10) compared with individuals without IAS (194± 11 b.p.m., n=103, p=.002). In 7/17 subjects receiving IAS for rapidly conducted SVT/atrial tachycardia, a VT detection zone had been programmed at 174± 15 b.p.m. This was significantly lower compared with the remaining patients having a VT detection zone programmed (194± 11, n=106; p<.001). Complications and unanticipated interventions during FUP: Most common complication was lead malfunction requiring surgical revision/reimplantation as observed in 23/195 (12 %) patients. Patients with lead failure were younger and of less body weight (15.4± 13.8 vs. 24± 13.9 years, p=.006; 42.2± 31.9 vs. 61.4± 24.8 kg, p=.001) than those who had not. Extracardiac ICD system had a significantly higher lead failure rate compared with TV-ICD systems (n=12/42, 29 % vs. n=11/153, 7 %; p=.001). Only 2/33 patients with a subpleurally implanted shock coil required surgical revision due to shock coil fracture (p<.001).

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Kurt (2018)	Prospective design Secondary data analysis: single-center registry data	Total: n=212 Subgroups: ▪ Group-VDD: n=77 ▫ Sex: 66 (86 %) male ▫ Mean Age: 61.4 (SD=12.7) years ▪ Group VVI: n=135 ▫ Sex: 109 (81 %) male ▫ Mean Age: 63 (SD=15) years	We hypothesize that the use of a VDD-ICD system reduces the incidence of inappropriate ICD therapy without additional risk compared to traditional single-lead ICD system	Device FUP: Shock impedance of ventricular leads with the atrial-sensing electrode was consistently higher compared to leads without the atrial-sensing electrode except for the case of 1-month FUP. The RV pacing threshold of ventricular leads with the atrial sensing electrode was consistently lower as compared to leads without the atrial-sensing electrode except for the case of 1-year FUP. Appropriate and inappropriate ICD therapy: The incidence of inappropriate ICD therapies in Group-VDD and Group WI were 1 % (1/77) and 9 % (12/135), respectively. Kaplan-Meier analysis demonstrated a lower incidence of inappropriate ICD therapy in Group-VDD (log-rank, p=.028). Even if the one patient with a lead fracture was excluded, a significantly lower incidence of inappropriate ICD therapy in Group-VDD was still demonstrated (log-rank; p=.038).
Kuschyk (2021)	Retrospective design Secondary data analysis: FUP data, EGM data	Total: n=183 Sex: 78 (43 %) female Mean Age: 40 (SD=15) years Subgroups: ▪ TV-ICD: n=86 ▫ Sex: 43 (50 %) female ▫ Mean Age: 40 (SD=16) years ▪ S-ICD: n=97 ▫ Sex: 35 (36 %) female ▫ Mean Age: 40 (SD=15) years	to assess the long-term outcome of S-ICD patients compared to TV-ICD patients in a selected cohort of patients with either cardiac arrhythmia syndromes or genetic CM.	Occurrence of AS and IAS: During a mean FUP of 4.3 ± 2 years, 30 (16 %) patients had at least one appropriate ICD therapy. No ineffective shocks were observed in any of the groups and both devices terminated ventricular tachyarrhythmias with the first defibrillation. IAS occurred in 15 (8 %) patients. 9 patients had a TV-ICD and 6 patients an S-ICD (p=.76). Major drivers for IAS in the TV-ICD cohort were short V-V intervals falsely classified as VF (due to lead fracture, n=7). The number of overall shocks was higher in patients implanted with a TV-ICD than in patients with S-ICD. The relative risk for any shock was reduced by 39 % for S-ICD patients (OR 0.61, 95 %CI 0.46–0.821). Lead failures and necessity for lead revisions: Lead failures of the defibrillation lead occurred more frequently in the TV-ICD group (17 % vs. 2 % in S-ICD group; p<.001) and required surgical lead revision due to a significant loss of function of the ICD. The most frequent cause of lead failure in the TV-ICD group was lead fracture, commonly resulting in ventricular oversensing and/or sudden rise of impedance. Battery life span: The median time to pulse GE in the S-ICD group was 5.2 years as opposed to 7.7 years in the TV-ICD group (p=.2). 93 % of TV-ICDs and 86 % of S-ICDs did not require replacement after median FUP of 4.3 years.

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Lacour (2020)	Prospective observational study Quantitative, primary data	Total: n=77 Sex: 53 (68.8 %) male Mean Age: 71.3 (SD=10.2) years Subgroups: ▪ No iron deficiency (ID): n=34 ▫ Sex: 24 (70.6 %) male ▫ Mean Age: 68.6 (SD=11.8) years ▪ Functional ID: n=19 ▫ Sex: 11 (57.9 %) male ▫ Mean Age: 71.6 (SD=10.1) years ▪ Absolute ID: n=24 ▫ Sex: 18 (75 %) male ▫ Mean Age: 74.8 (SD=6.6) years ▪ ID: n=43 ▫ Sex: 29 (67.4 %) male ▫ Mean Age: 73.4 (SD=8.4)	to assess the impact of functional and absolute ID at CRT implantation on reverse cardiac remodelling, clinical response, and outcome of CRT	<u>Response to CRT:</u> Clinical improvement (change in NYHA class) occurred in 62.3 % of the patients during FUP. <u>Predictors of non-response to CRT:</u> In univariate analysis, ID, right bundle branch block (RBBB), and an LVEF at baseline ≥25 % significantly correlated with echocardiographic CRT non-response. ID, RBBB, an LVEF at baseline ≥25 %, and a higher LV global longitudinal strain were significant predictors of a lack of improvement in NYHA class on univariate analysis. After multivariate analysis, including co-morbidities with p<.05 and known predictors of CRT response, (male sex, coronary artery disease (CAD) and QRS width <150 ms), ID, RBBB, and LVEF ≥25 % at baseline were identified as independent predictors of echocardiographic CRT non-response. <u>Death from any cause:</u> The secondary outcome, death from any cause during a mean FUP of 29 ± 8.4 months, occurred in 12 patients (15.6 % of the study population) in the ID group died, as compared with three patients (3.9 %) in the group without ID (p=.045). Analysis of functional and absolute ID as subgroups revealed a significant increase in all-cause mortality in patients with absolute ID (p=.022) but not in patients with functional ID. <u>Hospitalization:</u> 25 patients (32.5 % of the study population) were hospitalized for worsening of HF at least once during the FUP period (72 % with ID vs. 28 % without ID). <u>Short-term and long-term cardiac remodelling:</u> Cardiac reverse remodelling in the period between short-term FUP and long-term FUP was more pronounced in patients with no ID compared with patients with absolute ID. Corresponding differences in LV global longitudinal strain improvement were statistically significant (p=.026).
Larbig (2018a)	Retrospective design	Total: n=139 Subgroups: ▪ SQ1010-SICD: n=91	To analyse the impact of device and software up-	Major differences in the incidence of TWOS/IAS were uncovered since the Emblem patients presented a significantly lower incidence of TWOS/IAS (SQ: 15.4 %, n=14/91 vs. Emblem 4.2 %, n=2/48; p=.049). Based on our findings we concluded that, indeed, the change in device generation but also probably software updates successfully reduced the incidence of TWOS/IAS in S-ICD patients. Between 2010 and 2016, we

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	Secondary data analysis: university patient database	▫ Sex: 59 (64.8 %) male ▫ Mean Age: 41.4 (SD=15.3) years ▪ Emblem-SICD: n=48 ▫ Sex: 35 (72.9 %) ▫ Mean Age: 44.1 (SD=15.7) years	dates on the prevention of TWOS and IAS in S-ICD patients	were able to uncover a reduction of these harmful events after implementation of the new software (SMR8 update August 2014) and device updates (Emblem-S-ICD implantation starting January 2015; mean 1-year incidence of TWOS/IAS 2010–2014=7.94± 2.77 % vs. mean 1-year incidence of TWOS/IAS 2015–2016=3.50± 2.40 %). The lowest 1-year incidence of TWOS/IAS of 1.8 % was observed in 2016 when 55 out of 139 S-ICD patients had an Emblem-SICD and all SQ1010-S-ICD patients were already updated with the SMR8 software.
Larbig (2018b)	Retrospective design + FUP Secondary data analysis: patient data, FUP data	Total: n=123 Subgroups: ▪ No stress test performed: n=61 ▫ Sex: 40 (65.6 %) male ▫ Mean Age: 43.2 (SD=14.8) years ▪ Stress test performed: n=62 ▫ Sex: 43 (69.4 %) male ▫ Mean Age: 41.2 (SD=17) years	Hypothesis: Postoperative ergometry facilitates primary and secondary prevention of TWOS or other potential causes of IAS and optimizes S-ICD programming.	<u>Primary Prevention:</u> TWOS could be provoked in 3.7 % (3/82) of all screened patients who underwent postoperative ergometry. In these 3 cases, we found a short episode of TWOS due to a low QRS amplitude in the S-ICD electro cardiogram (ECG). If TWOS/IAS occurred, the median number of events was not reduced by using ergometry guided-programming (EMGP). The incidence of IAS only was not affected by EMGP. We observed that the combined endpoint of TWOS/IAS was not affected by EMGP regardless if the age-related workload was achieved in the routine postoperative ergometry or whether ergometry was performed < 7 days after implantation (in 45 out of 62 patients). <u>Secondary Prevention:</u> We found TWOS/IAS to be promoted by different pathophysiologies, which were only partially exercise-related. SVT rhythm (provoked by exercise or other reasons) was observed in 6 cases including 4 cases of confirmed sinus tachycardia in a total of 11 patients presenting with the combined endpoint of TWOS/IAS. We analyzed TWOS/IAS in patients who underwent device reprogramming after a previous episode of TWOS/IAS. When EMGP was used, 6 out of 9 patients did not develop any further episodes of TWOS/IAS. We conclude that the EMGP approach successfully suppressed further episodes of TWOS/IAS resulting in a 66.7 % reduction of these events within the FUP time span.
Leitz (2021)	Prospective observational design	Total: n=102 Sex: 75 % male Mean Age: 74 (SD=10)	to re-evaluate different electrocardiographic and clinical vari-	<u>Adverse events:</u> Device-related infections with need of antibiotic therapy (n=3), stroke (n=1), transcatheter aortic valve replacement (n=1), ST elevation myocardial infarction (n=1), LVAD implantation (bridging for HTX, terminal HF) (n=3)

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	+ long term FUP Quantitative, primary data	Subgroups: ▪ Survivors: n=36 ▫ Sex: 65.8 % male ▫ Mean Age: 70 (SD=10) years ▪ Deceased: n=52 ▫ Sex: 85.8 % male ▫ Mean Age: 76 (SD=9) years	ables as predictors for very long-term survival in our previously described cohort of HF and reduced EF patients with an indication for CRT, according to the European Society of Cardiology (ESC) guidelines from that time.	<u>Survival:</u> 36 months: 89 %, 60 months: 83 %, 96 months: 62 %, 120 months: 51 %, Median survival: 126 months <u>Possible Predictors of Long-Term Outcomes:</u> Using a univariate analysis of age (p=.03), NYHA class (p<.001), CHA2DS2-Vasc score (p<.001), GFR (p=.007), arterial hypertension (p=.004), presence of CAD (p=.001), presence of NICM (versus ICM; p=.01), clinical response to resynchronization therapy (p=.008), and NT-proBNP (p<.001), the results showed a significant association with survival. Multivariate analysis retained NYHA class (p=.03), presence of NICM (p=.003) and QRS width during biventricular stimulation (p=.01) as independent predictors of survival. Stratified analysis was performed to evaluate robustness of data. QRS width during biventricular stimulation in the subgroups of men (p=.04), patients with wider native QRS (p=.006) throughout all age groups (p=.04 in the younger (<74 years) and p=.05 for the elder half group) remained statistically significant. NYHA class showed significant associations only in men (p=.01) and the younger half group (p<.04). NICM remained statistically significant only in the elderly (p=.02). Concerning the secondary endpoint in the multivariate Cox regression analysis, only NYHA class at the time of implantation revealed to be an independent predictor of hospitalization.
Ludwig (2018)	Retrospective case-controlled analysis Secondary data analysis: German statutory health insurances	Total: n=4699 (n=3233 de novo; n=1466 replacement) Subgroups: ▪ CIED infection: n=158 ▫ Sex: 84 % male ▫ Mean Age: 62.4 years ▪ no infection: n=2690 ▫ Sex: 84 % male ▫ Mean Age: 68.5 years	to estimate the incidence and incremental healthcare expenditures for patients receiving ICD and CRT-D therapies who experience a CDI during the first year after their device implantation.	<u>Rate of CIED infection:</u> There were 158 CDIs in the 12 months after implantation, an annual risk of 3.4 % (95 % CI: 2.8–3.9 %). By implantation (p<.01): de novo: 2.9 % (95 % CI: 2.2–3.3 %), replacement: 4.4 % (95 % CI: 3.6–5.8 %) By severity: minor infections: 57 % (95 % CI: 49.2–65.3 %), major infections: 43 % (95 % CI: 34.7–50.8 %) CDIs treated: ambulatory 40 % (95 % CI: 32.8–48.8 %), hospital inpatient setting 60 % (95 % CI: 51.2–67.2 %) Considering infection severity and treatment setting in combination: minor infections treated in ambulantory setting: 70 %, minor infections treated in inpatient setting: 30 %, major infections treated in ambulantory setting: 0 %, major infections treated in inpatient setting: 100 % <u>Before-and-after observational analysis (prior to propensity score matching (PSM)):</u> Patients who experienced a CDI, compared with those who did not (prior to PSM), had significantly higher rates of several known risk factors for CDI: kidney disease, having malignancies or being immunocompromised or taking oral anticoagulant drugs.

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				Case-controlled analysis: Estimated rates of healthcare utilization were greater in the 12 months following implantation for those with an infection compared with matched controls: ▪ 2.9 (infection group) compared with 1.2 (CG) hospital inpatient stays (p<.01). ▪ 3.8 hospital inpatient stays for patients with major infections, compared with 2 stays for minor infections (p<.01). ▪ 37.8 (infection group) versus 11.5 hospital inpatient days (CG) (p<.01). ▪ 54.7 inpatient days for patients with major infections, compared with 22.7 days in hospital for minor infections (p<.01). ▪ 39.4 (infection group) versus 33.9 outpatient visits (CG) (p=.03).
Ludwig (2019)	Retrospective case-controlled analysis Secondary data analysis: healthcare claims data	Total: n=12,922 De novo n=9339 Replacements n=3583	To study PM complications and their associated costs in the German healthcare system, to estimate the incidence of PM-related complications and associated healthcare costs.	Costs of complications: case-control analysis: Healthcare utilization was higher in patients with complications compared with the marched CG. On average, patients with complications had 1.4 hospitalisations per year compared wirh 0.89 in the CG (p<.0001) and the hospitalizations was nearly twice as long as parients withour complications (14 days vs 7.7 days; p<.0001). Patients with a device removal had a higher number of hospital stays (2.1 per year) with longer length of scay (21.1 days). Patients with complications also incurred more outpatient visits per year compared with matched patients (39.2 vs 34.2; p<.0001).
Lüker (2018)	Survey + systematic review	Total: n=60	To provide an insight on the real-world approach towards CIED patients during	Prevalence and shock protocol of CIED patients: 11 % (1809/16,554) of patients undergoing cardioversion carry a PM/ICD. Prevalence of CIED patients ranged from 0 to 30 % (average 11 ± 9 %) among the centers. Distribution among the different devices was 41 ± 15 % ICD, 40± 14 % PM and 19 ± 10 % CRT. All centers perform device interrogations immediately after

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	Quantitative, primary data		electrical cardioversion in clinical practice and to gather data on the incidence of shock related complications.	electrical cardioversion, 75 % also interrogate the device prior to shock and only 2 centers (6 %) regularly schedule a FUP interrogation after discharge. <u>CIED related complications of cardioversion:</u> Complications associated with electrical cardioversion of PM/ICD patients in 11/1809 pts (0.6 %, range 0–4 %) and were deemed as not life threatening. <u>Systematic literature review:</u> Incidence of CIED complications ranged from 0 to 50 %. Vast majority of complications occurred in right sided PM and with unipolar RV leads, after several monophasic shocks of high energy and with an atrial lead orientation. No reports on ICD lead or generator malfunctions.
Müller (2019)	Retrospective design + FUP Quantitative, primary data	Total: n=36 Sex: 14 (38.9 %) female Median Age: 6 (IQR=1.9–8.4) years (at implantation) Subgroups: ▪ Subcutaneous shock coil/abdominal device position: n=7 ▪ Pleural shock coil/abdominal device position: n=5 ▪ Pleural shock coil fixation/subcardiac device fixation: n=24	To report our experience applying a non-TV-ICD system to infants and children< 12 years of age and < 45-kg body weight.	<u>ICD-Discharges:</u> During median FUP of 5.2 (IQR 2.7–7.2, range 0.1–11.5) years: 121 ICD therapies including ATP and IAS. AS in 12/36 (33 .3 %) patients (primary prevention n=1 , secondary prevention n=11), total of 77 shocks delivered. 4 out of 36 individuals (11.1 %, primary prevention n=1, secondary prevention n=3) experienced 44 IAS. Reasons for IAS: rapidly conducted atrial tachycardia (n=2), far-field sensing of external alternating current (n=1), and lead fracture (n=1). <u>Complications and system survival:</u> In 12/36 (33.3 %) patients 25 surgical revisions were required due to non-TV-ICD malfunction. Patients with subcutaneous shock coil/abdominal device configuration: 7/7, Majority of surgical revisions (18/25, 72 %) needed. Patients with pleural shock coil/abdominal device position: 4/25 (16 %) surgical revisions necessary in 3/5 patients. Patients with pleural shock coil/subcardiac device: 2/24 patients , 3/25 (12 %) surgical revisions. <u>Kaplan-Meier analysis:</u> Significantly improved performance of pleural shock coil/subcardiac device configuration compared to subcutaneous shock coil/abdominal device combination (p≤.001) with respect to surgical revisions. Pleural shock coil/subcardiac device approach superior with respect to the need for surgical revision Pleural shock coil/subcardiac device configuration noninferior when compared to complications reported after TV- or S-ICD implantation in pediatric population.

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Nägele (2021)	Retrospective design Quantitative, primary data	Total: n=2743 Mean Age: 68.5 (range: 59.6–74.6) years Subgroups: ▪ CRT: n=1113 ▫ Sex: 24.4 % female ▫ Mean Age: 68.7 (SD=10) years ▪ VVI/DDD: n=1630 ▫ Sex: 18.8 % female ▫ Mean Age: 64.6 (SD=12) years	To analyze the various causes of death in patients with ACIDs after long-term FUP.	<u>All-cause mortality stratified by patient characteristics:</u> Survival times significantly different between age quartiles (p<.001), between high and low LVEF quartiles (p<.001) and between estimated GFR quartiles (p<.001). Patients with primary vs. secondary indication were significantly older (66.9± 10.9 years vs. 64.1 ± 13.1 years, p=<.001), had lower LVEF (28.3 ± 9.5 % versus 38 ± 14.4 %, p<.0001) and worse prognosis (p=.002). Total survival rates differentiated between ICD types at the first implantation. Patients with CRT significantly older (68.7 ± 10 years versus 64.6± 12 years, p<.0001), significantly lower LVEF at baseline (27.3 ±8.1 % versus 33 ±1 3.1 %, p=<.001) and estimated GFR (61.7 ± 23 versus 69.4± 25 /1.73 m2, p<.0001) and worse prognosis compared to those with single chamber and dual chamber devices (p<.001). Patients with ICM had the worst prognosis (p<.001) and women showed a significantly lower survival rate compared to men (p=.002). Survival analysis comparing implants from the years 1990–2009 (n=1290) and 2010–2020 (n=1453) showed significant changes in prognosis, becoming evident after 5 years (p=.001). <u>Analysis of the specific causes of death:</u> Fewer women than men in the infection group (p<.03). Significantly more life years were lost associated with procedures compared to other classifications (12.1 vs. 9.3 years except SD, p=.02). Patients dying suddenly younger at implant and time of death than the other groups. Significantly more life years lost associated to SCD compared to other classifications (11.9 vs. 9.3 years except procedures, p=.02).
Nedios (2021)	Single center, retrospective design Quantitative, primary data	Total: n=65 Subgroups: ▪ Permanent AF at FUP: yes: n=18 ▫ Sex: 16 (89 %) male ▫ Mean Age: 71 (SD=8) years	To identify predictors of sinus rhythm (SR) stability or future permanent AF in a real-word cohort of CRT patients with AF.	<u>Predictors of permanent AF:</u> Patients who developed permanent AF: similar characteristics with rest of the cohort, but higher incidence of persistent AF (83 % vs. 38 %, p=.002) and larger left atrial diameter (53 ± 7 vs. 49 ± 6 mm, p=.026). Biventricular pacing (BP) similar between groups, but less patients with permanent AF achieved BP of >92 % (61 % vs. 87 %, p=.03) compared to non-permanent AF. Persistent AF at the time of implantation (OR: 8.01, 95 % CI: 2.0–31.7, p=.003) only significant predictor associated with progression to permanent AF. Bigger left atrial diameter (OR: 1.2 per mm, 95 % CI: 1.03–1.4, p=.025) and higher age (OR: 1.15 per life-year, 95 % CI: 1.01–1.3, p=.032) were independent predictors of

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
		▪ Permanent AF at FUP: no: n=47 ▫ Sex: 35 (75 %) male ▫ Mean Age: 68 (SD=8) years		future permanent AF. Patients with all criteria (n=10) had a higher risk for continuous mode switch (OR: 18, 95 % CI: 3.307–97.96, p=.001). <u>Predictors of stable SR:</u> Patients with stable SR (mode switch < 1 %) during FUP had higher incidence of paroxysmal AF at implantation (75 % vs. 38 %, p=.007) and higher average BP (98 ± 2 vs. 92 ± 8 %, p<.001) than rest of the cohort. Patients with persistent AF at implantation: patients with stable SR during FUP (mode switch < 1 %, n=5) had higher BP compared to those with AF recurrence (98 ± 2 vs. 92 ± 8 %, p<.001).
Nowak (2017)	Retrospective design Secondary data analysis: Database of the Institute of Quality Assurance Hessen	Total: n=5075 Subgroups: ▪ alive: n=5005 ▫ Sex: 53.6 % male ▫ Mean Age: 76.3 (SD=9.9) years ▪ deceased: n=70 ▫ Sex: 50 % male ▫ Mean Age: 79.6 (SD=8.7) years	To evaluate the database of the Institute of Quality Assurance Hessen to study if primary PM implantation associated mortality was procedure related, thereby a meaningful marker for public reporting.	<u>Patients and mortality:</u> Deceased patients: significantly older (79.6+8.7 vs. 76.3+9.9 years, P=.006), worse ASA physical status (P<.001), lower EF (P<.001), significantly greater prevalence of high-degree AV-block (44.3 vs. 35 %, P=.001), lower rate of SSS (24.3 vs. 39.3 %, P=.01), more likely to have received single-chamber devices (41.4 vs. 25 %, p=.002); P-wave amplitude significantly lower (procedural data), dual-chamber implantation, operation times and fluoroscopy significantly longer. Post-operative stay significantly shorter in surviving patients: 10.6+10.3 vs. 23.1+22.8 days (P< .001). <u>Cause of death:</u> No causal relationship with PM implantation.
Ohlow (2021)	Retrospective cohort analysis study Quantitative, primary data	Total: n=1868 Sex: 1273 (68.2 %) male Mean Age: 70 (SD=11) years Subgroups: ▪ CIED complications: n=199 ▫ Sex: 132 (66.3 %) male	To analyze a large cohort of patients after first CIED implantation to assess the timing of complications and thereby evaluate if early	Patients in the complication group were significantly more likely to have lower EF (39 ± 15 % vs. 42 ± 16 %), to be on (oral) anticoagulation (42.7 % versus 34.9 %; OR 1.4, 95 % CI 1–1.9), and received an ICD (58.3 % vs. 48.4 %; OR 1.5, 95 % CI 1.1–2). Patients with chronic renal failure undergoing PM implantation had significantly higher incidence of complications (43.2 % vs. 29.8 %; OR 1.8, 95 % CI 1.1–2.9). 3 most frequent complications during 12 months of FUP: lead-related re-intervention in 101 (5.4 %), pneumothorax in 40 (2.1 %), and pocket hematoma needing evacuation in 33 (1.8 %) cases.

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		▫ Mean Age: 70 (SD=9.9) years ▪ no CIED complications: n=1669 ▫ Sex: 1141 (68.4 %) male ▫ Mean Age: 70 (SD=11) years	discharge (the same day or after< 24 h) post-implantation could be a strategy to be pursued.	All "potentially life-threatening acute complications" occurred during first 72 h, only less than 50 % of the total complications occurred in this time frame. Patients undergoing ICD implantation (58.3 % versus 48.4 %; OR 1.5, 95 % CI 1.1–2.0), especially CRT-ICD (32.7 % vs. 24.6 %; OR 1.5, 95 % CI 1.1–2.0), more likely to experience any complication: Higher incidence of pocket hematoma needing evacuation (2. 7 % vs. 1 %; OR 3 .0, 95 % CI 1.3–6.7) and infection (2.1 % vs. 0.4 %; OR 4.5, 95 % CI 1.5–13). Complications after median of 7 days after surgery, most frequent complications access-/lead-related
Parahuleva (2017)	Retrospective design single-center, parallel, noninferiority case series study Quantitative, primary data	Total: n=364 Subgroups: ▪ Active group (AG): n=217 ▫ Sex: 51 (23.5 %) female ▫ Mean Age: 67.5 years ▪ CG: n=147 ▫ Sex: 35 (23.8 %) female ▫ Mean Age: 69 years	To examine how the safety and efficacy of the home monitoring (HM) system in patients after ambulatory implanted primary CIEDs compare to patients with a standard procedure and hospitalization.	<u>Duration of hospitalization:</u> Mean duration of hospitalization 73.2 % shorter in the AG than in the CG (95 % CI: 58 %-88 %), corresponding to 20.5± 13 fewer hours (95 % CI: 6.3–29.5; p<.01) spent in the hospital (7.5 ± 1.5 h vs 28 ± 2.5 h). 78.8 % shorter postoperative period in the AG (95 % CI: 71 %-85 %) compared with the CG (5.5 ± 1 vs 26 ± 2 h) <u>Adverse events and treatment actions:</u> 47 (13 technical and 34 clinical) adverse events in the AG vs 52 (14 technical and 38 clinical) in the CG PM: most important reported benefit early detection of sustained AF (5.6 % in AG, 11.8 % in CG), early detection of lead failure (5.1 % in AG, 6.7 % in CG), or ventricular arrhythmias (2 % in AG, 2.5 % in CG) ICD: most important reported benefit early detection of lead failure (1 patient in AG, 2 patients in CG), early detection of AF (1 patient in AG, 1 patient in CG). CRT: most important reported benefit early detection of loss of biventricular capture and worsening HF <u>Treatment modifications:</u> Changes in lead parameters in AG were 5.3 % versus 8.2 % in CG (log-rank p=.22). Observing daily updated FUP parameters on mode switch episodes in relation to patient's activity and mean heart rate helped detect worsening arrhythmia (AG, n=12; CG, n=15)=> adjustment of individual medical therapies or electrophysiological studies with ablation (AG, n=8; CG, n=10) and observing patients' compliance in taking β-blockers (AG, n=7; CG, n=9). SVT episodes observed in 3 patients (AG, n=1; CG, n=2)=> outpatient treatment in 2 patients. Occurrence of VT requiring immediate treatment reported in 4

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				patients in SM-AG and in 3 patients in SM-CG. Total of 2 (AG, n=1; CG, n=1) clinically related adverse messages reflected low percentage of CRT pacing=> early reprogramming of the AV interval within 2 weeks in the AG and 4 weeks in the CG QOL: No difference between groups.
Pecha (2017)	Retrospective design Quantitative, primary data	Total: n=171 Subgroups: ▪ Single coil: n=37 ▫ Sex: 28 (75.7 %) male ▫ Mean Age: 56.3 (SD=16.6) years ▪ Dual coil: n=134 ▫ Sex: 93 (69.4 %) male ▫ Mean Age: 59.9 (SD=15.8) years	To Compare success rates and complication rates of laser lead extraction procedures for single- and dualcoil leads.	Success rates: single-coil group: complete procedural success in 36 of 37 (97.3 %) cases, clinical success in all cases (100 %), no extraction failure dual-coil group: complete procedural success in 131 of 134 (97.8 %) patients, clinical success in 132 of 134 cases (98.5 %), extraction attempt failed in 2 cases (1.5 %). No group differences between extraction success rates (39/41 (95.1 %) single-coil leads, 143/145 (98.6 %) dual-coil leads (p=.9)). Mean laser treatment time was 1.8 ± 1.5 for single-coil group and 2.5 ± 1.2 min for dual-coil group, significantly longer laser treatment time in the dual-coil group (p=.002). Complications: single-coil group: overall complication rate 2.7 %. No minor complications in this group. dual-coil group: overall complication rate 3.7 %. Minor complications in 4 patients (3 %): pocket haematoma with surgical (n=2, 1.5 %), discrete pericardial effusion without haemodynamic relevance (conservative management, n=1, 0.7 %), pneumothorax requiring chest tube drainage (n=1, 0.7 %). Extraction of dual-coil leads associated with increased laser treatment times but had similar complication and procedural success rates, when compared with the extraction of single-coil leads.
Pecha (2021)	Retrospective design Quantitative, primary data	Total: n=154 Sex: 105 (68.2 %) male Mean Age: 65.8 (SD=15.9) years	To Investigate success- and complication rates of lead extraction procedures in patients	Success rates: Complete procedural success in 141/154 patients (91.6 %), clinical success in 149/154 (96.8 %) cases. Failure of extraction in 5 (3.3 %) patients. 344/362 (95 %) leads completely extracted, partial removal in 10 leads (2.8 %). Complete failure of lead extraction in 8 (2.2 %) leads in 5 patients (3.2 %). Leads that could not be

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			with leads implanted for more than 10 years	completely removed were significantly older than leads where complete extraction success was achieved (18.2 vs 13.2 years; p=.016). Complications: The overall complication rate was 4.6 %. Five major (3.3 %) and 2 (1.3 %) minor complications occurred. No procedure-related death occurred in any group. In-hospital mortality was 1.3 %.
Rafla (2018)	Retrospective design Quantitative, primary data	Total: n=80 Subgroups: ▪ Non Responder: n=24 ▫ Sex: 20 (83.3 %) female ▫ Mean Age: 75.77 (SD=6.73) years ▪ Responder: n=57 ▫ Sex: 47 (82.7 %) female ▫ Mean Age: 72.15 (SD=9.01) years	to study the value of upgrading patients with PM to CRT and assess the significant parameters between responders and non-responders in this special population.	Responders/Nonresponders: Of 81 cases, 24 (29.6 %) were non-responders and 57 (70.3 %) were responders Revascularization: 87.5 % vs 50.9 %, p=.002 (ICM cases and those with previous infarction were less responders than NICM; revascularization was done in most ischemic patients) Significant influence on response to CRT: Less Responder with: Higher CRP, presence of TR, presence of pulmonary hypertension, presence of previous myocardial infarction, being ICM vs NICM (less responder with ICM).
Rivinius (2019)	Registry study Secondary data analysis: routine clinical data	Total: n=621 Subgroups: ▪ permanent pacemaker implantation (PPM) after HTX: n=36 ▫ Sex: 27 (75 %) male ▫ Mean Age: 55 (SD=6.5) years	To investigate the risk factors, indications, perioperative outcomes and complications of PPM implantation after HTX as well as the underlying effect on post-	Risk factors for PPM implantation after HTX: recipient age in years (HR: 1.03; 95 % CI: 0.98–1.08; p=.2), recipient BMI in kg/m2 (HR: 1.10; 95 % CI: .01–1.21; p=.03), recipient arterial hypertension (HR: 1.43; 95 % CI: 0.65–3.14; p=.37), donor age in years (HR: 1.07; 95 % CI: 1.03–1.10; p<.01), and biatrial HTX (HR: 2.63; 95 % CI: 1.22–5.68; p=.01) Indication: Patients with early PPM after HTX: significantly higher rate of sinus node dysfunction (66.7 % versus 29.2 %; p=.03), patients with late PPM after HTX: higher percentage of AVB (70.8 % versus 33.3 %; p=.03) FUP measures of PPM implantation after HTX:

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
		▪ No PPM after HTX: n=585 ▫ Sex: 460 (78.6 %) male ▫ Mean Age: 51.8 (SD=10.5) years	transplant mortality including causes of death.	Patients with early PPM after HTX significantly lower percentage of atrial and ventricular pacing: ▪ At baseline: atrial: 8 %±4.8 % vs. 20.9 %±26.9 %; p=.04; ventricular: 19.4 %±21.5 % vs. 42.5 %±41.9 %; p=.04 ▪ 6-months: atrial: 2 %±1.7 % vs. 25 %±30.2 %; p<.01; ventricular: 0.5 %±0.8 % vs. 34 %±43 %; p<.01 ▪ 24-months: atrial: 1.3 %±1.1 % vs. 21.9 %±29.2 %; p=.03; ventricular: 0.3 %±0.3 % vs. 45.6 %±47.5 %; p<.01 Survival after HTX: Stratified by early PPM (PPM ≤1 year after HTX), late PPM (PPM >1 year after HTX), and no PPM after HTX: statistically significant inferior 5-year post-transplant survival of patients with early PPM after HTX
Rudic (2017)	Single Center Experience and Long-Term FUP Quantitative, primary data	Total: n=62 Sex: 41 (66 %) male Mean age at diagnosis: 35 (SD=13) years Mean age at implantation: 38 (SD=13) years	to investigate prevalence of IAS in patients with inherited arrhythmia syndromes with S-ICD in a single center experience and long-term FUP	Clinical Episodes of Ventricular Arrhythmias: 20 discrete spontaneous episodes of VT/VF recorded in 10 patients that required defibrillator therapy, 9 of 10 patients that had ventricular tachyarrhythmia during FUP had a second prevention ICD indication. All 20 events were effectively converted within the first shock (100 % first shock efficacy at 80 J) IAS: 2 of 62 patients (3.2 %) experienced IAS Therapy Failures and Premature Revisions: No patient has died during FUP. Apart from reported ones during VT/VF episodes, no patient reported syncopal episodes during FUP. It may be indicative of undersensed/untreated ventricular arrhythmias. No premature battery depletions or pocket-site infections.
Rudic (2020a)	Retrospective single-center study Quantitative, primary data	Total: n=25 Sex: 1 (4 %) female Mean Age: 49 (SD=15) years	To determine the outcome of DFT (defibrillation threshold) testing in patients undergoing replacement of an	Indications for defibrillator implantation: secondary prevention after aborted cardiac arrest due to documented VF (n=10, 40 %), idiopathic VF (n=6, 24 %), ICM (n=6, 24 %), NICM (n=2, 12 %) Pulse GE and conversion testing:

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			S-ICD pulse generator shock efficacy was analyzed in consecutive patients undergoing elective S-ICD pulse GE	▪ n=5 (20 %): no response to VF/VT conversion with the first and second 65-J shocks and required external defibrillation, of which n=4 (80 %) were in need of fluoroscopy-guided repositioning of the device; n=1: a new defibrillation lead was placed ▪ in patients with conversion failure, extensive removal of the fibrous capsule surrounding the device was performed; all patients then showed an increase of shock impedance compared to the initial implantation; shock impedance increased significantly from 80 ± 20 Ω at initial implantation to 98 ± 26 Ω (p<.001 at the time of pulse GE) <u>Intraoperative medication and PRAETORIAN score:</u> ▪ Patients with ineffective DFT had longer operation duration and higher propofol doses, but propofol ratio per minute did not significantly differ between the 2 patient groups; ▪ PRAETORIAN score did not differ between the 2 patient groups; all patients showed an increase of shock impedance over time. However, this increase was more pronounced in patients with failed DFT testing compared to patients with effective DFT testing (119 ± 17 Ω vs 93 ± 26 Ω; p=.03) patients with ineffective DFT testing did not show significant clinical differences that could have contributed to the negative outcome The high proportion of patients with DFT failure after S-ICD pulse GE replacement indicates that DFT testing is mandatory to ensure safe function of the S-ICD
Rudic (2020b)	Retrospective single-center study Secondary data analysis: FUP data	Total: n=239 Sex: 185 (77 %) male Mean Age: 57.3 (SD=16) years	To analyse single episodes of IAS and their association with comorbidities, patient characteristics, and programming parameters, in order to explore mechanisms of	<u>Defibrillator shocks:</u> 27 patients (11 %) had 43 AS, 19 patients (8 %) had 30 IAS. Patients with IAS were significantly taller than patients without IAS (179± 0.1cm vs. 174± 0.1cm; p=.006). IAS more prevalent in patients with first generation S-ICD compared to second generation (11 %vs.6 %). In second S-ICD generation, activation of SMART pass filter reduced incidence of IAS in all enabled devices. <u>Sensing vectors and defibrillator shocks:</u> Group of patients with IAS: significantly higher proportion of patients with primary sensing vector compared to patients without shocks (p=.03). IAS caused by myopotentials almost exclusively registered on primary sensing vector (7 of 8 cases). IAS caused by TWOS in 6 patients and 17 episodes, equal distribu-

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			IAS in S-ICD patients, along with guidance for IAS prevention	tion among the primary and secondary vector. No inappropriate therapies with the alternate vector. Patients with IAS caused by myopotentials on average taller (mean 183± 0.1 cm) and younger (mean 46.3± 13.5 years) than patients without IAS (p=.034 and p=.001) in contrast to patients with IAS related to TWOS and QRS undersensing. Multivariate analysis of predictors for IAS: body height ≥182 cm, programmed primary sensing vector, presence of first-generation S-ICD device (1010) independently and significantly associated with IAS. IAS led to a higher rate of rehospitalization compared to patients without any shocks. Other MACCE (death, occurrence of VT/VF, and myocardial infarction) not increased in patients with IAS compared to patients with AS or patients without shocks.
Rusnak (2020)	Observational and retrospective registry-based analysis Secondary data analysis: clinical data	Total: before matching: n=528 after matching: n=432 Subgroups: Before matching ▪ LVEF ≥35 %: n=271 ▫ Sex: 216 (79 %) male ▫ Median Age: 55 (range 21–75) years ▪ LVEF <35 %: n=257 ▫ Sex: 210 (82 %) male ▫ Median Age: 62 (range: 44–75) years After matching ▪ LVEF ≥35 %: n=216 ▫ Sex: 176 (82 %) male	To evaluate the impact of LVEF on secondary prognostic outcomes in ICD recipients with index episodes of ventricular tachyarrhythmias, focusing on recurrences of ventricular tachyarrhythmias, ICD-related therapies, rehospitalization, and all-cause mortality	<u>Primary end point:</u> Freedom from first episodes of recurrent ventricular tachyarrhythmias decreased in patients with LVEF < 35 % compared to those with LVEF ≥35 % (40 vs. 49 %, log-rank p=.014; HR=1.381; 95 % CI 1.066–1.788; p=.034). This difference mainly observed in patients with primary preventive ICD (32 vs. 46 %; log rank p=.005; HR=1. 810; 95 % CI 1.185–2.766; p=.006), but not in secondary preventive ICD recipients (log rank p=.379). Differences in recurrences of ventricular tachyarrhythmias can presumably be attributed to the higher rate of sustained VT in LVEF < 35 % patients (20 vs. 33 %, p=.001), also reflected by increasing rate of overall sustained VT (25 vs. 40 %, p=.001). Freedom from first episodes of recurrent ventricularn achyarrhythmias was still reduced in LVEF < 35 % vs. LVEF ≥35 % after PSM (40 vs. 46 %; HR=1.316; 95 % CI 0.985–1.759; p=.063). <u>Secondary end points:</u> Freedom from overall first appropriate device therapies was decreased in LVEF < 35 % at 5 years (28 vs. 41 %, log rank p=.001; HR=1.656; 95 % CI 1. 231–2. 227; p=.001). This difference presumably driven by increasing rates of appropriate ATP (16 vs. 21 %) and AS (12 vs. 19 %) in LVEF < 35 %. Inappropriate device therapies comparable in both groups. Patients with LVEF < 35 % higher rates of overall first rehospitalization (23 vs. 34 %), mainly attributed to VT recurrence, and higher rate of allcause mortality at 5 years (13 vs. 29 %).

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
		▫ Median Age: 67 (range 21–80) years ▪ LVEF <35 %: n=216 ▫ Sex: 176 (82 %) male ▫ Median Age: 67 (range: 42–87)		Freedom from overall first appropriate device therapies was decreased in the LVEF < 35 % group at 5 years after PSM (30 vs. 38 %, log rank p=.024; HR=1.441; 95 % CI 1.048–1.982; p=.001). After PSM patients with LVEF < 35 % higher rates of overall first rehospitalization and all-cause mortality at 5 years.
Safak (2018)	Retrospective design Quantitative, primary data	Total: n=93 Sex: 81.5 % male Mean Age: 58.9 (SD=12.3) years	To present the long-term performance of a new generation ICD electrode with floating atrial dipole (Linox S DX, Biotronik, Berlin, Germany).	In 47 patients, 460 arrhythmic episodes were detected, stratified, and sent automatically by device RM. Of these, 185 messages (40.2 %) incorrectly stratified by device in 25 patients. and resulted mainly from far-field sensing of ventricular signal (67 %) in atrial channel. In 4 patients, incorrect messages were induced by a mechanical problem (either lead isolation defect or loose connection between lead and ICD). In 3 patients 9 episodes of VT (shortest tachycardia cycle length 338 ms) inappropriately classified as SVT and, for this reason, no therapy was activated. 9 patients experienced adequate (9.6 %) and 7 (7.5 %) inappropriate ICD therapy (4 IAS). No significant differences in patients with or without inappropriate therapies apart from the fact that patients with inappropriate ICD therapy had been implanted with leads having tip-to-ring distance of 17 cm (p=.03). When excluded from analysis patients with lead isolation issues and faulty lead-device connection (loose screw), no significant difference in the tip-to-ring distance was seen in patients with and without inappropriate ICD therapy
Safak (2019a)	Retrospective design Secondary data analysis: German Device II Registry	Total: n=783 Subgroups: ▪ AS: n=34 ▫ Sex: 5.9 % female ▫ Median Age: 68 (IQR=58–77) years ▪ IAS: n=24 ▫ Sex: 16.7 % female	To evaluate rates and clinical determinants of IAS after ICD	3 sub-groups: ▪ patients that had experienced AS (n=34/4.3 %), IAS (n=24/3.1 %), and no shocks (n=725/92.6 %); n=4 out of 783 patients (0.5 %) experienced both AS and IAS; ▪ cumulative incidence of IAS at FUP was below 5 % ▪ Patients experiencing IAS were significantly younger (p=.03), had been more often referred for primary prophylaxis (p=.01), had a significantly higher resting heart rate (p=.003), had been more often in AF (p=.006), and had a shorter QRS complex duration on routine 12-lead ECG (p=.001) a) Operation duration was significantly longer in the no shock patients (p=.004)

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		▫ Median Age: 59 (IQR 51–68) years ▪ No Shock: n=725 ▫ Sex: 20.4 % female ▫ Median Age: 66 (IQR=56–75)		b) Implantation of a single-lead ICD (VVI-ICD) was more common in the IAS group (p=.002) c) At a median FUP of 18.2 months (75 % IQR 13.6–22.4 months), no in hospital mortalities were observed in the IAS group, one (2.9 %) in the AS group, and 36 (4.9 %) in the no shock group. No group differences (p=.9) d) Kaplan-Meier-estimated 1-year survival was similar in the 3 groups (p=.7) e) device revision in 3 % in AS group, in 12.5 % in IAS group, in 2.6 % in no shock group (p=.03) f) Hospital readmissions for cardiovascular reasons (including ICD revisions) and visits to the outpatient cardiology departments were both significantly more common in patients experiencing IAS g) no group difference in satisfaction with the treatment received (p=.8), the perception of the ICD as a protection tool against sudden death and the level of fear generated by a potential ICD shock (p=0.1)
Safak (2019b)	Retrospective design Quantitative, primary data	Total: n=170 Subgroups: ▪ Non-PICM: n=159 ▫ Sex: 58.8 % male ▫ Mean Age: 71.5 (SD=9.7) years ▪ PICM: n=11 ▫ Sex: 4.1 % male ▫ Mean Age: 69 (SD=17) years	To evaluate the prevalence of PICM at midterm FUP after PPM implantation.	Patients developing PICM had a significantly lower preimplantation LVEF (58.4 ± 8 % vs. 67.3 ± 8.4 %; p=.005), a significantly higher reduction (delta) of the baseline LVEF values (20.4 ± 7.9 % vs. 2.3 ± 9.9 %; p<.0001), a significantly lower rate of PPM indication for SSS (18.2 % vs. 61 %; p=.009), and a significantly higher rate of second-grade cardiac conduction block (36.4 % vs. 11.3 %; p=.03). The multivariate logistic regression model to chase independent determinants for PICM included mainly three variables, i.e., preimplantation LVEF, the presence of pre-procedural SSS, and the presence of AV cardiac conduction block of second degree or higher. Only preimplantation LVEF (OR=0.88; CI 0.80–0.96; p=.006) and the presence of SSS (OR=0.1; CI 0.03–0.9; p=.04) were independently related (inverse relationship) to FUP PICM.
Scheurlen (2021)	Retrospective single-center analysis	Total: n=70 Sex: 61 (87 %) male Mean Age: 78.6 (SD=3.7) years Subgroups:	to assess mortality after ICD implantations or GE in elderly patients	<u>Mortality:</u> After ICD implantation or GE, 40/70 pts (57 %) died during FUP period of 3.3 years. Mortality was significantly higher in group 80+ (16 of 18, 89 %) compared to group 75–79 (24 of 52, 46 %) (p=.002). 1-year and 2-year mortality was significantly higher in group 80+ (72 % and 56 %) compared with group 75–79 with 27 % and 17 % (p<.001 and p=.002).

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	Quantitative, primary data	▪ Group 75–79: n=52 ▫ Sex: 45 (87 %) male ▫ Mean Age: 76.8 (SD=1.4) years ▪ Group 80+: n=18 ▫ Sex: 16 (89 %) male ▫ Mean Age: 83.7 (SD=3.8) years		No group difference in average survival after ICD intervention(p=.09) Comorbidity: Besides significantly higher number of strokes in group 75–79 (p=.04), no statistically significant differences in comorbidities between the two groups. Among deceased patients, more patients suffered from chronic renal failure (deceased: n=34, 85 %, vs. alive: n=16, 53 %, p=.004). Significantly more of deceased patients had peripheral artery disease n=7, 18 %), compared with surviving pts (n=0; p=.02). Primary vs. secondary prevention indication: Of the 35 patients in primary prevention group, 30 patients were 75–79 years old (86 %), 5 patients 80 years and older (14 %). Of the 35 patients in secondary prevention group, 22 patients were 75–79 years old (63 %) and 13 patients 80 years and older (37 %). Among patients with an ICD for secondary prevention, all of the patients in the age group 80+ (n=13) and half of the patients in the age group 75–79 (n=11) died during post-operative period. Adequate and inadequade ICD therapies: FUP of 3.3± 1.2 years: 7 patients experienced ICD therapies: 4 adequate for VT or VF, 3 inadequate, none directly related to a mortality event. Shocks: 4 shocks patients 75–79, 3 in group 80+, 4 in primary and 3 in secondary prevention indication group
Schiedat (2021)	Prospective design Quantitative, primary data	Total: n=33 Sex: 25 (76 %) male Age: 68.3 (SD=10.4) years	To examine the acute effect of SyncAV and multipoint pacing (MPP) on electrical synchrony in patients with newly and	Electrical synchronization: Compared to biventricular pacing with SyncAV at patient-specific optimised offset, MPP with SyncAV at patient-specific optimised offset (MPPSyncAVopt) resulted in significantly shortened QRSd 108.7 ± 16.5 ms vs. 117 ± 19 ms (p<.001). Greatest overall QRSd reduction relative to intrinsic conduction was achieved by MPP with a patient tailored SyncAV offset (–31.6 % ± 11.1 %; p<.001). Fusion of CRT and intrinsic conduction with shortening of QRSd was present in all patients while MPPSyncAVopt showed the most significant shortening in each individual patient.

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
			chronically implanted CRT devices.	By using MPPSyncAVopt, QRSd shortened significantly in these 8 (24.2 %) patients relative to baseline (145 ± 21.6ms vs. 114 ± 13.4ms; p<.001). All patients with MPPSyncAVopt showed >10 % shortening of QRSd compared to the baseline ECG. <u>MPP SyncAV offset optimization:</u> An offset of 60 ms led to a significantly longer QRSd compared to all other offsets (p<.01). Offset of 50 ms resulted in significantly longer QRSd compared to offsets 40, 30, and 20 ms (p<.01), but not compared to 10 ms (p=.16). QRSd for 10 ms offset was significantly longer compared to offsets 40, 30, and 20 ms (p<.05). Patient-tailored optimization of SyncAV offset was associated with a significant shortening in QRSd compared to default setting (108.7 ± 16.5ms vs. 121.2 ± 17.1ms, p<.001). <u>Difference of synchronization according to baseline characteristics:</u> Intrinsic QRSd was significantly shorter in patients with Non-left bundle branch block (LBBB) compared to patients with LBBB (142.7 ± 26.1ms vs. 162.1 ± 19.7ms, p<.05). MPPSyncAVopt achieved the greatest QRSd reduction in Non-LBBB patients compared to intrinsic conduction (117.7 ± 19.4 ms vs. 142.7 ± 26.1 ms, p<.05). Shortening of QRSd with a patient tailored offset (MPPSyncAVopt) was significantly higher in LBBB compared to Non-LBBB patients (LBBB: –33.1 % ± 10.4 % vs. Non-LBBB: –17 %±8.3 %, p<.05), although the final absolute value of QRSd with MPPSyncAVopt did not differ significantly between these two groups (LBBB: 107.8 ± 16.3ms vs. Non-LBBB: 117.7 ± 19.4ms, p=.48). Shortening of QRSd with MPPSyncAVopt was significantly higher in patients with longer intrinsic QRSd (Spearman-Rho=–0.585, p<.001).
Schober (2021)	Retrospective design Secondary data analysis: Registry Regensburg ICD Survival Trial	Total: n=895 Subgroups: ▪ novel programming (NP): n=233 (full therapy data n=202) ▫ Sex: 192 (82.4 %) male (full therapy data: 171 male (84.7 %)) ▫ Mean Age: 66 (SD=13.4) (full therapy	to present the long-term effects of this NP strategy on the mortality and morbidity rate in a large real-life cohort, which consists of patients with pri-	<u>Appropriate Therapies:</u> NP associated with significantly lower occurrence of appropriate therapies (AS and ATP) than CP (18.8 % vs. 42.2 %, p<.001),also evident after stratification for each shock and ATP therapy (AS 10.5 % vs. 23.8 %, p<.05; ATP 11.1 % vs. 31.2 %, p<.001). Significant reduction in appropriate therapies with NP persisted after stratifying study group for primary and secondary prevention indication (primary prevention 10.2 % vs. 39.3 %, p<.001; secondary prevention 26.1 % vs. 45.2 %, p<.05). No significant group difference in shock therapies (6.9 % vs. 17.2 %, p=.058). <u>Primary and secondary prevention:</u> Probability for ATP therapy was for NP-patients in primary prevention group significantly lower (4.6 % vs. 31.5 %, p<.001) than for CP-patients.

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	(Res-IST)	data: 66 (SD=13.5)) years ▪ conventional programming (CP): n=662 (full therapy data n=384) ▫ Sex: 532 (80.2 %) male (full therapy data: 314 male (81.6 %)) ▫ Mean Age: 64 (SD=12.7) (full therapy data: 64 (SD=13.3)) years	mary and secondary ICD indication.	For primary prevention, NP-patients had received significantly less appropriate therapies compared to CP-patients (7.5 appropriate therapies per 100 patient years vs. 27.3 appropriate therapy per 100 patient years, p<.001). Same was found for secondary prevention (21.6 vs. 35.6 appropriate therapies per 100 patient years, with NP vs. CP, respectively, p<.05). Inappropriate Therapies: NP significantly less inappropriate therapies (1st prevention: 3.1 vs. 9.1 per 100 patient years, p<.05; 2nd prevention: 4.3 vs. 11.9 per 100 patient years, p<.05). Probability for receiving IAS in NP significantly lower than in CP (3.5 % vs. 10.2 % p<.05). Mortality: Significantly less deaths in NP-patients than with CP (6.5 per 100 patient years vs. 15.2 deaths per 100 patient years, respectively [p=.001]). NP associated with significantly reduced cumulative mortality compared with CP (11.4 % vs. 25.4 %, p<.001). Mortality rate significantly lower in NP after stratifying for primary and secondary prevention (8.2 % vs. 20.9 % in primary prevention and 14 % vs. 28.8 % in secondary prevention, each p<.05) NP associated with a 66 % relative reduction in mortality (HR=0.34, 95 % CI 0.20–0.60, p<.001). Similar relative risk reduction in primary and secondary prevention (HR=0.21, 95 % CI 0.06–0.67 vs. HR=0.42, 95 % CI 0.22– 0.80, each p<.05). Risk of appropriate ICD therapies with NP vs. CP: 59 % relative reduction (HR=0.41 95 % CI 0.27–0.62; p<.001) Inappropriate therapies: 77 % relative reduction favoring novel ICD programming (HR=0.23, 95 % CI 0.10–0.54; p<.001)
Schupp (2019)	Observational and retrospective registry-based analysis	Total: n=592 Subgroups: ▪ Non-recurrence (before PSM): n=329 ▫ Sex: 256 (78 %) male	to comprehensively evaluate the prognostic impact of recurrences of ven-	Survival according to recurrences of ventricular tachyarrhythmias: Patients with recurrences of ventricular tachyarrhythmias had higher rates of CKD (48 % vs. 39 %), LVEF<35 % (54 % vs. 44 %) and secondary preventive ICDs (62 % vs. 54 %). They were associated with increased long-term all-cause mortality at 5 years (mortality rates 26 % vs. 17 %, log rank p=.024; HR=1.498; 95 % CI=1.052–2.132; p=.025) and with impaired survival from the second year of FUP. The rates of re-

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	Secondary data analysis: Registry of Malignant Arrhythmias and SCD-Influence of Diagnostics and Interventions (RACE-IT)	▫ Median Age: 66 (range 19–84) years ▪ Recurrence (before PSM): n=263 ▫ Sex: 215 (82 %) male ▫ Median Age: 67 (range 15–87) years ▪ Non-recurrence (after PSM): n=225 ▫ Sex: 184 (82 %) male ▫ Median Age: : 66 (range 19–84) years ▪ Recurrence (after PSM): n=225 ▫ Sex: 182 (81 %) male ▫ Median Age: 67 (range 21–87) years	tricular tachyarrhythmias and ICD-related therapies on long-term all-cause mortality and cardiac re-hospitalization in consecutive ICD recipients with index episodes of ventricular tachyarrhythmias on admission.	hospitalization were higher in patients with recurrences. Thereafter, recurrences of ventricular tachyarrhythmias were still associated with impaired long-term survival at 5 years (mortality rate 26 % vs. 18 %, log rank p=.034; HR=I.542; 95 % CI=1.030–2.307; p=.035). Both patients with sustained VT and VF were associated with impaired long-term survival compared to patients with non-sustained VT (log rank p<.015). Patients with sustained or non-sustained VTs plus VF were associated with worse survival compared to patients with sustained or non-sustained VTs only (log rank p=.045). <u>Survival according to appropriate ICD therapies:</u> Patients with appropriate ICD therapies were associated with increased long-term mortality (mortality rates 30 % vs. 16 %, log rankp=.001; HR=1.874; 95 % CI=1.318–2.666; p=.001). Both patients with ICD shocks (mortality rate 36 % vs. 18 %, log rank p=.001; HR=2.276; 95 % CI=1.572–3.294; p=.001) and patients with episodes of ATP only were associated with increased mortality at long-term FUP (mortality rate 30 % vs. 18 %, log rank p=.003; HR=1.711; 95 % CI=1.191–2.460; p=.004). Impaired mortality in patients with ICD therapies was evident already at 2 years of FUP. <u>Stratification by indication of ICD implantation:</u> After propensity-matching (177 matched pairs), appropriate ICD therapies were still associated with increased mortality at 5 years (mortality rates 30 % vs. 16 %, log rank p=.001; HR=2.007; 95 % CI=I.28–3.147; p=.002). Focusing on those patients with recurrences of ventricular tachyarrhythmias at 5 years only within the unmatched cohort, those with appropriate ICD therapies still revealed increased long-term mortality (mortality rates 30 % vs. I 0 %. log rank p=.008; HR=2.949; 95 % CI=1.275–6.821; p=.011). <u>Stratification by indication of ICD implantation:</u> Recurrences of ventricular tachyarrhythmias treated by appropriate ICD therapy were associated with increased mortality (unmatched: HR=1.857; 95 % CI 1.026–3.362; p=.041; matched: HR=1.802; 95 % CI 0.89–3.649; p=.102). Patients with appropriate ICD therapy were associated with increased mortality even after propensity-score matching (matched: HR=2.100; 95 % CI I.166–3.785; p=.0014). <u>Predictors:</u> Within multivariable Cox regression analyses, NICM (HR=1.503; 95 % CI=1.019–2.217; p=.040) and AF (HR=1.319; 95 % CI=1.003–1.734; p=.048) were strongest predictors of recurrences of ventricular tachyarrhythmias at long-term FUP. Age (HR=1.016; 95 % CI=1.002–1.029; p=.023), LVEF < 35 % (HR=1.431; 95 %

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				CI=1.053–1.947; p=.022), AF (HR=1.327; 95 % CI 0.974–1.807; p=.073, statistical trend) and NICM (HR=1.713; 95 % CI=1.126–2.607; p=.012) were strongest predictors of appropriate ICD therapy at long-term FUP.
Schwab (2018)	Prospective, non-randomised, multicentre trial Secodary data analysis: LION registry	Total: n=283 Sex: 236 (83 %) male Mean Age: 65.7 (SD=10.9) years	to evaluate the atrial and ventricular pacing, the changes in PM settings, and the association between atrial and ventricular pacing and the development of atrial arrhythmias.	Intraindividual comparison of % ventricular pacing for first 45 HM transmissions vs. last 45 HM transmissions for 275 analysable patients revealed that 38.2 % showed significant increase in % ventricular pacing (alpha level .05) while 24.4 % had a significant decrease (alpha level .05). Subjects with atrial arrhythmia burden (AB) during FUP differed from subjects without AB during FUP: More frequently in NYHA functional class ≥ III (AB=0: 15 % vs. AB > 0: 31 %, p=.003), lower mean LVEF (AB=0: 36.6 %± 13.6 % vs. AB > 0: 33.1 % ± 12.2 %, p=.047), more frequently a history of AF (AB=0: 13 % vs. AB > 0: 40 %, p<.001). Of 211 patients with no documented history of AF and AB data, 59 patients without history of AF (28 %) developed de novo high rate atrial tachyarrhythmias during FUP. For 63.5 % of patients with history of AF, AB > 0 detected during observation period. No pre-existing AF history predicted absence of device-based AF in 72 % during 15 months FUP. Association between AB, Percentage of Atrial Pacing, and Percentage of Ventricular Pacing: Mean % ventricular pacing significantly different in patients with device-detected atrial arrhythmias (26.9 % vs 13.7 % those without, p<.00001).
Schwerg (2020)	Cross-sectional study Quantitative, primary data	Total: n=1869 Sex: 1051 (56 %) male Mean Age: 77.7 (SD=10.8) years Subgroups: ▪ LVEF >45 %: n=1662 ▫ Sex: 894 (53.8 %) male ▫ Mean Age: 77.6 (SD=10.8) years ▪ LVEF <45 %: n=207	to analyze the prevalence and causes of systolic left ventricular dysfunction (LVD) in a real-life cohort to identify patients for potential upgrade to His pacing.	845 (45.2 %) patients reported regularly seeing cardiologist in addition to PM outpatient clinic. <u>Predictive factors for LVD:</u> Compared to patients without LVD, in patients with LVD the percentage of patients with VVI PM was significantly higher (p=.004) and had a significantly longer time since implantation of the PM (9.5± 7.3 vs. 10.6± 6.8 years; p=.004). The percentage of males was higher in LVD patients compared to all patients (p<.001). The percentage of RV pacing was significantly higher in LVD patients compared to with patients with preserved LVEF (56 % vs. 78 %: p<.0001). In patients without any other causes for LVD except RV pacing, reduced LVEF was unknown in 54.7 % of the patients. LVD was unknown in only 29.4 % of the patients with other causes for LVD. <u>Symptom burden:</u>

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		▫ Sex: 157 (75.8 %) male ▫ Mean Age: 78.6 (SD=10.8) years		81 % of LVD patients reported symptoms consistent with HF. Subgroup of patients with CAD, the percentage of asymptomatic LVD was 5.6 % in contrast to the other entities of LVD with 24.2 % patients in NYHA I. In the subgroup of patients with RV pacing induced LVD, percentage without symptoms of HF was 31.3 %.
Seegers (2017)	Single-center retrospective study, FUP Secodary data analysis: registry patients	Total: n=605 Sex: 498 (82 %) male Mean Age: 65 (SD=11) years	to assess the association of T-wave loop area and circularity with ICD shocks.	Patients with a larger size of the loop were at lower risk for AS during FUP. In the 25 % of patients having the largest loops (vs. the 75 % of patients with smaller loops), a lower incidence of shocks was found. In the 25 % of patients with the least compact loops (i. e. the highest T-wave loop circularity values), the incidence of shocks was higher. Both variables, T-loop area and T-wave loop circularity, remained significant when entered into a multivariate Fine and Gray regression model together with all significant variables, i.e. mode of prevention, LVEF, use of amiodarone and history of AF. Although statistically significant, the correlation between T-loop area and T-wave loop circularity was weak (Pearson correlation coefficient of 0.35). The correlation between QRSd and T-loop area was moderate (Pearson correlation coefficient of 0.68), correlation between QRSd and T-wave loop circularity was weak (-0.24). QRSd was associated with mortality (HR per 10 ms increase of duration, 1.10; 95 %-CI, 1.02±1.18; p=.018). To ensure the validity of the ECG dataset, total cosine of the of three-dimensional R-to-T angle was analyzed and found to be lower in patients who died during FUP (HR for mortality per unit decrease, 1.98; 95 %-CI, 1.37±2.87; p=.00029).
Seifert (2018)	Single-center observational and retrospective study FUP Quantitative, primary data	Total: n=62 Sex: 55 (89%) male, 7 (11 %) female Mean Age: 68 (SD=10) years	To investigate the success rate of redo CRT implantation in a small cohort of patients following extraction of the device, the rate of subclavian and coronary sinus vein thrombosis, reinfection rate, and	<u>Success of redo CRT implantation:</u> In 53 (85 %) patients, the redo CRT implantation was successful, and a stable and functional coronary sinus (CS) lead was placed. However, the original CS vein could be re-used only in 28 (45 %) of these patients, owing to complete or partial thrombosis of the CS vein. In 9 of the 62 (15 %) patients, the redo CRT implantation was unsuccessful. <u>Thrombosis in CS veins and superior vena cava:</u> Compared to the non- oral anticoagulants group, fewer patients taking oral anticoagulants had coronary vein thrombosis associated with previous lead removal (20 of 28 [71 %] vs. 8 of 33 [24 %]; p=.001; Fisher's exact test; univariate OR 7.8 [95 % CI: 2.6–26]). <u>Prognosis of second CRT implantation:</u>

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			the long-term-prognosis.	The all-cause mortality rate was 7.1 % after 1 year, 15.9 % after 2 years, 25.2 % after 3 years, and 29.8 % after 4 years. The all-cause mortality was significantly higher for patients with N terminal pro B-type natriuretic peptide level ≥ 3000 pg/mL (p<.001), aged ≥64 years (p=.028), those with CAD (p=.042), with chronic kidney insufficiency (p=.001), with AF (p=.001) and whose blood culture showed the presence of S. aureus (p=.014). Re-infection that required a second system extraction occurred in 4 (6.5 %) patients; all these patients showed coagulase-negative Staphylococcus in their blood cultures, and two of them had the same bacterium in their blood cultures as observed at the time of initial infection.
Spitzer (2017)	Observational survey-based study on nonrandomized patient groups Secodary data analysis: multicentre, nationwide German DEVICE registry	Total: n=2356 Subgroups: ▪ Discharged within 24 h: n=527 (FUP data: n=464) ▫ Sex: 461 (87.5 %) male ▫ Mean Age: 64.3 (SD=11.6) years ▪ Hospitalized for >24 h: n=1829 (FUP data: n=1679) ▫ Sex: 1501 (82.1 %) male ▫ Mean Age: 64.5 (SD=13.6) years	To analyse the long-term safety of ICDs in patients discharged within 24 h or after 2–5-day hospitalization, respectively, after complication-free implantation, in circumstances of actual care	One-year rates of death were 4.5 % in patients discharged within 24 h of the procedure, compared with 7.2 % in the hospitalized cohort. The only significant difference between the groups was in rates of MACCE, which were 5.2 % in the cohort of patients discharged within 24 h vs. 8.5 % in patients hospitalized post-procedure (p=.017). In both cohorts, improvements in QOL were reported for a majority of patients with highly similar distribution of patients reporting symptomatic improvements, unchanged or worsened. More patients were in NYHA Classes I and II at the end of FUP than at baseline, but no longitudinal analysis was performed to compare the time points. In both cohorts, >90 % of patients declared that they would opt for the procedure again in the same situation.
Stanner (2019)	Retrospective cohort study	Total: n=71 Sex: 39 (55 %) male Mean Age: 3 months (SD=3 month)	To evaluate the mid-term results of epicardial PM	Impedance of atrial leads increased during the FUP from 571 ± 131 at discharge to 612 ± 133 after more than 5 years (p<.001). Minimum energy threshold of atrial leads decreased significantly from 1± 0.9 µJ at discharge to 0.4 ± 0.3 HJ after more than 5 years (p<.001).

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	Quantitative primary data collection; review of medical records	Subgroups: ▪ Single-chamber PM: n=29 ▪ Dual-chamber PM: n=42	implanted in infants under 1 year of age	Impedance of ventricular leads showed a decrease from 603 ± 204 to 490 ± 152 (p=.009) from discharge to 5-years FUP. 63 device-related reoperations were performed in 33 patients (46 %) after primary implantation. 18 patients underwent one reoperation, 6 patients needed a second, 5 a third, 2 a fourth and 2 a fifth reoperation. During the 17 years of our study period, we identified 55 PM GE. There were 9 (16 %) early exchanges within 1 year of implantation and 46 (84 %) after 1 year. In a cox risk factor analysis young age (p=.018) and implantation of a single-chamber PM system (p<.001) were identified as risk factors for an early PM system reintervention.
Starck (2018)	Retrospective design Secondary data analysis: data from the electronic clinical information system	Total: n=35 Sex: 9 (25.7 %) female Mean Age: 67.7 (31–86) years	To evaluate the results of a concomitant percutaneous, minimal-invasive aspiration procedure with the use of an extracorporeal circulation in TLE procedures in patients with large lead vegetations	▪ Outcome percutaneous aspiration procedure Complete procedural success: 31 (88.6 %) ▫ Partial success: 3 (8.6 %) ▫ Major complications (aspiration procedure related): 0 (0 %) ▪ Lead extraction devices: ▫ Locking stylet: 53 (63.8 %) ▫ Polypropelene extraction sheath: 1 (1 .2 %) ▫ Powered rotational extraction sheath: 46 (55.4 %) ▪ Outcome TLE procedure: ▫ Complete procedural success (per patients): 34 (97.1 %) ▫ Clinical success (per patients): 34 (97.1 %) ▫ Major complications TLE related high grade TR (per patients): 1 ▪ Mortality and Survival: ▫ Operative mortality (not procedure related): 1 (2.9 %) ▫ 30-day survival: 34 (97.1 %) Mean lead vegetation size was 22.6 mm. The location of lead-associated vegetations was the right atrium in all cases. Mean vegetation size did not differ in patients with regard to the kind of infection (systemic

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				infection versus combined local/systemic infection) or the outcome of the procedure (complete versus partial success versus failure). In all patients with partial success of the aspiration procedure (n=3), the remnant vegetation material that was left over was vegetation material attached to the tricuspid annulus or the tricuspid valve itself, which could not fully be aspirated with the percutaneous aspiration system. With regard to the aspiration procedure, no major complications were observed. All leads were completely extracted (100 %). Complete procedural success as well as clinical success was 97.1 %. No procedure-related mortality occurred.
Staudacher (2017)	Prospective design, FUP Quantitative, primary data	Total: n=391 Sex: 142 (36.3 %) female Mean Age: 70.3 (SD=0.7) years Subgroups: ▪ Manual data processing: n=126 ▫ Sex: 79 (63 %) male ▫ Mean Age: 72 (SD=1.1) years ▪ Fully digital data processing (FDDP): n=265 ▫ Sex: 170 (64 %) male ▫ Mean Age: 69 (SD=1) years	To evaluate the feasibility of digital CIED data processing using MediConnect software in a high-volume tertiary hospital	Patient characteristics: Physicians who performed conventional CIED FUP displayed 3.2 ± 0.2 years of previous electrophysiological experience, whereas experience was lower in the FDDP cohort (1.8 ± 0.1 years; p<.001). Efficiency of digital data transfer: Errors included general failure to import interrogation data, incomplete or incorrect import of single values and insufficient transfer of interrogation values into software created documents, respectively. Written patient reports and device identification cards produced through MediConnect software were free from errors in 98 % of cases. Software updates improved the quality of data transfer. Multivariate analysis revealed an influence of physician's experience and device type on device FUP duration among potential determinants (i.e., age, gender, concomitant cardiac disease, device type and manufacturer, physician's experience in clinical electrophysiology, and conventional vs. FDDP FUP). The duration of ambulatory FUP was shorter when performed by more experienced physicians. Technical and clinical events observed during ambulatory FUP: Interrogation of cardiac PM, ICDs, or CRT devices revealed technical issues such as low battery voltage and extended investigation of ICD leads under advisory in a minority of patients of both groups. VT or VF episodes detected by defibrillator devices represented the most frequent events and were encountered in 16 % (manual data transfer group) and 23 % of patients (FDDP; p=.088). In these cases, further evaluation was necessary and options for antiarrhythmic treatment optimization were discussed and initiated when appropriate.

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Tischer (2020a)	Prospective design Secondary data analysis	Total: n=152 Subgroups: ▪ PM: n=125 ▫ Sex: 67 (53.6 %) male ▫ Mean Age: at death: 85 (SD=6.7) years ▪ ICD: n=27 ▫ Sex: 23 (85.2 %) male ▫ Mean Age: at death: 75 (SD=7.9) years	to analyze CIEDs from deceased persons to explore the current implementation of CIED deactivation prior to death in practice and the occurrence of shocks in the end of life setting.	125 (100 %) PMs and 27 (96.4 %) ICDs were analyzed with a mean operation time of 44 ± 34.3 months for PMs and of 47.0± 30.1 months for ICDs. 55.6 % (n=15) ICD patients died in hospital, of whom five (33.3 %) died in palliative care units. PM patients died in hospital less frequently (43.2 %, n=54). In 86.7 % of ICD patients and 88.9 % of PM patients, the hospital physicians had the opportunity to reprogram CIEDs. The mean ventricular pacing rate since the last interrogation prior to death was 69 ± 36 % for PMs with a mean lower pacing rate of about 64 ± 5.9 bpm. The indication for device implantation in PMs was programmed in only 57.6 % of cases. The leading indication for ICD implantation in 74.1 % of cases was primary prophylaxis and for PM implantation AV block in 39.2 % of cases, followed by SSS (22.9 %) or both (2.7 %). Overall, 5 (3.3 %) CIEDs had therapy withdrawal: 1.3 % (n=2) of the PMs and 11.1 % (n=3) of the ICDs. Antitachycardia therapies and defibrillator functions were switched off in all 3 (11.1 %) ICD patients, all of whom died in a palliative care unit. In 1 (3.7 %) of the ICDs, lead output was also programmed to the lowest possible output and to insufficient function. The latest premortem programming of the 3 ICDs was performed 58, 21, and 1 day before death. All devices were programmed to VVI mode with ventricular rates of 30 bpm, 40 bpm, and 50bpm. One (0.7 %) PM was programmed to the lowest possible ventricular output and insufficient function. The other PM (0.7 %) presented with deactivation of lead stimulation by programming to OVO mode. In all PMs, therapy withdrawal was performed on the day of death. Six (25 %) of all active (25 ICDs) ICDs presented at least 1 shock within 24 h prior to death; 2 of these patients (33.3 %) died in hospital.
Tischer (2020b)	Prospective design Secondary data analysis	Total: n=72	To analyze the extent of individual PM programming with respect to automatically controlled parameters. and to determine the number of individual patient and lead data	The time from last PM FUP before death to interrogation after death was a mean 6.2±7.1 months. In 88 % of cases, the study parameters were not automatically adjusted. A mean of 49.3 % parameters had been manually changed compared with the delivery settings, whereas 37.8 % remained unchanged. In 2 PMs (2.8 %), programming of all analyzed parameters was unchanged. Changes in the parameters mode, lower rate, upper tracking or sensor rate, sleep function, and ventricular refractory time were unchanged: in 34.7 % of devices for upper tracking or sensor rate and up to 91.7 % for ventricular refractory time. In 61.3 % of devices, PMT intervention was not revised, thereby not activated, compared with the factory settings. In the case of deactivation, in only 5.9 % of the PMs was the output unchanged compared with the delivery settings. Ventricular sensing assurance was available in 54 (75 %) of the PMs. In 3.6 % of them, this feature was switched off. In the case of deactivation, in 20 % of devices the programming was the same as the delivery settings. If ventricular sensing assurance was not available, in 50 % of cases the programming of ventricular sensitivity remained unchanged from the delivery settings. Alterations in atrial

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			entered in current PMs.	sensitivity, however, remained unchanged in 62.5 % of the devices compared with the delivery settings in devices without ASA. When analyzing the changes in output in detail, it was noted that alterations occurred mainly in pulse amplitude than in pulse duration.
Toner (2018)	Prospective design Secondary data analysis	Total: n=40 Sex: 12 (30 %) female Mean Age: 65 (SD=13) years Subgroups: ▪ Responder: n=26 ▫ Sex: 10 (38 %) female ▫ Mean Age: 62 (SD=13.7) years ▪ Nonresponder: n=14 ▫ Sex: 2 (14 %) female ▫ Mean Age: 70.4 (SD=9.67) years	To examine the nature of electrical remodeling following CRT using the intracardiac electograms (EGM) recorded from the quadripolar LV leads to quantify electrical remodelling and correlate with structural response to CRT	<u>Response to CRT:</u> Thirty-two (80 %) patients had a response to one echo measure, 29 (72.5 %) had a LV end systolic volume ≥15 % relative reduction, and 29 (72.5 %) had a LVEF ≥ 5 % absolute improvement. Responders were more symptomatic at baseline (NYHA 2.71 vs 2.07) and younger (62 vs 70.4 years). The mean QRSd reduced from 154.1 ± 8.1 ms to 138.7 ± 15.1 ms, p<.05. <u>Electrical remodelling and echocardiographic response:</u> Significant reduction in the EGM parameters between baseline and 12 months during both paced and intrinsic conduction. Changes in EGM values were larger for echocardiographic responders. Mean EGM reduction during intrinsic rhythm of responders was 14.9 ± 8.5 ms as compared with 8.9 ± 7.9 ms, for nonresponders (p=.02). <u>Activation sequence:</u> Intrinsic activation sequence changed in 16 of 40 (40 %) patients during the 12-month FUP. 12 of 26 (46 %) responders and 4 of 14 (29 %) non-responders had a change in intrinsic activation sequence over 12 months (p=.145). Among those with change in activation sequence, LV end systolic volume improved in 18.5 % compared to 16.8 % (p=.28) for those without. EF: Those with change in activation sequence had an improvement of 11 % compared 6 % (p=.10) for those without change in activation sequence.
Vogler (2018)	Prospective cohort study Quantitative, primary data	Total: n=78 Sex: 52 (66.7 %) male Mean Age: 68 (SD=12) years Subgroups: ▪ Cephalic vein: n=24 ▫ Sex: 11 (45.8 %) male	to compare a sole cephalic vein access on an intention-to-treat basis to a subclavian vein access in CRT implantation procedures with	The majority of CRT implantations in our study was performed from the left side (100 % in the cephalic vein group versus 92.6 % in the subclavian vein group; p=ns). Only radiation exposure was significantly higher in the cephalic vein group (2984 ± 2370 vs. 1580 ± 1316 cGy*cm2; p=.001). Periprocedural complications occurred in 10 of 78 patients.

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
		▫ Mean Age: 66 (SD=12) years ▪ Subclavain vein: n=54 ▫ Sex: 41 (75.9 %) male ▫ Mean Age: 68 (SD=12) years	respect to feasibility and periprocedural outcome including complication rates.	
Weidner (2019a)	Observational and retrospective registry-based analysis Secondary data analysis: clinical data	Total: n=585 (before matching) n=435 (after matching) Subgroups: Before matching: ▪ Non-CKD: n=333 ▫ Sex: 263 (79 %) male ▫ Median Age: 56 (range: 15–75) years ▪ CKD: n=252 ▫ Sex: 202 (80 %) male ▫ Median Age: 61 (range: 44–72) years After matching: ▪ Non-CKD: n=218 ▫ Sex: 178 (50 %) male ▫ Median Age: 60 (range: 33–75) years ▪ CKD: n=217	To evaluate the impact of CKD on recurrences of ventricular tachyarrhythmias, device-related therapies, rehospitalization and all-cause mortality in ICD recipients surviving index episodes of ventricular tachyarrhythmias and to identify subgroups of patients at higher risk to develop recurrent ventricular tachyarrhythmias to	<u>Primary endpoints:</u> The primary endpoint of first recurrence of ventricular tachyarrhythmias was increased in CKD patients (50 % vs. 40 %, log-rank p=.008; HR=1.398; 95 % CI 1.087–1. 770; p=.009), irrespective of the presence of primary and secondary preventive ICD indication (primary: 45 % vs. 36 %; log rank p=.057; HR=1.468; 95 % CI 0.986–2.186; p=.059; secondary: 53 % vs. 44 %; log rank statistical trend p=.089; HR=1.306; 95 % CI 0.959–1.778; p=.090). Differences of recurrences of ventricular tachyarrhythmias were attributed to higher rates of VF (11 % vs. 5 %) and electrical storm (10 % vs. 5 %). <u>Secondary endpoints:</u> Freedom from first appropriate device therapy was decreased in CKD patients (41 % vs. 30 %, log rank p=.002; HR=1.532; 95 % CI 1.163–2.018; p=.002). The difference of first appropriate device therapies was driven by increasing rates of AS (19 % vs. 11 %). No differences were seen for overall rehospitalization at 5 years in both groups, whereas CKD patients had higher rates of all-cause mortality compared to non-CKD patients (30 % vs. 14 %, p=.001; HR=2.451;95 % CI 1.707–3.519; p=.001). <u>Multivariable cox regression models:</u> There was a 1.4-fold higher risk of appropriate ICD therapy (HR=1.353; 95 % CI 1.001–1.825; p=.049) in CKD patients. Patients ≥ 74 years were associated with a 1.5-fold higher risk and patients with an LVEF < 35 % were associated with a 1.4-fold higher risk of appropriate ICD therapy. <u>PSM:</u> CKD was not associated with the the primary endpoint of recurrences of ventricular tachyarrhythmias (41 % vs. 48 %; log rank p=.111), but with the secondary endpoint of appropriate device therapies (39 % vs.

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
		▫ Sex: 178 (82 %) male ▫ Median Age: 62 (range: 44–72) years	ensure their optimal long-term survival	33 %, log rank statistical trend p=.076; HR=1.329; 95 % CI 0.965–1.823; p=.077) and AS (26 % vs. 14 %, log rank p=.001, HR=2.249; 95 % CI 1.444–3.502; p=.001).
Weidner (2019b)	Observational and retrospective registry-based analysis Secondary data analysis: Registry of Malignant Arrhythmias and SCD-Influence of Diagnostics and Interventions (RACEIT)	Total: n=592 (before matching) n=230 (after matching) Subgroups: Before matching: ▪ Age < 75: n=461 ▫ Sex: 365 (79 %) male ▪ Age ≥ 75: n=131 ▫ Sex: 106 (81 %) male After matching: ▪ Age < 75: n=115 ▫ Sex: 101 (88 %) male ▪ Age ≥ 75: n=115 ▫ Sex: 95 (83 %) male	To evaluate the impact of age on recurrences of ventricular tachyarrhythmias, devicerelated therapies, rehospitalization, and all-cause mortality at 5 years of FUP in consecutive ICD recipients with documented index episodes of ventricular tachyarrhythmias.	<u>Unmatched cohort:</u> In patients ≥ 75 years: ▪ increased rate of first overall recurrence of ventricular tachyarrhythmias (49 % vs. 43 %, log-rank p=.015; HR 1.418; 95 % CI 1.07–1.881; p=.015) ▪ decreased freedom from first appropriate device therapies (40 % vs. 33 %, log-rank p=.011; HR 1.500; 95 % CI 1.096–2.052; p=.011) ▪ decreased freedom from first appropriate ATP (33 % vs. 24 %, log-rank p=.005; HR 1.655; 95 % CI 1.164–2.354; p=.005) ▪ decreased freedom from first AS (26 % vs. 19 %, log-rank p=.009; HR 1.687; 95 % CI 1.133–2.511; p=.010) ▪ higher all-cause mortality at 5 years (31 % vs. 18 %, p=.001) <u>Subgroup analysis:</u> ▪ with LVEF < 35 %: decreased freedom from first appropriate device therapies in patients aged ≥ 75 (54 % vs. 36 %, log-rank p=.002; HR 1.931; 95 % CI 1.271–2.932; p=.002). ▪ with LVEF ≥ 35 %: no age-related difference (28 % vs. 27 %, p=.781) Even after multivariable adjustment, patients age ≥ 75 years were still associated with a 1.5-fold higher risk of first recurrences of ventricular tachyarrhythmias (HR 1.476; 95 % CI 1.085–2.008; p=.013), as well as of first appropriate ICD therapies (HR 1.569; 95 % CI 1.117–2.203; p=.009). <u>After propensity score-matching:</u> Age ≥ 75 years was still associated with decreased freedom from ventricular tachyarrhythmias (49 % vs. 42 %, log-rank p=.045; HR 1.482; 95 % CI 1.007–2.182; p=.046).

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
Willy (2019)	Single-center retrospective study, FUP Large-scale single-centre S-ICD registry	Total: n=20 Sex: 12 (60 %) male Mean Age: 40.5 (SD=11.5) years	To assess the safety and reliability of S-ICD in adult patients with CHD	▪ sensing vector at time of implantation ▫ Primary: 10 (50 %), Secondary: 8 (42 %), Alternate: 2 (8 %) ▪ Operation related S-ICD complications: 2 (10 %) ▪ Pocket haematoma: managed conservatively: 1 (5 %), requiring surgical revision: 1 (5 %) ▪ Operation time (min): 38.2 ± 7.1 ▪ Local anaesthesia preferred due to critical preoperative state: 2 (10 %) ▪ Successful defibrillation test: 19 (95 %); Defibrillation test foregone because of perioperative instability: 1 (5 %) ▪ S-ICD explantation due to infectious problems: 1 (5 %) ▪ Death during FUP: 3 (15 %), due to: ▫ congestive HF in palliative patients after deactivation of the S-ICD telemonitoring (TM): 2 (10 %) ▫ pulmonary embolism: 1 (5 %) AS: 9 AS deliveries in 3 patients, all of them terminating VT with the first shock. 2 episodes were monomorphic VTs (a cycle length of around 240ms), the others polymorphic (mean cycle length 260ms). IAS: IAS appeared in 2 patients (10 %) and could effectively be addressed by reprogramming of the S-ICD. IAS were mainly attributed to TWOS (39 %) and SVT above the discrimination zone (24 %), which could be lowered by dual-zone programming and the addition of the SMART PASS filter. Other results: Conditional shock zone was programmed at a median rate of 200 b.p.m. (range 180–220 b.p.m.), and the shock zone was programmed at a median rate of 230 b.p.m. (range 200–250 b.p.m.). Safety: No perioperative mortality or need for intensive care unit treatment occurred. In our cohort, every induced ventricular arrhythmia was terminated.

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Willy (2020a)	Single-center retrospective study, FUP Large-scale single-centre S-ICD registry	Total: n=227 Mean Age: 44.4 (SD=17.2) years Subgroups: ▪ Structural heart disease: n=144 ▫ Sex: 121 (84 %) male ▫ Mean Age: at implantation: 47.6 male ▪ Electrical/idiopathic VF: n=83 ▫ Sex: 47 (56.5 %) male ▫ Mean Age: at implantation: 38.9 years	To compare these two groups (patients with idiopathic VF or an EHD vs. patients with structural heart diseases) and try to answer the question whether there is a more or less suitable disease entity for S-ICD implantation or if performance is comparable between different patient groups	Death (n=3): 2 patients from the structural heart disease group and one patient without structural heart disease died There was no relation to the implanted S-ICD. AS: There were 19 (resp. 8) AS in 17 (resp. 7) patients in the structural heart disease group (resp. electric group) All of the shocks could terminate the ventricular arrhythmia with the first effort. IAS: The number of inadequate shocks was significantly lower with the second-generation S-ICD in the whole study population. This result is driven by patients with structural heart disease while the difference was not significant in patients with EHD or idiopathic VF. These inadequate shock rates were mainly driven by HCM patients. Revision and replacement: There were 6 cases in which surgical revision was necessary during observation time. In two patients (one with HCM, the other one with idiopathic VF) revision was necessary due to dislocation of a hypermobile lead. 4 patients required revision because of hematoma (three under anticoagulation, one with liver cirrhosis and compromised blood coagulation). There was no need for explantation because of surgical complications. There were 3 changes from S-ICDs to TV-ICDs due to bradycardia in the group of patients with structural heart disease and one change in the group without structural heart disease because of an ineffective shock. Other: Conditional shock zone was programmed at a median rate of 200 bpm (range 180–220 bpm) and the shock zone was programmed at a median rate of 230 bpm (range 200–250 bpm). During the initial implantation, the first defibrillation test was successful in about 90 % of the patients in both groups. Safety: There were very few operative revisions (about 2–3 % in both groups) without a need for explantation of the S-ICD, no perioperative mortality or postoperative intensive care unit treatment, and no wound infections requiring surgical intervention. All revision operations were due to postoperative hematoma in patients with compromised blood coagulation. Every induced ventricular arrhythmia was terminated within

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				the operation procedure. No adverse events occurred concerning intraoperative defibrillation. In 3 patients, defibrillation testing was dispensed because of a pre-existing thrombus formation.
Willy (2020b)	Single-center retrospective study, FUP Large-scale single-centre S-ICD registry	Total: n=30 Sex: 17 (57 %) male Mean Age: 40.5 (SD=15) years	To examine the safety and reliability of S-ICD in cases with borderline S-ICD indication that require a high amount of individual balancing of therapeutic options	▪ Sensing vector at time of implantation ▫ Primary: 13 (43 %), Secondary: 15 (50 %), Alternate: 2 (7 %) ▪ Operation time (min): 38± 15 ▪ Successful defibrillation test (n): 29 (97 %) ▪ Defibrillation test foregone because of LV problems: 1 (3 %) ▪ Oversensing episodes: 7 ▫ Resulting in inadequate shock delivery: 5 (71 %) ▪ Ventricular arrhythmia: 6 ▫ VF: 4 (67 %), Adequate shock delivery: 6 (100 %) ▪ S-ICD change to TV-ICD: 2 (6 %) ▫ Due to refractory oversensing: 1 (3 %), Due to need for antibradycardia pacing: 1 (3 %) ▪ Death during FUP: 0 ▪ Explantation due to personal reasons: 1 (3 %) ▪ Elective replacement due to battery depletion: 6 (20 %) ▫ Regular battery depletion: 5 (17 %), median longevity of 6.1 years (± 15 months) ▫ Premature battery depletion: 1 (3 %), after 32 months ▪ Post-traumatic stress disorder (PTSD): 1 (3 %) <u>Other:</u> Conditional shock zone was programmed at a median rate of 200 bpm (range 180–220 bpm) and the shock zone was programmed at a median rate of 230 bpm (range 200–250 bpm). In 25 of 30 patients, the first defibrillation test after intraoperative induction of VF was successful. In two patients shock was effective after changing of the shock polarity. In 2 patients, shock delivery was effective with an elevated energy of 70 Joule (initially 65 Joule) and in one patient testing was dispensed because of a LV thrombus.

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				Revision and replacement: There were no adverse events concerning the replacement procedure. In one patient, who received an S-ICD on her explicit wish because of a strong family history of SCD and a suspected catecholaminergic polymorphic VT, the system was explanted upon her request after battery depletion and no arrhythmia documentation in 6 years of FUP. Safety: No need for surgical revision, no perioperative mortality or need for intensive care unit treatment and every induced ventricular arrhythmia was terminated. No adverse events occurred concerning intraoperative defibrillation and in one patient S-ICD testing was not performed because of a LV thrombus.
Willy (2021)	Single-center retrospective study, FUP Large-scale single-center S-ICD registry	Total: n=40 Sex: 25 (63 %) male Mean Age: 40 (SD=16.3) years	to present patients from a large tertiary centre suffering from complications with an S-ICD and propose possible solutions.	▪ FUP duration (months): 50.3 ± 41 ▪ Appropriate ICD therapy: 5 (13 %) ▪ Complications due to ▫ Oversensing: 19 (48 %), Myopotentials: 5 (13 %), Need for pacing: 2 (5 %), CRT indication: 2 (5 %), Haematoma: 4 (10 %), Hypermobility: 2 (5 %), Infection: 5 (13 %), IAS due to tachycardic AF: 1 (2.5 %), Ineffective shocks: 1 (2.5 %) ▪ Operative revisions ▫ Change to a TV-ICD: 8 (20 %), Keeping the S-ICD: 4 (10 %), Explantation, no re-implantation: 3 (8 %) ▪ Scheduled GE 3 (8 %) Two patients had a history of TV-ICD explantation. One was changed to the S-ICD after multiple electrode revisions due to oversensing and pocket infection. The other one suffered from IAS due to TWOS of the DDD-ICD. None of the patients with an infected S-ICD had a history of TV-ICD implantation. 23 of the 40 patients (58 %) presented with oversensing. Of these, 18 had TWOS or P wave oversensing leading to IAS in 15/18 patients. In the remaining 5 patients, oversensing was related to myopotentials resulting in IAS. 3 of these patients performed physical activity (yoga, sit-ups) and thereby induced oversensing episodes. In another patient with non-compaction CM, 2 IAS occurred due to AF with rapid ventricularresponse and the ICD system was, therefore, changed to a transvenous system to enhance possibilities for discrimination of arrhythmia origin.

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				In two patients, the S-ICD was explanted because of the need for antibradycardia stimulation. Both patients suffered from SSS. Two further patients, of whom one patient also suffered from oversensing, underwent re-operation because of an emerging indication for CRT. In a young patient with short-coupled variant of torsade de pointes ineffective shocks occurred during electrical storm despite effective ICD testing during implantation procedure. While in patients with TWOS , re-programming was effective in preventing further episodes of oversensing, e. g. by changing of the sensing vector (13/18 patients), in all other types of complications revisions were necessary. Most complications occurred in patients with HCM (12) and EHD/idiopathic VF (8/4 resp.).
Zartner (2021a)	Retrospective audit study Quantitative, primary data	Total: n=47 Mean Age: at time of the first CIED implantation: 9.4 (range: 0.05–29.3) years at latest FUP: 17.6 (range: 0.28–35.6) years	To review the data of our patients with Fontan circulation and a CIED with regard to lifetime, lead material, and lead parameters during the last 18 years.	Electronic devices: After a mean lifespan of 0.92–11.48 years (mean 6.59 years, SD 2.54 years) 23 CIED were replaced because of battery depletion with a small sub xiphoidal incision only. 13 CIEDs were replaced after 0.42–6.31 years (mean 3.4 years, SD 1.96 years) through a thoracotomy with a necessary modification of at least one lead. 47 CIED are still active with an actual lifetime of 0.12–10.90 years (mean 4.42 years, SD 2.89 years). These consist of one atrial (AAI), two ventricular (VVI), 27 double chambers (DDD), 13 CRT-P, and four CRT-D systems. In 3 patients with CRT-P, one ventricular lead was switched off after 1.4, 2, and 2.1 years because the pacing threshold had increased to more than 3 V, to save for battery life. Leads: A total of 123 epimyocardial electrodes and four shock coil finger leads were implanted of which 99 and the 4 finger leads are still active. The lifetime of all pacing leads (PL) ranges from 0.32–18.2 years (mean 6.99 years, SD 4.3 years). The lifespan of the 99 still active PL ranges from 0.32–18.2 years (mean 7.46 years, SD 4.39 years). The lifetime of the 24 already explanted or inactivated leads ranges from 1.1 to 14.32 years (mean 5 years, SD 3.32 years). The RV PL show the fastest decrease but 80 % were still active after 7 years, as were 81 % of all leads after 10 years. Lead Types: The average changes of the lead parameters between implantation and last measurement were for the pacing threshold+0.18 V (SD 0.89 V, p=.0305), pacing impedance −56 Ω (SD 352 Ω, p=.0793) and sensing amplitude −0.96 mV (SD 4.56 mV, p=.0214). The relative increase of the pacing threshold was higher for

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				the ventricular leads (RV+0.31 V, LV+0.39 V) than for the atrial leads (–0.08 V). There was no difference between the screw-in and the buttoned leads, except for the lead impedance, which differed significantly between the time of implantation (p=.0001) and at latest FUP (p=.0003). The initial mean pacing threshold of the already inactivated leads and their subgroups was above 1.64 V, and revealed a significant difference in comparison to the pacing thresholds of all leads (1.27 V with p=.0005) and to the leads still active (1.17 V with p=.00004). Both types of PL used are bipolar by design. During the observation period, the sensing polarity of 11 leads was changed from bipolar to unipolar, and for pacing, 20 electrodes were changed to unipolar. Two patients died 2 and 4 years after their latest PM revision with a known history of frequent ventricular extrasystoles and ventricular runs at the age of 21 and 22 years. Both had refused an upgrade to a CRT-D. A post mortem interrogation of the devices could not be performed, so the cause of death remains unknown. The stimulation threshold of the RV leads in two DDD CIED exceeded 5 V, and led to an early system revision with an upgrade to a CRT-P system.
Zartner (2021b)	Single-center retrospective data analysis Quantitative, primary data	Total: n=48 (n=34 Biotronik CIED, n=14 Medtronic system) Mean Age: ▪ at latest cardiac surgery: 4 (SD=3.3, range: 0.3–18) years ▪ at CIED implantation: 9.6 (SD=8.6, range: 0.05–29) years ▪ at latest FUP: 18 (SD=9) years	To determine whether the data regularly transmitted by two TM systems can be reliably interpreted, are clinically relevant, and be used for decision-making.	313 clinically relevant event message, such as atrial tachycardia, atrial flutter or AF, VT, high rates of premature ventricular contraction, elevated mean heart rate, and high or increasing thoracic impedance were received from 18 patients. Combined with information obtained from the daily arriving statistical data followed online, ECG, Holter ECG, and reported clinical symptoms led to therapeutic changes initiated in 21 patients. These consisted of initiating or modifying the antiarrhythmic therapy for atrial flutter (n=2), atrial tachycardia (n=5), and high rate of premature ventricular contraction (n=1). Messages of high pacing thresholds led to cortisone therapy in three patients. 10 patients showed signs of HF with reduced patients' activity, elevated mean heart rates, and increasing thoracic impedance, which led to adaptation of the individual diuretic medication. These changes were also monitored via TM in the further course. For the TM-HM system, we received 3.9 (SD 3.3) event message /patient/month and 1.4 (SD 1.7) recordings/patient/month, and for the TM-CareLink system, 1.9 (SD 2.7) event message/patient/month and 1.1 (SD 1.8) recordings/patient/month. Shock efficacy of the 3 epimyocardial CRT-D systems was tested during the implantation procedure, but so far none of the patients suffered from VT requiring a therapeutic shock. The shock impedance is part of the SD and reported daily by the TM-HM.

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				Comparing the two groups of cortisone-coated PL used, there is, in regard to the sensing amplitude and the pacing threshold, a significant (p=.05) but small advantage for the Medtronic 4968 compared with the Greatbatch 1084-T lead independent of the CIED they are connected to.
Ziegelhoeffer (2020)	Retrospective design, single center, FUP Secondary data analysis	Total: n=328 Subgroups: ▪ Paroxysmal atrial fibrillation (px-AF): n=132 ▫ Sex: 109 (82.6 %) male ▫ Age: 67.4 (range: 39–87) years ▪ Persistent atrial fibrillation (ps-AF): n=70 ▫ Sex: 57 (81.4 %) male ▫ Age: 67.5 (range: 19–83) years ▪ Long-standing persistent atrial fibrillation (lp-AF): n=126 ▫ Sex: 95 (75.4 %) male ▫ Age: 68.59 (range: 45–86) years	To provide decision guidance, we analyzed the outcome of CRT patients with AF. In particular, we investigated the course of an atrial arrhythmia after CRT-device implantation with the objective of gaining adequate information about the persistence of AF or the probability of SR conversion under CRT.	When dividing the patients according to AF, 130 (98.5 %) out of 132 in the px-AF, 66 (94.3 %) out of 70 in the ps-AF, and 81 (64.3 %) out of 126 patients in the lp-AF group received initially an atrial lead. All patients initially received transvenous LV-lead implantation. During the initial device and lead implantations, we did not observe any major complications. Re-interventions: 30 re-interventions had to be carried out during the 5-year observation period, which corresponds to 9.1 % of the entire cohort. px-AF: 12 re-interventions (9.1 %). 5 LV, 1 RV and 1 atrial lead need to be revised due to an increase in pacing threshold, a decrease of sensing, or phrenic nerve stimulation. 5 patients were initially pre- and intraoperatively categorized as lp-AF and, therefore, the atrial lead implantation was primarily omitted. However, these patients were noticed postoperatively with an SR and, therefore, they obtain an atrial lead in a second intervention. ps-AF: 9 re-interventions (12.9 %). From these, 2 left and five RV leads were revised due to an increase in pacing threshold, a decrease of sensing, or phrenic nerve stimulation. In 2 cases, stable SR was observed in repeated routine ambulatory FUP visits and, therefore, an atrial lead was later implanted in a second intervention. lp-AF: 9 re-interventions (7.1 %). LV lead malfunction was responsible for this in 7 cases. In 2 lp-AF patients, meanwhile, stable SR was diagnosed in the FUP and consequently, a second intervention for de nova implantation of the atrial electrode was carried out. Again, also during the re-surgery, we did not observe any major complications leading to additional intervention.

Referenz (Jahr)	Design/Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung	Zentrale Ergebnisse
				Finally, 5 device exchanges (2 in px-AF, 0 in ps-AF, 3 in lp-AF) had to be carried out due to elective replacement interval within the 5-year FUP period.

AB = atrial arrhythmia burden (atriale Arrhythmielast); AF = atrial fibrillation (Vorhofflimmern); AG = active group (aktive Gruppe); AS = appropriate shock (angemessener Schock); ASA = American Society of Anesthesiologists; ATP = antitachycardia pacing (Antitachykardie-Pacing); AV = atrioventricular (atrioventrikulär); BMI = Body Mass Index ; BP = biventricular pacing (biventrikuläres Pacing); CAD = coronary artery disease (koronare Herzkrankheit); ccTGA = congenitally corrected transposition of the great arteries (kongenital korrigierte Transposition der großen Gefäße); CDI = cardiac device infections (Infektion des kardialen Implantats); CG = control group (Kontrollgruppe); cGycm = centigray-centimetres ; CHD = congenital heart disease (angeborene Herzerkrankung); CI = confidence interval (Konfidenzintervall); CIED = Cardiac Implantable Electric Device (kardiale elektronische Implantate); CKD = chronic kidney disease (chronische Nierenerkrankung); CM = cardiomyopathy (Kardiomyopathie); CP = conventional programming (konventionelle Programmierung); CRP = C reactive protein (C-reaktives Protein); CRT = Cardiac resynchronization therapy (kardiale Resynchronisationstherapie); CRT-D = biventricular defibrillators (biventrikuläre Defibrillatoren); CRT-P = biventricular pacemakers (biventrikuläre Schrittmacher); CS = coronary sinus (Koronarvenensinus); CVC = cephalic vein cut-down (Cutdown der Vena cephalica); DAP = dose-area product (Dosisflächenprodukt); DFT = defibrillation threshold (Defibrillationsschwelle); ECG = Electro cardiogram (Elektrokardiogramm); EHD = electrical heart disease; EF = Ejection fraction (Ejektionsfraktion); EGM = intracardiac electograms (Elektrogramm); EMGP = ergometry guided-programming (Ergometrie-geführte-Programmierung); FDDP = Fully digital data processing (vollständig digitale Datenverarbeitung); FUP = follow-up; GE = generator exchange (Aggregatwechsel); GFR = glomerular filtration rate (glomeruläre Filtrationsrate); HCM = hypertrophic cardiomyopathy (hypertrophe Kardiomyopathie); HF = heart failure (Herzinsuffizienz); HM = Home Monitoring (Heimüberwachungssystem); HR = hazard ratio; HTX = heart transplantation (Herztransplantation); IAS = inappropriate shocks (unangemessene Schocks); ICD = implantable cardioverter-defibrillator (implantierbarer Kardioverter-Defibrillator); ICM = ischemic cardiomyopathy (ischämische Kardiomyopathie); ID = Iron deficiency (Eisenmangel); IQR = interquartile range (Interquartilsabstand); LBBB = left bundle branch block (Linksschenkelblock); lp-AF = Long-standing persistent atrial fibrillation (langanhaltendes persistierendes Vorhofflimmern); LV = leftventricular (linksventrikulär); LVAD = left ventricular assist device (linksventrikuläres Unterstützungssystem); LVD = left ventricular dysfunction (linksventrikuläre Dysfunktion); LVEF = Left ventricular ejection fraction (linksventrikuläre Ejektionsfraktion); MACCE = Major adverse and cerebrovascular events (schwere kardiale und zerebrovaskuläre Komplikationen); MPP = multipoint pacing (MultiPoint-Pacing); NICM = non-ischemic cardiomyopathy (nicht-ischämische Kardiomyopathie); NP = novel programming (neuartige Programmierung); NYHA = New York Heart Association ; OR = odds ratio; PICM = pacemaker induced cardiomyopathy (Schrittmacher-induzierte Kardiomyopathie); PL = pacing lead (Schrittmachersonde); PM = pacemaker (Schrittmacher); PPM = permanent pacemaker (permanente Schrittmacherimplantation); ps-AF = Persistent atrial fibrillation (persistierendes Vorhofflimmern); PSM = propensity score matching; px-AF = Paroxysmal atrial fibrillation (paroxysmales Vorhofflimmern); QRSd = QRS duration (QRS-Dauer); RBBB = right bundle branch block (Rechtsschenkelblock); RM = remote monitoring (Fernüberwachung); RV = right ventricular (rechtsventrikulär); SCD = sudden cardiac death (plötzlicher Herztod); SD = Standard deviation (Standardabweichung); S-ICD = Subcutaneous ICD (subkutaner ICD); SP = subclavian puncture (Subclavia-Punktion); SR = sinus rhythm (Sinus-Rhythmus); SSS = sick sinus syndrome (Sick-Sinus-Syndrom); SVT = supraventricular

tachycardia (supraventrikuläre Tachykardie); TLE = transvenous lead extraction (transvenöse Sondenextraktion); TM = telemonitoring (Telemonitoring); TV-ICD = transvenous ICD (transvenöser ICD); TWOS = T-wave oversensing (T-Wellen-Oversensing); VF = ventricular fibrillation (Herzkammerflimmern); VT = ventricular tachycardia (ventrikuläre Tachykardie).

Anhang B.3.2 Patientenperspektive

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
Auld (2020) USA	Secondary analysis of data from a randomized clinical trial	Total: n=301 Sex: 222 male, 79 female Mean Age: 64.14 ± 11.9 years Subgroups: ▪ 1° prevention without cardiac resynchronization therapy (CRT): n=100 ▫ Sex: 23 (23 %) female ▫ Mean Age: 61.1 ± 13.7 years ▪ 1° prevention with CRT: n=78 ▫ Sex: 29 (37.2 %) female ▫ Mean Age: 70.03 ± 8.87 years ▪ 2° prevention after cardiac arrest: n=66 ▫ Sex: 14 (21.2 %) female ▫ Mean Age: 62.32 ± 10.64 years ▪ 2° prevention for other reasons: n=57 ▫ Sex: 13 (22.8 %) female	to examine the response to intervention for patients with an initial implantable cardioverter defibrillator (ICD) by reasons for primary versus secondary ICD indication. Intervention: Patient-only (P-only) : (1) information booklet with strategies for health recovery after ICD implant, (2) nurse telephone support (3) pager access to a study nurse 24 h/7 (4) an informational video provided by the device company. Patient plus partner (P+P): same elements plus integration of partner and separate phone group for partner with different content (1) partner care of the ICD patient, (2) partner self-care, (3) relationship impact, (4) ICD components and planning for the	Physical health status: For the entire sample, physical health was relatively poor at baseline (physical composite score (PCS)=36.22 ± 10.22), improved significantly at 3 months (41.20 ± 11.10, p<.001) with this increase sustained at 12 months (41.26 ± 11.50; p<.001). All groups showed improvement in physical health status, but the rates of change differed by group. Mental health status: Baseline mental health in the full sample was about average for the U.S. population (51.67 ± 10.93). Mental health status improved significantly at 3 months (53.71 ± 9.25, p<.001). Patients receiving an ICD for 2° prevention after cardiac arrest, were the only group to have a significant rate of improvement in mental health status. Physical symptoms: For the full sample, physical symptom frequency declined significantly from baseline (29.16 ± 20.65) to 3 months (26.13 ± 22.35, p<.001) and remained significantly lower than baseline at 12 months (27.63 ± 23.47; p=.024). For the 2° Cardiac Arrest group, the rate of improvement in physical symptom frequency differed significantly in magnitude. Depression: Baseline depressive symptoms were mild for the sample as a whole (5.11 ± 4.52). Depressive symptoms significantly decreased at 3 months (3.85 ± 4.14, p<.001) and remained significantly lower than base line at 12 months (4.09 ± 4.41, p<.001). Depressive symptoms improved significantly in the 2° Cardiac Arrest group compared to 1° CRT group. Anxiety: For the entire sample, anxiety was mild at baseline (31.10 ± 10.58), decreased significantly at 3 months (28.23 ± 9.76, p<.00 1), and remained significantly lower than baseline at 12 months (29.19 ± 10.76, p<.001).

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		▫ Mean Age: 63.40 ± 10.76 years	future, and (5) open-ended topics and questions	
Barisone (2022) USA, Sweden, Norway, Canada, Spain, Italy, Japan, Iran, Turkey and Hong Kong	Systematic review and meta-synthesis of qualitative studies	Total: Studies: n=24 Patients: n=394 Sex: 290 male, 104 female	To explore and synthesize the results of qualitative studies addressing the experiences of patients with an ICD	<u>Fear and insecurity:</u> a) Acceptance of ICD implantation, because of protection from sudden death. b) Report of multiple problems with physical and psychological adaptation (slow process; feelings of insecurity) to their new condition. c) recurrent feelings of vulnerability, uncertainty and anxiety by fear of shock which limited patient's daily activities d) Fears became source of frustration for some patients, generating a sense of overprotection in their families <u>Need for information:</u> a) Need for more information and support from health professionals, regular follow-ups (FUP), monitoring. to prevent feeling abandoned after discharge b) Need for more 'useful' information upon discharge, (specially concerning the ICD, any precautions in daily activities, any beliefs about ICD). c) Some of the information was more about technical aspects than adapting to the new condition. <u>New impacts on life:</u> a) Concerns about consequences on their lives, limitations on daily activites and potential loss of autonomy for some patients b) Sense of limitation in carrying out some activities due to the fear of a potential ICD-shock <u>Living with ICD shocks:</u> a) Possibility of sudden ICD-shock was main source of fear and stress b) Experience of a shock was described as a violent, dramatic event <u>Gender differences:</u>

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				a) Women tended to accept and familiarize themselves with the ICD better than men, expressing a more constructive attitude towards it b) For male patients, it was essential to maintain their masculine image, even if their device was invisible to others. They appeared more concerned than women about the effects on their physical prowess.
Baskar (2018) USA	Cross-sectional	Total: n=538 Sex: 242 (46 %) female Mean Age: 53 ± 16 years Subgroups: ▪ Age at diagnosis < 18 years: n=70 ▫ Sex: 30 (44 %) female ▫ Age: 29 ± 13 years ▪ Age at diagnosis > 18 years: n=468 ▫ Sex: 212 (46 %) female ▫ Mean Age: 56 ± 12 years	To address the complex issues surrounding hypertrophic cardiomyopathy patients' understanding of their disease and interventions as well as their satisfaction with care.	a) Although most patients had discussions with their physicians about sudden cardiac death (SCD)/sudden cardiac arrest (SCA) and about ICDs, those with ICD were more likely to have discussed ICD management. b) Patients without an ICD discussion had less understanding of the utility of an ICD in hypertrophic cardiomyopathy. c) Among patients with ICD (n=356), 19 patients (5.3 %) (strongly) disagreed that benefits of an ICD outweighed risk and deleterious effects of lifestyle in hypertrophic cardiomyopathy. d) Most patients in each group discussed SCA and the groups had a similar time duration of ICD placement from the time of discussion and recommendation with the physician. e) Patient satisfaction with physician's explanation for the need for ICD was the only statistically significant group difference in bivariate analysis. Half of the patients who felt strongly against the benefits of ICD were dissatisfied with the physician's explanation for its need. f) On logistic regression analysis, satisfaction with physician's explanation for the need for ICD (odds ratio (OR) 0.12, 95 % CI; 0.04, 0.36], p=.0004) and a history of a problem with lead replacement (OR 4.0, 95 % CI [1.3, 12.3], p=.01) were significant in differentiating patients who did or did not feel that the benefits outweighed the complications in ICD placement.
Bergmann (2020) Germany	Cross-sectional	Total: n=548 Sex: 314 (57.3 %) male, 222 (40.5 %) female Age: ▪ 21 to 30: n=2 (0.4 %)	To examine patient satisfaction and influencing factors of inpatients alter cardiac pacemaker (PM) or ICD implantation.	Most of the patients assessed the length of stay as appropriate (67.7 %). A minority of study participants reported complications subsequent to discharge (8.8 %). <u>Descriptive statistics:</u> a) Most of the respondents rated overall satisfaction as excellent (26.5 %) or good (59.9 %). Minority rated overall satisfaction as fair (8.4 %), sufficient (1.1 %), poor (0.9 %), very poor (0.4 %)

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		▪ 31 to 40: n=4 (0.7 %) ▪ 41 to 50: n=3 (0.5 %) ▪ 51 to 60: n=22 (4 %) ▪ 61 to 70: n=88 (16.1 %) ▪ 71 to 80: n=233 (42.5 %) ▪ >80: n=196 (35.8 %)		b) Participants were most satisfied with kindness of physicians and nursing staff (grouped median 1.51, resp. 1.56) c) Patients rated the preparation for the period after discharge (2.08) and information about medication (2.10) lowest <u>Bivariate analysis:</u> a) Patients were most satisfied if they judged the length of stay appropriate and most dissatisfied if they assessed it as too short b) Patients without complications after discharge were more satisfied than patients with complications (such as pain, infections, bleeding, dyspnea) <u>Multivariate analysis:</u> a) Being satisfied with treatment outcome multiplies by 11.51 the probability of the patient being satisfied with the hospitalization b) Predictors of overall patient satisfaction: individualized medical care by physicians (OR=5.04), kindness of nurses (OR=4.83) organization of procedures and operations (OR=4.45), kindness of the physicians (OR=3.46), and preparation for discharge (OR=2.69)
Carroll (2018) Canada	Qualitative substudy within a randomized controlled trial Semi-structured interviews	Total: n=16 Sex: 10 male, 6 female Age: range 47–87 years Subgroups: ▪ Patient decision aid (PDA) n=10 ▪ Usual Care (UC) n=6 ▪ ICD implantation n=10 (7 PDA and 3 UC) ▪ ICD declined n=3 (2 PDA and 1 UC)	To investigate patients' understanding of their values in the context of considering the risks/benefits of receiving an ICD	<u>Factors that mattered directly in ICD decision making</u> <u>Good quality of life (QOL):</u> a) Concerns about losing their driver's license b) Worrying about being a burden c) ICD facilitated greater enjoyment of life and provided "back-up" or peace of mind <u>Family's views:</u> a) Family played a significant role in the decision making process (eg, choosing the device to allay family anxieties) (For almost all participants) b) Family was an important source of emotional and informational support <u>Information about the ICD:</u>

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		▪ Decision deferred n=3 (1 PDA and 2 UC)		a) Most participants valued information about the ICD's function b) Information acquired through books, videos, Internet, conversations with doctors/family c) For PDA recipients, risks, benefits and background information were important <u>Control over decision and medical authority:</u> a) Control was of great importance (for a small majority) b) Some valued the doctor's expertise above all else c) Some thought of it as a shared decision making (SDM), made in consultation with their doctor, but taking individual circumstances into account <u>Factors that mattered indirectly in ICD decision making</u> <u>Changing values:</u> a) Decision would be different if made 20 years ago or 20 years in the future b) Emotional state had impact on the decision making c) Individuals' health histories had impact on decision making
Carroll (2020) USA	Randomized controlled trial + Program Medical details regarding the participant's ICD were collected via self-report and confirmed by the medical record	Total: n=21 Sex: 38 % female Age: 62 years old on average (standard deviation (SD)=9 years) Subgroups: ▪ Quality of Life Therapy (QOLT) intervention n=11 ▪ Heart Healthy Education (HHE) n=10	Evaluate the feasibility and acceptability of a positive psychology intervention (QOLT), compared to a HHE control, among ICD patients <u>Intervention:</u> Baseline responses on QOLI used to guide the intervention targets; only individual therapy sessions (in-person/ telephone) session content: (1) review	<u>Treatment structure and content:</u> a) Of the 16 topic areas, Health was the most commonly discussed (mean=5.5 sessions, SD=3.1), and along with Goals and Values (mean=4.2 sessions, SD=2.6) was the only topic that was discussed at least once by each participant. The five topics that were least discussed were Money, Creativity, Community, Neighborhood, and Learning <u>Treatment acceptability:</u> a) On the Program Evaluation Survey, a greater proportion of QOLT participants (62.5 %) rated their sessions as "very" helpful compared to HHE participants (10 %; p=.019), though all participants across groups rated their sessions as helpful b) Participants were interested in the intervention because they viewed it as a useful resource to them, and because it would allow them to make the changes they wanted to make <u>QOLT outcomes:</u>

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			of previous week's content and homework, (2) new material and/or techniques, (3) relaxation exercise, and (4) discussion of new content, homework assignment and barriers to treatment adherence. HHE control: attention-matched control, to provide participants with information about health and lifestyle issues related to cardiovascular disease. No therapeutic techniques or instructions.	a) Nearly all QOLT participants (87.5 %) reported improved mental health whereas nearly all HHE participants (90 %) reported improved physical health (p=.001) b) Over the 12 weeks of the intervention, QOLT participants' happiness levels increased modestly with average scores of 5.6 (SD=1.6) at Session 1 to 6.1 (SD=1.8) at Session 12 (d=0.31) b) QOLT participants' self-reported life satisfaction across various domains of functioning increased, with QOLT standard scores that placed them in the low average range at baseline (T=44, SD=12) and to average at end-of-treatment (T=50, SD=10; d=1.02) c) HHE participants also evidenced a smaller but moderate increase in QOLI scores from baseline (T=49, SD=12) through end-of-treatment (T=55, SD=12; d=0.84)
Christie (2021) Australia	Qualitative study Semi-structured interviews	Total: n=10 (Six out of ten participants had a family member present during the interview) Sex: 8 male, 2 female Age: 35–78 years	To understand the educational experiences and needs of adult patients with ICDs within a metropolitan tertiary hospital in Queensland.	<u>Understanding the information needs of patients:</u> a) Information covered only institutional information, but not to living with the device b) Information about (S-)ICD and the insertion procedure provided by the electrophysiology consultant was useful for addressing needs c) A range of information was given, but not all were understood d) Local doctors were not familiar with the device functions, causing participants anxiety around their continuity of care <u>Psychological aspects:</u> a) since implantation patients experienced feelings of depression b) 9 participants made reference to understanding the necessity of the device and their deep thankfulness of being alive

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				Fearful of the ICD shock: a) Lack of understanding of what to expect when the device delivered an electrical charge b) Education received was not provided in a sensitive manner to prepare patients sufficiently Physical concerns: a) Physical concerns post-ICD insertion (limitations in their daily activities and clothing concerns) persisted relatively shortly b) Participants highlighted some physical restrictions (lifting arm, playing sports, learning to use a phone with other hand) c) Some had felt forced to stop working when illness event occurred (for example because of the physical nature of their work) Importance of family inclusion: a) Experience of needing an (S-)ICD for life-threatening health condition makes some participants and their families feel vulnerable b) Confusion and feelings of anxiety when information was not communicated effectively (one family member) c) Feeling left out of the conversations because of not being involved with the education session and not understanding the information (Participants' wives, in particular)
Daeschler (2017) USA	Cross-sectional	Total: n=60 Sex: 42 (70 %) male Mean Age: 59 (range 23–89)	To explore patient perspectives on ICD or CRT-defibrillator (CRT-D) deactivation, including unilateral deactivation.	a) A small majority of the respondents had an advanced directive (only one respondent's advance directive (AD) mentioned what they would like done with their ICD or CRT-D at the end of his/her life,) b) 15 % of respondents had thought about what they would like done with their ICD or CRT-D if they were to lose decision-making capacity and develop a serious illness from which they were not expected to recover c) 3 % had ever discussed with a physician what should be done with their device d) Majority of respondents (76.7 %, n=46) stated that deactivation of ICD shocking function in accordance with a patient's wishes was not a form of physician-assisted suicide

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				e) Majority (65 %, n=39) indicated that deactivation of ICD shocking function in a patient with a pre-existing do not resuscitate order was right decision and that the CIED should be turned off f) A majority (60 %, n=36) indicated that they thought two physicians, who believed treatment to be futile, should not unilaterally deactivate the device against a patient's wishes g) A large majority responded that it was not ethical or moral for the physicians to deactivate a device against the patient's wishes, and 6.6 % said that their answer would depend on the patient's age, prognosis, decision-making capacity, and/or QOL
Daley (2017) USA	Qualitative, exploratory study with a 3-month technology trial Semistructured, in-depth interviews	Total: n=21 Sex: 76 % male Mean Age: 67 (SD=14, range 36–86)	To explore: 1. Patients' attitudes and perceptions about receiving ICD data through a personal health record. 2. Insights about how to present the data in a meaningful way.	<u>ICD-Related Questions and Concerns:</u> a) When participants spoke about their device, over one-third (n=8) referenced it to (not) receiving shocks and/or what it might feel like b) They had questions regarding physical sensations with their device or heart rhythm and some were concerned not knowing what type of activity might cause the ICD to fire <u>Perceptions and Understanding about remote monitoring (RM):</u> a) 9 participants appreciated RM: low effort, efficiency and reduction of number of in-office checks b) 10 participants stated perceiving RM as reassuring c) Although participants felt reassured by RM, some (n=5) demonstrated a general lack of understanding about how RM works and how often the transmissions occur <u>Reasons for Using the personal health record:</u> a) Participants expressed different reasons for logging into the personal health record that provided value to them, whether it was to satisfy interest, knowledge, or the potential to act upon the information <u>Insufficiencies of the ICD Data Summary:</u> a) 8 patients provided feedback that the volume of information provided in "View Additional Data" was overwhelming. The widget display with fewer information was more effective

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				b)10 participants shared explicit interest and/or appreciation for having more data as compared with the standard letter
Doolan-Noble (2021) New Zealand	Qualitative study Semi-structured interviews with ICD recipients and their partners	Total: n=23 Sex: 1 female Age: range 57–89 years Subgroups: ▪ ICD recipients: n=14 ▪ partners/carers/whānau (family): n=9	To answer the following questions: 'Does living rurally impact the ICD recipient experience and that of their partners?' and 'Can understanding their experiences inform best practice care for those living rurally with an ICD?'	<u>Recipient/Spouse/Carer Dyad:</u> a) Within the dyad the health and wellbeing of one member was prioritised over the other, resulting in potential unmet healthcare needs of spouses and other whānau/carers b) Almost total absence of any reference to the health and wellbeing needs of spouses or other whānau/carers <u>Recipient/Spouse Challenges post implantation:</u> a) Challenges included advance care planning and a conversation about deactivation of the ICD, the absence of a support group, healthcare experiences and technology. b) Setup of a RM unit could be a challenge for old participants, in part exacerbated by lack of information. c) Fewer interactions with the health professionals was not always viewed favourably. <u>Recipient Life with an ICD:</u> a) Overwhelming agreement by both recipients and their partners that an ICD should be viewed as an enabling device b) Emotions: More anxious, changing moods, more emotional than ever used to be c) Unmet information needs: No Information about driving d) Restrictions: Not allowed to drive or use technical equipment (chainsaw) for self-supply
Dougherty (2019) USA	2-group randomized controlled trial	Total: n=602 Sex: 300 male, 302 female Mean Age: patients: 64.14± 11.9 (range: 26–93 years); partners: 62.46 :±: 12.4 years (range 28–91 years)	To report the primary outcomes of the patient plus partner randomized controlled trial. <u>Intervention:</u> The patient intervention, consisting of educational	<u>Patient physical function:</u> a) Frequency of self-reported Patient concerns assessment (PCA) symptoms fell significantly between intervention groups at 12 months, with patients in the P+ P group reporting fewer symptoms than in the P-only group (p=.02) b) Fear of dying and distress reduced in both groups over time

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		Subgroups: ▪ P-only group: n=151 ▫ Sex: 106 (70.2 %) male, 45 (29.8 %) female ▫ Mean Age: 65.01 ± 11.26 years ▪ P+P group: n=150 ▫ Sex: 116 (77.3 %) male, 34 (22.7 %) female ▫ Mean Age: 63.26 ± 12.50 years	materials, nurse-delivered telephone coaching, videotape demonstrations, and access to a nurse via a 24/7 pager, was implemented in both groups. P+P also incorporated partner participation	c) Patients in both intervention groups reported lower levels of physical health (PCS) than of mental health (mental composite score [MCS]) at study enrollment and throughout 12 months. <u>Partner physical function:</u> a) Partners in both intervention groups reported lower levels of physical health than of mental health throughout the study. b) Number of physical symptoms reported by partners was lower than reported by patients. Overall general health of partners was better than patient's (from enrollment to final FUP) <u>Psychological adjustment:</u> a) Patient anxiety (STAI) declined over time, with no significant group differences b) For P+ P vs P only, patient depression severity (p=.006 and p=.01, respectively) were lower at 12 months c) Partner anxiety and depression remained relatively stable across 12 months, without significant group differences <u>Patient health care utilization:</u> a) Hospitalization rate in both groups was 7.9 % in the first month post-ICD implantation, 20.6 % at 1–3 months, 23.3 % at 3–6 months, and 36.9 % at 6–12 months b) Total hospital days in both groups ranging from 2 to 6 days c) Patients in the P+ P group had fewer outpatient visits over the course of the trial than those in the P-only group (2.54 vs 3.09; p=.03), which were most often ICD related for both group <u>ICD indication: primary vs secondary prevention:</u> a) Outcomes at 3 months showed that patients receiving an ICD for secondary prevention had greater reductions in symptoms (PCA; F=7.70; p=.006), better physical health (SF-36 PCS; F=8.91; p=.001), and greater ICD knowledge (F=5.02; p=.02)
Ford (2019) USA	Web-based psychosocial intervention +	Total: n=46 Sex: 23 (51.1 %) female	To develop, employ, and evaluate a novel, Web-	a) Post-intervention scores on the Posttraumatic Stress Disorder Check List (mean=37.59, SD=13.02) were significantly lower than pre-intervention scores (mean=46, SD=9.65), t(16)=2.24, p=.04, with a large effect size, d=0.55.

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	Pretest and posttest measurement standardized	Mean Age: 34.39 (±11.04) years	based, cognitive-behavioral intervention specifically designed for ICD patients with Post-traumatic stress disorder symptoms.	b) Significant reductions in hyper arousal (p=.03) and avoidance (p=.05). c) Significant and large increases in device acceptance from before to after intervention d) Out of 17 participants included in final analysis, 5 participants (29 %) had reliable improvement on the Posttraumatic Stress Disorder Check List, all but 4 had reductions in scores and 0 had a statistically reliable increase in symptoms e) 9 (53 %) participants had reported symptom reduction on the Posttraumatic Stress Disorder Check List, which would be considered clinically meaningful. f) All participants had increased patient acceptance and 9 (53 %) had reliable increases in device acceptance, as measured by the Florida Patient Acceptance Survey (FPAS). g) 7 (41 %) participants' had reliable reductions in shock anxiety following intervention. h) 7 (41 %) patients had statistically reliable reductions in depression score.
Forman (2018) Canada	Qualitative study	Total: n=15 Sex: 13 male, 2 female Median Age: 42 years (range: 20–68)	To explore patients' experiences of living with a subcutaneous ICD (S-ICD).	Influences on decision-making a) Being told to be suitable or to met parameters to have an S-ICD b) Unable to articulate an understanding of their implant indications c) Participants had a high regard for physician expertise Unmet education needs: a) Limited information about living with the S-ICD (impact on daily life, physical activity, driving restrictions, device battery-life, post-operative pain, education specific to underlying health condition) Physical impact: a) Feeling of discomfort and post-operative pain (resolved <4 weeks) b) General awareness of physical presence of CIED and was felt during many routine activities c) With a relatively young median age (42 years), returning to pre-procedure levels of participation in physical activities was a prominent subtheme Psychological impact

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				a) Anxiety was related to uncertainty of making the right decision b) Those who had previously experienced cardiac arrest worried about the impact on family members, recovery and potential for negative outcomes if they had another cardiac arrest c) Believing that others thought differently about them and the challenges they faced involved their ability to integrate the device into one's self d) the acceptance of the device and adaptation to their new body image was an ongoing process for participants Recommendations a) Individualized support needs (e.g. education, psychosocial) were not always considered and integrated into care b) Some participants felt that they did not receive adequate information prior to the implant or enough time to make an informed decision c) Some recommended more information regarding the experiences of living with the device d) Improved access to psychological support was also recommended
Fowler (2018) USA	Mixed-methods study Semi-strcutured interviews with patients and their relatives	Total: n=30 Subgroups: ▪ Patients: n=15 (9 PM, 6 ICD) ▫ Sex: 9 (60 %) male, 6 (40 %) female ▫ Cognitive status of patient: – n=8 (53.3 %) Alzheimer disease	To compare the decision-making experience of a cohort of patients with and without cognitive impairment who received a cardiac device as well as a family member who was involved in the decision to get a cardiac device.	The limited influence of the patient's cognitive status in medical decision making: a) In all cases but one, it was unclear if the physician was aware of the patient's MCI or Alzheimer's disease or if they believed that it was an important factor to be discussed. Only one out of 10 patients with cognitive impairment had a diagnosis or notation in the medical record. b) Because the patients and family members largely did not bring it up, there was no discussion about the impact of the device on prolonging life, improving QOL, or risks post-implantation in the setting of also having MCI or Alzheimer's disease. c) None of the patients with cognitive impairment or their family members reported discussing their cognitive status with the physician implanting the device or its role in the decision to get a device. The Physician's Recommendation:

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		– n=2 (13.3 %) mild cognitive impairment (MCI) – n=5 (33.3 %) not impaired ▪ Caregivers: n=15 (n=8 (53 %) spouse and n=7 (47 %) adult children) ▫ Sex: 3 (20 %) male, 12 (80 %) female		a) Many family members and patients believed that if the physician says the patient needs it, there are no other options. b) Family members reported that physician strongly advised that the patient get the device c) 5 stated that did what the physician recommended without discussion and 10 reported involvement in the decision-making <u>Decision Regret:</u> a) Some patients reflected that it was not a "good decision" b) Some family members of patients with MCI reported reflecting on whether getting the device was a "good decision" <u>Not a Decision:</u> a) An overwhelming majority of patients and family members did not acknowledge that getting the device was a decision and were strongly influenced by the presentation of information by the physician, especially regarding its impact on symptom relief b) Some patients and family members reported that the physician described the implant of a cardiac device as "necessary" and would help the patient "feel better" c) Some patients and family members did not perceive getting the cardiac device as a choice, rather a decision that was made by their doctor and simply presented to them <u>Risks, benefits and long-term implications of cardiac implantable electric devices (CIEDs):</u> a) Few family members and patients reported a conversation about the benefits, risks and long-term implications of getting the device. b) Many family members reported wishing to have discussed more about the risks and alternatives to getting a cardiac device <u>Decision Quality Measures:</u> a) Most participants described having an active role in the decision and levels of decisional regret and -conflict were low to moderate.

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Fraiche (2021) USA	Qualitative study Semi-structured interviews with patients and providers	Total: n=28 Sex: 32 % female Age: 61 (range 27–84) years Subgroups: ▪ patients: n=15 ▪ clinicians: n=13 (non-electrophysiologist cardiologists: n=6, electrophysiologists: n=2, device nurses: n=2, device technicians: n=2, cardiology nurse practitioner: n=1)	To explore knowledge, expectations, preferences, economics/costs, and privacy involved in the RM of CIEDs.	Limited understanding of how RM works: a) Many participants, particularly patients, admitted a lack of understanding about how RM works, yet felt it was not concerning as long as the device did what it was designed to do. Desire for formalized training in RM: a) Both patients and clinicians described insufficient formalized education in RM b) Several clinicians described training as mostly experience-based during clinical activities Opinions regarding alert customization: a) Some clinicians and patients: patient preferences should be integrated into RM alerts b) Some interviews felt that patients should be notified for all alerts, but others stated it should only happen for life-threatening alerts Conflicts between patient trust and autonomy: a) Several patients described RM as akin to an alarm system whereas device clinic providers explicitly stated they purposefully attempt to educate patients to the contrary in order to empower them not to rely on RM
Gist (2019) USA	Cross-sectional study Standardized, validated questionnaires	Total: n=141 Sex: 75 (52.8 %) male Age: 14.2 (2.8) years Subgroups: ▪ Axillary devices n=55 (39 %) ▪ Infraclavicular devices n=86 (61 %)	To compare scar perception scores and QOL in pediatric patients with axillary CIED implant location versus the standard infraclavicular approach.	PSAQ scores: a) Patients with an infraclavicular device scored higher (poorer scar perception) in appearance (p=.01) and consciousness (p=.006) domains compared to those with an axillary device. b) Patients with an infraclavicular ICD scored higher (poorer scar perception) in the appearance (p=.001), consciousness (p=.0008), and satisfaction with appearance (p=.01) domains when compared to those with an axillary ICD. Pediatric Quality of Life Inventory (PedsQL): a) In comparison to healthy controls, device patients and parent-proxy reports had lower health-related quality of life (HRQOL) regardless of device location.

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Gopinathannair (2017) USA	Cohort study	Total: n=1461 Sex: 1184 (81 %) male Age: ▪ 65.3 ± 11.7 years ▪ Under 50: 166 ▪ 50–64: 545 ▪ 65–79: 654 ▪ ≥80: 165 Subgroups: ▪ DDDR automatic atrioventricular search hysteresis (AVSH): n=502 ▪ VVI: n=486 ▪ Nonrandomized patients were placed in an observational cohort and followed on the same schedule as randomized patients	To analyze HRQOL outcomes longitudinally following ICD implant as well the impact of age, gender, and ICD shocks on QOL in the INTRINSIC RV population by employing a global measure of HRQOL	<u>Overall study cohort:</u> a) Highly statistically significant improvements from baseline (p<.01) were observed in all SF-36 subscales, PCS, and MCS scores at every FUP visit except for Physical Functioning at 12 months (p=.053) and General Health at 12 months (p=.66) b) Substantial differences from baseline were seen in Role-Physical (11.9 points at 12 months), Social Functioning (7.2 points at 12 months), and Role-Emotional (6.5 points at 12 months). c) Differences from baseline to 12 months were clinically meaningful for all subscores except for Physical Functioning and General Health. The greatest change in QOL was noted in the first 3 months after ICD implant. <u>Randomized groups:</u> a) DDDR AVSH and VVI groups improved significantly in all domains except General Health b) The only significant differences in response between DDDR AVSH and VVI were in Role-Physical and in the PCS, in which the VVI group improved by larger margins than the DDDR AVSH group (p=.023 and p=.029, respectively) <u>QOL comparisons (gender, age, clinical characteristics, ICD shocks):</u> a) Females scored substantially lower in QOL at baseline versus males (statistical significant). Particularly severe disparities were noted in Physical Functioning (11 points), Role-Physical (10.5), Vitality (10.4), and Role-Emotional (15.2). b) Among the four age groups, the youngest patients scored lowest on 7 of 8 domains at baseline. During FUP, 5 of 8 domains and both component scores showed significant differences from baseline. Improvements in QOL tended to diminish with age, with most of the significant differences driven by the fact that the youngest patients showed the strongest change from baseline and the oldest, the least. Patients under age 50 showed significant change from baseline (p<.001) across subscales and component score except for General Health, including a nearly 20-point improvement from baseline in Role-Physical. c) Patients with New York Heart Association (NYHA) III/IV experienced significant improvements across subscales and component scores compared to patients with New York Heart Association (NYHA) I/II during FUP.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				d) QOL in patients who did or did not receive ICD shocks improved from baseline. Patients receiving shocks improved by smaller margins in 6 of 8 scoring domains and on PCS and MCS
Hadler (2019) USA	Qualitative study Standardized, validated questionnaires	Total: n=18 Sex: 6 (33 %) female Mean Age: 64 years Subgroups: ▪ Heart failure (HF) Stage II: n=7 (39 %) ▫ Mean Age:69 years ▪ HF Stage III: n=7 (39 %) ▫ Mean Age:62 years ▪ HF Stage IV: n=4 (22 %) ▫ Mean Age: 60 years	To assess perceptions of cardiac devices in patients with HF and how these perceptions impacted advance care planning and future expectations.	<u>Perception that device is 'lifesaver', confidence in device:</u> a) Several had previously been defibrillated and were quick to note that they might not be alive had they not received the shock. b) The conviction that the device provided a concrete and substantial benefit was often accompanied by confidence on the part of the participants about their understanding of the device and its functionality, even when inaccurate <u>Overestimation of role in on going disease management:</u> a) Misconceptions about device role in overall disease management were pervasive b) Respondents with ICDs in particular viewed their device's role as much broader than its clinical definition would suggest <u>Absent discussion of device 'if your disease were to worsen':</u> a) Respondents with CIEDs had experienced little counseling regarding the device role as their disease progressed, a factor that likely contributed to their misperceptions. b) 14 reported having had no conversation about possible device deactivation in the future; only 1 participant had discussed turning off his defibrillator in the event of further decline <u>Focus on technical aspects of device:</u> a) Education about devices frequently centered around technical aspects of management, specifically device maintenance b) Focus on technical features of devices, left respondents unprepared to talk about the broader implications of their disease <u>Deference to cardiology team in discussion/planning:</u> a) Many respondents with devices denied any discussion with their cardiologist about their choices regarding their device if their disease were to progress.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				b) Respondents deferred to their cardiologists regarding device management, attributing the same lifesaving properties to the provider as to the device. Cardiologist drove discussions.
Hamel (2018) Sweden and USA	Qualitative literature review and synthesis	Total: Studies: n=12 Decision-making stakeholders: n=313 Subgroups: ▪ Patients: n=173 ▪ Caregivers: n=84 ▪ Clinicians: n=56	To examine decision-making through the course of device treatments for patients with HF.	Processing the decision: a) Participants recognized it as discrete period, described as "complicated decision context" b) This was a time where in clinicians discussed concern that they would overly influence patient decisions or complicate the process by introducing difficult discussions Transmission of information: a) Some participants: time was overwhelming and could not process what they were told b) Others discussed voiding information that was fearful or they felt would sway their decision c) Clinicians tried to find a balance between imparting key information without adding to the difficulties for patients and caregivers. d) Although understanding that education is a key to SDM and informed consent, clinicians were cautious about overemphasizing the risks and further complicating the decision Timing of the decisions: a) Decisions should move at a slow pace, allowing careful consideration of treatment options b) In practice the process may need to be sped up or truncated (disease progression) Judging health status: a) One study described patients having difficulty understanding being ill enough to consider ventricular assist device but not to proceed with implantation b) Participants: assessing their health status and realizing that treatment was needed
Hammash (2019) USA and Australia	Cross-sectional	Total: n=263 (190 participants from the US and 73 participants from Australia) Sex: 190 (73 %) male Mean Age: 61 ± 14 years	(1) To determine whether perceived control is an independent predictor of HRQOL in ICD recipients and (2) identify predictors	Relationship between perceived control and HRQOL: a) Higher levels of depression (β=-0.30, p<.01), anxiety (β=-0.18, p<.05), and lower perceived control (β=0.30, p<.01) predicted lower levels of HRQOL Mobility:

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			of perceived control in ICD recipients.	a) Patients with higher level of depression were 5.56 times more and patients with low perceived control were 2 times more likely to have problems with mobility <u>Usual activities:</u> a) Patients who received ICD shocks were 3 times more, patients with higher level of depression were 4.66 times more and patients with low perceived control were 2 times more likely to have problems with performing usual activities <u>Pain:</u> a) Patients with higher level of anxiety were about 11.4 times more and patients with lower perceived control were 3 times more likely to report problems with pain <u>Anxiety/depression:</u> a) Patients with lower perceived control were 3 times more likely to report symptoms of anxiety and depression <u>Predictors of perceived control:</u> a) Higher anxiety scores β=-0.17, p<.05), higher depression scores (β=-0.23, p<.05), lower social support (β=-0.26, p<.01), and higher ICD concerns scores (β=-0.16, p<.05) were independently associated with lower levels of perceived control
Herman (2018) USA, Czech Republic, Canada, Germany, Netherlands and Israel	Systematic review	Total: Studies: n=9 (five quantitative studies and four qualitative studies). Patients: n=24,770 Physicians: n=362	To identify problems that may delay the deactivation of ICD and address possible considerations for ICD management to improve end of life (EOL) care in adult patients with HF.	<u>Clinical practice and management of ICD deactivation:</u> a) Of the 150 patients in one study, 135 patients had ICDs and 15 patients had PM. Requests for deactivation of CIEDs made by: 74 patients (49 %), surrogate decision makers (51 %). 85 patients (57 %) had ADs, but only one patient had specifically mentioned the management of his/her ICD during the EOL phase. Most CIED deactivations were carried out by nurses (55 %), followed by physicians (31 %) and industry-employed allied professionals (15 %). b) In a retrospective cohort study of 91 patients, only one patient had a consent form with documentation stating the option for ICD deactivation at the EOL. c) In a retrospective cohort study, 98 patients were examined and categorized into three groups: group 1 (n=15) underwent ICD deactivation, group 2 (n=36) without ICD deactivation but in hospice care or had do not resuscitate orders, and group 3 (n=83) without ICD deactivation

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				and not in hospice care and did not have a do not resuscitate order. Shocks within the 24-hour period before death: no shock in group 1, 1 shock in group 2 and 3 shocks in group 3. In group 1, most requests for deactivation were initiated by patients and family members (53 %). <u>Patient perceptions of ICD deactivation:</u> a) In a qualitative study of 15 patients with ICDs, patients did not understand accurately the indication for an ICD and its role in the context of their health. All patients described having anxiety regarding future shocks but viewed ICD therapy as exclusively beneficial to their health. None of the participants recalled having a discussion about deactivation and knew that the option of ICD deactivation existed. b) In a qualitative study, 25 patients identified three stages where they felt the discussions of ICD deactivation should occur: (1) before implantation, (2) with any significant health deterioration, and (3) at the EOL, which was defined as terminal deterioration. Most patients (68 %) said that they would consider ICD deactivation, whereas 24 % were undecided, and 8 % were adamant that they would never deactivate the ICD. c) In a quantitative study, only 8 of 109 patients (7 %) had discussions with providers regarding ICD deactivations. 50 patients (46 %) indicated that they had never considered ICD deactivation during EOL situations, 44 patients (40 %) wanted more information about ICD deactivation and 29 patients (27 %) refused any additional information pertaining to deactivation. <u>Provider perceptions of ICD deactivation:</u> a) A qualitative study of 177 patients found, that 38 physicians (36 %) reported initiating the discussion of ICD deactivation would depend on specific circumstances , with only 24 physicians (13 %) accepting responsibility for these discussions. Only 27 physicians (15 %) believed that the topic of ICD deactivation is important, and 13 physicians (7 %) expressed that patient or family should be the first to initiate the discussion. In readiness to pursue palliative care, 38 physicians (21 %) preferred initiating life-pro longing therapies in contrast to 6 physicians (3 %) who endorsed deactivation discussion and suggested additional palliative treatments. 16 physicians (9 %) expressed lack of education and awareness regarding ICDs. b) In 185 responses, physicians were less comfortable discussing deactivation of ICDs compared with other life-sustaining therapies (e. g. ventilation, dialysis and tube feeds; p=.005).

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Hill (2019) UK	Qualitative study Semi-structured interviews	Total: n=29 Subgroups: ▪ Patients: n=10 ▫ Sex: 7 male ▫ Age: range 49–82 years ▪ Family members: n=10 ▪ Healthcare professionals involved in each case: n=9	To explore patients', family members' and health-care professionals' perspectives and attitudes towards discussing ICD deactivation	<u>Limited information by professionals:</u> a) Some professionals perceived discussing deactivation equated to the 'preparing for death' and patients were not at that stage b) Many professionals rationalised their reluctance to patients impaired mental state after recently surviving a life-threatening event c) Patients reported written information was 'rudimentary' d) Many patients were uncertain of the quantity and depth of information that they would be comfortable with receiving. e) Both patients and professionals valued a supportive professional: with patients placing 'trust in what we were told' and professionals desiring an understanding of patients' information and emotional needs before embarking on this sensitive topic f) Majority of the professionals believed it was appropriate to wait until the patient broached the subject of deactivation g) Limiting information to be in the patient's best interests as each patient has to be managed as an individual h) Triangulated data from all sources confirm that generally deactivation was not discussed prior to device implantation. <u>Inaccurate understanding of ICD functionality:</u> a) Patients and family members could not comprehend that shock could be inappropriate b) Only when patients were diagnosed as in the advanced stages of illness, did professionals question the role of the ICD c) Patients within this study did not understand the functions of their device and held an optimistic belief into its ability. <u>Patient's choice and decisions compromised:</u>

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				a) Clinical indicators that inhibited professionals from initiating the discussion included: the patient's management was 'going down the treatment route', the health problem was a 'retrievable situation' or the patient 'has been through a life-threatening illness' b) Patients: decision to deactivate device should be made in the last few minutes of life. c) Majority of patients wanted to be involved in the decision to device deactivation, but final judgement is to a medical professional d) Involvement of family members was valued: the decision should be 'made with them, my family and hopefully partner and me'. e) Professionals: 'ICD deactivation is something you need to have the family on board with, to help when the patient would no longer be around to pick up the pieces and face the fall-out`. f) When the patient was incapable or unconscious, professionals, carers and patients agreed that the decision then resides with the doctor. Professionals often relied on clinical indicators to determine discussing deactivation
Hopgood (2020) USA	Mixed methods study Semi-structured interviews	Total: n=16 Sex: 11 (69 %) male, 5 (31 %) female Age: 19.5 (14–24) years Subgroups: ▪ HigherQOL: n=8 ▫ Sex: 8 (100 %) male ▫ Age: 20 (16–22) years ▪ Lower QOL: n=8 ▫ Sex: 3 (37.5 %) male, 5 (62.5 %) female ▫ Age: 18 (14–24) years	To compare salient characteristics and antecedents (e.g., time with device, number of nondevice procedures, number of shocks) of QOL obtained through qualitative methods with quantitative measurement of QOL (PedsQL measure). These antecedents will be dichotomized based on median QOL score, and correlations between QOL (PedsQL) and measured antecedents.	<u>Comparison of Median QOL Scores:</u> a) There were statistically significant differences between the higher and lower scores in terms of the PedsQL from all domains (PedsQL global score: Higher QOL: 87 (75–95.7) vs Lower QOL: 59.8 (54.3–69.6); Physical: 85.9 (68.8–100) vs 53.1 (34.4–81.8); Psychosocial: 86.7 (78.3–93.3) vs 61.7 (55–71.7) b) The PedsQL Cardiac 3.0 score showed a statistically significant difference between the higher and lower QOL groups [88.8 (75.5–97.4) vs 73 (51–76.9)] suggesting disease severity, as measured by this instrument, was related to QOL grouping. <u>Symptoms:</u> a) The higher QOL group (n=7) had a greater number of individuals describing the symptoms compared with the lower QOL group (n=6) <u>Functional status:</u> a) The higher QOL group described a change in capabilities in the first 6 weeks after device placement in which their functional status was reset. Their baseline functional status changed

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				eventually, but during this time, there was successful adjustment. The lower QOL group described the change in similar terms in that they had to determine what they could do for the first 6 weeks with the device. b) Ability and loss of ability were prominent features in the thematic analysis. This was reflected in the scores of the higher QOL group as their self-rating of ability to perform activity was 32 points higher than the lower QOL group. The expression of minimal loss of ability was more prominent in the higher QOL group. c) The higher QOL group had higher visual analog QOL scales, most notably the physical subdomain. Higher QOL individuals rated their ability to do activities 32 points higher than the lower QOL group. Social scores also were higher. <u>Characteristics of the individual:</u> a) The higher QOL group described more time with friends, shifting to more acceptable activities, emotions of frustration and optimism, and a willingness to discuss their disease. The lower QOL group described negative emotions more prominently with activities and had individuals who were hesitant to discuss their device and disease
Humphreys (2018) UK	Qualitative study Semi-structured interviews	Total: n=18 Sex: 7 males, 11 females Age: Partners range 28–68 years (mean age 55.7 years, SD=11.75) Subgroups: ▪ shock & primary prevention n=3 ▪ non-shock & primary prevention n=8 ▪ shock & secondary prevention n=2	To explore the experiences of partners of recipients of ICDs	<u>Feeling traumatised:</u> a) Partners of patients who had an out-of-hospital SCA and been fitted with an ICD for secondary prevention had experienced trauma <u>Anxiety and fear:</u> a) All partners worried about the recipient's cardiac health. Partners generally did not feel prepared to be the recipient's sole carer b) Many partners became hypervigilant and catastrophised and ruminated over recipients' physical symptoms c) Partners of those whose ICD had not fired (non-shock group) lived in fearful expectation of first shock, wondering how and when it would occur and if the device would fail to resuscitate <u>Problem solving:</u> a) Monitoring appeared to reduce over time, but not for everyone.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
		▪ non-shock & secondary prevention n=5		b) Linked to this monitoring was the use of protective behaviours, many of which were helpful and adaptive for the recipient. c) Protective behaviour involved attempts to reduce or avoid situations likely to increase a recipient's stress or acute physical exertion, including sexual intercourse <u>Emotion regulation:</u> a) Shocks were reported to have a significant impact on partners as they believed the shock meant that their partner's heart condition was getting worse b) Majority of non-shock partners and all the shock partners appeared to have 'accepted' the ICD after 1 year, but nature of this acceptance varied.
Jakub (2018) USA	Qualitative study Semi-structured interviews	Total: n=12 Sex: 12 (100 %) male Age: ▪ 26–33: 3 ▪ 41–62: 4 ▪ 66–85: 5	To examine men's long-term adjustment to living with an ICD as it relates to their social and psychological well-being at various stages in life.	<u>Maintaining a masculine image:</u> a) 5 men: varying degrees of bravado as adjusting to living with an ICD. Maintaining masculine persona or image was important, even though disability was invisible to others. b) They resented being told to restrict their activities for fear of a shock. Challenging themselves to demonstrate to others that they were not disabled or encumbered by their condition. c) All 12 men participating the study continued to reflect over time on their physical abilities and how they were perceived by others. <u>SCD and social implications through time:</u> a) Men attempted to resume a sense of normalcy by returning to their lifestyle and activities following SCD and ICD implantation. b) Family members hovered and became over-protective, which was accepted during post-implantation period, but became unwanted. <u>Self-image influenced by chronic illness:</u> a) Men who shared their feelings about having a heart condition, varied from being stoic denying its severance to feeling inferior.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				b) Men who received their initial ICD during their middle years (age 40–65) often had other comorbid conditions, but still viewed themselves as young and vibrant. They remained active both in their professional and personal lives.
Kelly (2021) Canada	Qualitative study	Total: ▪ Device clinics: n=22 (n=14 physicians, n=5 allied health professionals, n=3 allied professional clinic managers) ▪ Key informants: n=10 (n=5 electrophysiologists, n=2 nurse clinicians, n=1 cardiologists, n=1 nurse managers, n=1 clinical nurse educators) ▫ Sex: 6 (60 %) male ▪ Patients: n=506 ▫ Sex: 368 (72.3 %) male	To investigate real and perceived barriers to the use of remote patient management strategies in Canada and to better understand how remote models of care can be optimized	<u>Device clinics:</u> a) Patients with CRT-Ds or ICDs were most frequently reported as seeing a doctor at every visit, whereas patients with CRT-pacemaker and PM were more likely to be seen by a doctor only when clinically indicated. b) 7 clinics indicated that when CIED patients experience alerts triggered by remote FUP, they are instructed to present to the nearest emergency department. Most clinics contacted the patient on the next business day after an alert (77 %), whereas few provided an on-call number to contact their device clinic for further instruction. 8 clinics (36 %) routinely called patients after a remote transmission. <u>Key informants</u> a) ICD patients visit device clinics more often and may be prone to life threatening problems that may be picked up earlier with RM b) PM need to follow fewer issues (e.g., no leads, fewer safety alerts or recalls) and require manual transmissions (i.e. requiring the patient to download and send data to the clinic) c) Staff may have limited time to discuss/encourage RM or to teach patients to ensure optimal uptake or successful set-up and use d) Patients may find the concept of RM confusing, struggle to understand all of the information given to them upfront, or have concerns about privacy or how the data will be monitored e) Can make patients feel comforted or reassured (someone is keeping an eye on their data) <u>Patients</u> a) CIED recipients were generally satisfied or very satisfied with current QOL (90 %) b) Suggestions for how device clinic visits could be improved were on the basis of logistics of the visit, coordination of care and information needs

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				c) Less than 60 % knew how to recognize that an alert has been triggered on their device, yet 65 % (n=164) knew what to do when they receive an alert. Survey respondents knew what to do when they receive a shock (n=191; 75.8 %) <u>Identified barriers by device clincs and patients:</u> 1. Inconsistent and/or limited funding policies across jurisdictions for inclinic and remote visits 2. Lack of a unified, process-specific, and guideline-supported approach to FUP after CIED implant 3. Accessibility for all patients and types of devices 4. Resources (education, time, training) 5. Coordination of care 6. Visit logistics 7. Attitudes toward remote visits
Kindermann (2021) Germany	Monocentric prospective study	Total: n=132 Sex: 94 (71 %) male, 38 (29 %) female Mean Age: 61 ± 14 years Subgroups: ▪ <63 years: n=63 (48 %) ▪ >63 years: n=69 (52 %) ▪ ICD: n=88 (67 %) ▪ CRT-D: n=44 (33 %)	To evaluate heart-focused anxiety (HFA), general anxiety, depression, and QoL across four measurement occasions before and up to 24 months after ICD or CRT-D implantation.	<u>HFA and related subscores:</u> a) Before implantation, 44 % of participants had clinically relevant HFA (total score). HFA-related fear, attention, and avoidance were increased in 38 %, 26 %, and 44 % of the patients b) Significant improvements after implantation were observed in the mean total HFA score [$F(3, 393)=9.31$, $p<.001$, $\eta^2p=.07$], as well as in the HFA-attention and HFA-fear scores [$F(2.79, 364.82)=16.94$, $p<.001$, $\eta^2p=.12$ and $F(2.89, 378.29)=5.68$, $p=.001$, $\eta^2p=.04$] c) 2 years after implantation, 30 % of patients reported clinically relevant HFA (total score). HFA-fear, HFA-attention, and HFA-avoidance increased in 26 %, 14 %, and 37 % of participants <u>Subgroup analyses for HFA anxiety outcomes:</u> a) At baseline, older participants reported higher HFA-avoidance than younger patients [mean difference (MD)=0.5, 95 % confidence interval (CI) 0.1–0.8, p=.014]

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				b) Total HFA, HFA-fear, and HFA-attention decreased in most of the groups. In younger patients, total HFA and HFA-fear did not improve. In patients with ICD implantation, HFA-fear did not change c) Patients after shock/antitachycardia pacing reported no improvements in any HFA score <u>General anxiety, depression and QOL:</u> a) Increased levels of general anxiety were reported by 37 % of patients at baseline b) Depressive symptoms were increased in 33 %, and QoL was impaired in 68 % of participants c) Mean scores of general anxiety and QoL decreased significantly after implantation [F(2.84, 371.87)=6.17, p=.001, η^2p=.05 and F(2.68, 351.40)=6.74, p<.001, η^2p=.05] d) After 2 years, increased levels of general anxiety and depression were reported by 33 % and 35 % of patients, respectively, and impaired QoL by 58 % <u>Subgroup analysis for general anxiety, depression and QOL outcomes:</u> a) Younger patients experienced significantly higher general anxiety than older participants at baseline (MD=2.0, 95 % CI 0.5–3.5, p=.012) b) After implantation, general anxiety improved in older participants, patients with CRT-D and without shock/antitachycardia pacing, and men c) QOL was lower in CRT-D compared with ICD recipients at baseline (MD=8.1, 95 % CI 0.4–15.8, p=.040) and in women compared with men (MD=9.7, 95 % CI 1.7–17.7, p=.018) d) After implantation, QoL improved significantly in CRT-D recipients and in women
Köbe (2017b) Germany	Case-control-study	Total: n=84 (n=42 matched pairs) Subgroups: ▪ Transvenous ICD (TV-ICD): n=42 ▫ Sex: 30 (71.4 %) male ▫ Age: 44.7 ± 12.1 years	To analyze QOL with the new S-ICD® in comparison to patients with a conventional TV-ICD. Besides, the occurrence of posttraumatic stress disorders was studied.	<u>Posttraumatic stress disorders, depression, or/and other mental comorbidities (Results from the Posttraumatic Stress Diagnostic Scale and patient health questionnaire):</u> a) The Posttraumatic Stress Diagnostic Scale symptoms severity score was 6.4 ± 8.6 for TV-ICD patients and 6.9 ± 8.9 for S-ICD® patients (p=.95) b) Posttraumatic Stress Diagnostic Scale revealed a mild posttraumatic stress symptom score in 6 patients with a TV-ICD and also in 6 S-ICD patients (14.3 %, p=1.0)

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
		▪ S-ICD®: n=42 ▫ Sex: 30 (71.4 %) male ▫ Age: 44.6 ± 12.5 years		c) 4 conventional ICD patients (9.5 %) and 2 S-ICD patients (4.8 %) fulfilled criteria for a major depression (p=.68) d) The diagnosis of an anxiety disorder was made in three S-ICD patients (7.1 %) and was not revealed in the TV-ICD group (p=.24) <u>HRQOL (Results from SF-12 questionnaire):</u> a) The physical well-being score was 39.9 ± 12.5 in TV-ICD patients compared to 46.6 ± 9.9 in S-ICD patients (p=.01). b) The mental well-being score did not differ between groups <u>Limitations in the professional life, sporting activity, and sexual life (Results from a self-developed questionnaire):</u> a) No group difference in device-dependent limitations during work life (p=.99), limitations in sports activities (p=.83) and ICD-related thoughts (p=.49).
Kramer Freeman (2017) USA	Cross-sectional study	Total: n=196 Sex: 66 (33.7 %) male, 130 (66.3 %) female Mean Age: 45.61 (SD=12.54, range: 18–70) 60.1 % were under age of 50 years	(1) To examine what information is sought via social media by patients with ICDs (2) To determine whether a social media sample of patients with ICDs report more device-specific anxiety than clinic-based normative samples	<u>Communicating about ICD topics through an online social media modality:</u> a) Gaining emotional support from others going through the same thing as me (62.8 %) b) Anxiety about my ICD (55.6 %) <u>Comparisons on shock anxiety between the online sample and the typical clinical sample:</u> a) The online ICD group reported higher shock anxiety (t_{189}=10.36, p<.001); Analysis of variance revealed that recent shock was also a significant factor in shock anxiety; A main effect on shock anxiety for those experiencing the most recent shock was found (F_{2186}=33.19, p<.001) b) Shock history was further investigated related to 3 recent shock conditions: Group 1 (less than 4 months ago); Group 2 (more than 4 months ago); and Group 3 (never shocked): significant differences between Group 1 compared to Group 2 with a mean difference of 13.07 (p<.001), and Group 1 compared to Group 3 with a mean difference of 14.79 (p<.001).
Kutcher (2020) USA	Qualitative study	Total: n=5 (one family) Sex: 5 (100 %) female	To better understand the experiences of family caregivers of a terminally	<u>Patient's story:</u> a) Decision against another PM implantation, which would only prolong her life. Medical professionals persuaded her to consent to replacement and appeared to disregard her wishes

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
	In-depth, semistructured, open-ended interviews	Age: 50–72 years	ill person who was receiving hospice care at home and underwent deactivation of a PM.	and signs of declining QoL. Experience of living with a PM, despite her desire to die, dominated her last few months until she learned that device deactivation was an option Caregivers' story: a) They consistently respected her wishes and supported her decision to deactivate her PM. Lack of understanding and support from medical professionals, who showed enthusiasm for inserting a PM but reluctance when considering its deactivation. Most urgent need was to have the medical personnel accept the patient's wishes and support the caregivers' decision to support their loved one PM's story: a) Lack of information and support about the deactivation process. Had to rely on Internet sources for ethical views and the practical aspects of the process itself. They wanted help in discussing the process with their mother to reassure and confirm that what she wanted was not biased by their own opinions Health Care and Support Professionals' Story: a) None of the professionals (eg, from the lawyers drafting the will to the doctors) acted in accord with the patient's wishes. The caregivers expressed that understanding, support, and acceptance were provided only when their mother entered a hospice program and the hospice interdisciplinary group became involved in her care
Lee (2017) USA	Qualitative study Semi-structured interview	Total: n=6 Sex: 3 (50 %) female Mean Age: 55 (range: 18–84) years	To test the effects of a nurse-guided discussion in decision-making about ICD deactivation (turning off the defibrillation function) at the EOL.	Decision-Making Preference: a) Family members reported that patients prefer to have SDM with family members. Some patients deferred decision-making to the physician. Perception of ICD Deactivation: a) Most of the family members were surprised by the idea of deactivation and reported that the possibility of deactivation of patients' ICD had never been considered. b) Only 1 family member reported that the patient was aware of the option to deactivate. With the knowledge of ICD deactivation, patients preferred to keep the ICD active at EOL. Communication Methods:

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				a) Family members having direct conversations with patients regarding their EOL wishes experience more confidence in patients' decision compared to relying on a written AD only. b) Two family members described a prearranged use of a simple sign of the patients to indicate what they wanted about treatments. c) According to family, no documentation of ICD deactivation in patient's AD. One family member reported that the patients' AD was very clear and helpful in expressing patient's decisions. However, 2 family members expressed that they had not discussed the AD with the team and just assumed that medical team understands and respects patients decisions listed in AD.
Leppert (2021) Germany	Controlled longitudinal randomized open-label trial	Total: n=167 Sex: 137 (81.5 %) male Mean Age: 62.3 years Subgroups: ▪ RM: n=86 ▫ Sex: 69 (80.2 %) male ▫ Mean Age: 61.5 (SD=14.2) years ▪ In-office FUP (control): n=81 ▫ Sex: 68 (84 %) male ▫ Mean Age: 63 (SD=15.3) years	To Investigate the effect of RM in addition to standard in-office ICD FUP on patient-reported outcomes compared to patients receiving standard in-office ICD FUP only	Changes of QoL within the two study groups (intragroup comparison, over time vs. baseline, intention to treat): a) Moderate, but significant increase in QoL within the RM group (3.9 points, p=.04), while there was no significant change in QoL in the control group (1.2 points, p=.5) over 12 months; slight increase of 3.9 points in the RM group could be attributed to the RM subgroup capable of fully automatic data transmission (Biotronik Home-Monitoring, mean increase of 7.6 ± 20 points). Per protocol analysis for the primary endpoint: a) The results of the per-protocol analysis including 62 patients in the RM group (only patients who had used/activated the RM) and 81 patients in the control group confirmed that an additional FUP with successfully initialized RM did not add any benefit with respect to the primary outcome of QoL in RM or control group (mean change: + 5 points and + 1.2 points, respectively; p=.63).
Lewis (2018) Canada	Mixed methods study Acceptability and usability	Total: n=18 Sex: 10 (55.6 %) female Subgroups:	(1) To understand the current approach toward ICD replacement; (2) to seek feedback on PDA content,	Current approach: Automatic ICD replacement: a) The current ICD replacement approach was viewed by participants as automatic. Once battery depletion was detected on ICD interrogation, patients were informed that it was time for a device replacement with the procedure performed within weeks.

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	questionnaires, semi-structured interviews	▪ Clinicans (nurses, cardiac lectrophysiologists, palliative care specialist, psychologist): n=12 ▫ Sex: 7 (58.3 %) female ▪ Patients and family (including two interviews with patient-spouse dyad): n=6 ▫ Sex: 3 (50 %) female	acceptability, and usability; and (3) to elicit feedback on how best to implement it in clinical practice.	<u>Implicit persuasion:</u> a) Guided by strong clinical trial evidence, clinicians believed that the mortality benefit of ICDs outweighed potential burdens. ICD therapy was presented to patients as a lifelong treatment where ICD replacement is a necessary course of action. Patients unequivocally anticipated replacement once next battery ran low, some erroneously believing it was the only choice. <u>Influence of previous encounters:</u> a) Relying heavily on the information received (or not received) upon initial ICD implant, participants reported mixed messaging, inaccuracies and omitted information. b) At time of replacement, clinicians reported not raising option to decline ICD replacement in fear of surprising or upsetting patients. <u>Not knowing the patient:</u> a) Clinicians expressed wanting to know more about the patients' overall clinical status, personal circumstances, preferences and values related to the ICD to best prepare for the sensitive nuances inherent to ICD replacement discussions. b) Building meaningful rapport was considered difficult due to environmental barriers of time pressures, shared care model and inability to obtain documentation from external (noncardiac) encounters. <u>Shifting from an automated approach to an SDM process:</u> a) Clinicians, particularly nurses, referred to the need for a "hint" from their patients to ensure that raising the option of ICD replacement would be well received. The hint could be in the form of a declaration of a recent diagnosis, of a worsening prognosis, or of not coping well with the ICD, for example. b) Other participants believed that the invitation should be provided by the clinician considered the gatekeeper of the information, because some patients may otherwise be unaware or unsure of whether the topic can or should be discussed. <u>PDA implementation to support a SDM process</u> <u>Need for individualization:</u>

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				a) Patient-reported outcomes such as QoL and their values and preferences for continued ICD therapy were recognized as contextual, hence necessary to review throughout ICD pathway. b) Cognitive function, health literacy, and preference for role in decision-making (active vs passive) were noted. <u>Timing:</u> a) Presenting the option of ICD replacement needed to occur at 2 distinct time points: first, described before the initial implant or at the first clinic appointment after insertion and, second, discussed upon intensified FUP 6–12 months before battery depletion. Because battery depletion is monitored in the device clinic, most patients agreed that staff should initiate, control and lead this process. b) Presentation of options would be expected. It would allow for unhurried deliberation with family members and patient's healthcare team. <u>Education about ICDs and SDM:</u> a) Education was considered the remedy for patients' misunderstanding of ICD function, benefit, potential burdens and, most importantly, necessary for patients to understand the sudden versus prolonged trade-offs of ICD therapy. b) Clinicians external to the device clinic may be fueling patient misunderstandings given lower levels of device-related knowledge. c) Device clinic staff admitted to not being skillfully prepared to engage patients in discussions about ICD replacement citing that doing so was difficult and uncomfortable. Education about ICDs and SDM was proposed as the solution for all those involved. <u>PDA Content, Acceptability, and Usability:</u> a) All participants were willing to use the PDA or recommend its use. b) All participants agreed that the PDA is valuable for use in clinical practice, but not to be used as a standalone instrument.
Lewis (2019)	Multi-centre retrospective	Total: n=27	To evaluate the underlying causes of chronic pain and	<u>Characteristics of pain:</u>

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
USA	observational study Patient's electronic medical records	Sex: 14 (51 %) female Mean Age: 50 (± 16.2) years	the success of lead extraction in eliminating pain, in patients with prior CIED implantation	a) Prior to initial CIED implantation, 6 (22.2 %) patients used prescribed narcotics for pain management, 13 (48.1 %) patients used over-the-counter medications including non-steroidal anti-inflammatories and/or acetaminophen. b) Average onset after implantation 5 months ± 1.3 years (185.8 ± 503.5 days). Average pain severity 6.1± 2.3 out of 10 (p=.308). Pain quality: sharp 17 (58.6 %), dull and achy 4 (14.8 %), tender 1 (3.4 %). Pain triggered by movement and positional changes in 14 (51.8 %) patients. Radiation of pain from the pectoral region to the ipsilateral axilla, and shoulder in 13 (48.1 %) patients. Pain constant in 14 (51.8 %) patients, intermittent in 13 (48.1 %). <u>Outcomes of extraction:</u> a) Average time to lead extraction 4.08 ± 4.28 years. Following CIED extraction: free of pain 18 (66.6 %) patients, still pain at the initial implantation site 9 (33.3 %). Those with poorly formed CIED pockets and subclinical infections identified at the time of CIED extraction were subsequently free of pain. b) Patients underwent re-implantation following extraction (n=19, 70.3 %) or extraction alone (n=8, 29.6 %). 11 of 19 (57.8 %) device re-implantations were done immediately following extraction. The remaining 8 (42.1 %) were performed later. Of the 19 (70.3 %) patients that underwent CIED re-implantation, 11 were done at the contralateral pectoral region, 8 of them reported resolution of their pain. 8 of 19 re-implantations were performed at the ipsilateral pectoral region, 5 of them reported pain unresolved. Following extraction and relief of pain, 3 patients reported discontinuation of the use of their prescription narcotics. c) Of the 9 (33.3 %) patients that still reported pain following extraction, the average age was 44 ± 17.1 years (p=.252) and 7 were women (p=.056). Post-extraction, 5 (55.5 %) patients required continued pain management with narcotics, 3 of whom did so prior to extraction. The severity of pain decreased in 5, increased in 1, or remained the same 3 patients in this group, compared with the pain experienced before extraction. 2 of the 9 reported constant pain post-extraction, compared with 5 that reported constant pain prior to extraction. One patient had post-extraction pain despite extraction without re-implantation.
Li (2022)	Meta-analysis of randomized	Total: n=675	To explore the effectiveness of CBT in relieving	<u>Depression:</u>

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Denmark, USA, Canada, UK and France	controlled trials and cluster-randomized controlled trials	Sex: 511 (75.7 %) male Age: range 40–77 years Subgroups: ▪ cognitive behavioral therapy (CBT) group n=316 ▪ Control group n=359	symptoms of anxiety and depression experienced by patients with ICDs <u>Intervention:</u> CBT was performed by psychologists and nurses. The duration of CBT ranged from 6 to 24 weeks. The time per session of CBT varied from 30 to 120 min and comprised 2–10 individual sessions.	a) 5 of 6 studies (n=453 patients) assessed effectiveness of CBT in relieving symptoms of depression. Heterogeneity test result was low (p=.47, I2=0 %). Random-effects model showed that CBT was superior to standard care for relieving symptoms of depression experienced by ICD patients (standardized mean differences (SMD)=-0.2; 95 % CI: -0.39 to -0.01; p=.04). <u>Anxiety:</u> a) All studies (n=536 patients) examined effects of CBT on symptoms of anxiety experienced by ICD patients. Heterogeneity test was significant (p<.001, r2=77 %). Based on the random-effects model, overall results demonstrated that CBT was superior to standard care in improving symptoms of anxiety experienced by ICD patients (SMD=-0.70; 95 % CI: -1.10 to -0.30; p<.001). Sensitivity analysis revealed that no studies had significant impact on heterogeneity. b) A subgroup analysis was conducted to explore the short-term (≤ 6 months) and long-term (>6 months) effects of CBT on symptoms of anxiety experienced by ICD patients. Heterogeneity test result was moderate (p<.001, 12=54 %). The random-effects model indicated that CBT can significantly reduce anxiety compared with standard care over short- (SMD=-0.86; 95 % CI: -1.07 to -0.64; p<.001) and long-term (SMD=-0.85; 95 % CI: -1.59 to -0.12; p=.02) period.
Liberato (2021) USA	Interventional study	Total: n=301 patient/intimate partner pairs (150/151 dyads/group) Sex: 222 (73.8 %) Mean Age: 64 (± 11.9) years Subgroups: ▪ P-only: n=151 ▫ Sex: 106 (70.2 %) male ▫ Mean Age: 65.01 (± 11.26) years ▪ Patients from P+P: n=150 ▫ Sex: 116 (77.3 %) male	To test the extent to which the four ICD-specific dimensions of self-efficacy, defined as self-efficacy expectations, outcome expectations, self-management behaviors, and ICD knowledge, served as mediators between the interventions and physical and psychological health outcomes. <u>Intervention:</u>	<u>Measurement model for dependent variables:</u> a) For Physical Function, the indicator loadings were consistently strong, ranging from λ=0.46 to 0.83. For Psychological Adjustment, indicator loadings were similarly strong, ranging from λ=0.64 to 0.85. Loadings for the four dimensions of self-efficacy were fixed to 1.0, as they were single indicators and considered measured without error. <u>Comparison of intervention direct effects on self-efficacy dimensions and health outcomes:</u> a) The direct effects of P+P compared to P-only on self-efficacy expectations (SE) and outcome expectations (OE) at 3 months were relatively small but significant, indicating that these direct effects were stronger for P+P vs P-only (Panel A: path a, β=0.10, p=.02 and Panel B: path d, β=0.11, p=.02). b) Direct effects of P+P vs. P-only on psychological adjustment were significant for self-management behavior and ICD knowledge self-assessment models (Panels C and D, path n, β=0.10 and 0.11).

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		▫ Mean Age: 63.26 (± 12.5) years	P-only: patients received an intervention. P+P: patients received same intervention as in P-only. Partners participated in partner group sessions delivered by telephone and designed to address their specific concerns and needs. Interventions were delivered via telephone by trained cardiovascular nurses during the first 3-months after an ICD implant.	<u>Comparison of intervention indirect effects on health outcomes mediated through self-efficacy:</u> a) The comparison of P+P to P-only revealed a small significant indirect intervention effect through self-efficacy on physical function (Panel A, path a x b; Table 3, row 1: β=.04, p=.04), and on psychological adjustment (Panel A, path a x c; Table 3, row 5: β=.06, p=.04).
Liberato (2022) USA	Double-blind randomized prospective placebo control trial	Total: n=90 Sex: 96 % male Mean Age: 66 ± 10 years Subgroups: ▪ Placebo: n=46 ▫ Sex: 43 (93 %) male ▫ Mean Age: 66.5 ± 9.3 years ▪ Intervention (SPL): n=44 ▫ Sex: 44 (100 %) male ▫ Mean Age: 66.6 ± 10.9 years	To compare the impact of longterm use of spironolactone versus placebo on HRQOL and symptoms, and to describe the effect of ICD shocks on HRQOL and symptoms over 24-months in patients with an ICD who participated in the SPIRIT Trial.	<u>HF-specific HRQOL over 24 Months by Intent to Treat Groups:</u> a) No group difference over time in HRQOL between the spironolactone or placebo group with any of the three instruments. <u>PCA:</u> a) Between the two treatment groups, the PCA responses did not significantly change over time in any of the subscales or total scales. b) Placebo group initially had a lower number of total concerns and over time, the number of symptoms reported within the placebo group was lower than the spironolactone group (F=3.99, p=.05). c) Patients in the spironolactone group showed more concerns in PCA scales than the placebo group that remained relatively constant over time. The number of symptoms and concerns in this sample was higher than levels reported by others. <u>Short Form 36 Veterans version (SF-36V):</u>

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				a) Across time, no group differences between treatment groups (SF-36V subscales and component summary scores). b) Patients in the spironolactone group reported lower HRQOL compared to those in the placebo group on subscales and summary scores. Scales scores were higher in the placebo group compared to the spironolactone group in role physical (p=.01), social functioning (p=.01), role emotional (p=.05), and mental health (p=.03). c) Taking spironolactone did not improve or change HRQOL. <u>Kansas City cardiomyopathy questionnaire (KCCQ):</u> a) Between the two treatment groups, the KCCQ responses did not significantly change over time in any of the subscales or total scales. b) For both subscales and summary scores of the KCCQ, there were noted significant differences by group such that the placebo group reported higher HRQOL than the spironolactone group over time. This included differences in physical limitation (p=.01), symptom burden (.02), total symptoms (p=.04), QOL (p=.01), social limitation (p=.01), and the clinical and overall summary scores. c) The biggest drop of scores in the spironolactone group were at 6-month FUP and varied with less magnitude during the remainder of the 24-months of FUP. d) HRQOL scores in the placebo group were stable over time. <u>HRQOL Over 24Months by Shock Versus No-Shock Groups:</u> a) When comparing HRQOL between those who experienced at least one ICD shock between the FUP periods to those who had no ICD shocks, HRQOL was significantly lower at 6-months on the PCA total score (p<.001), SF-36V-PCS (p=.05) and MCS scores (p=.004), and the KCCQ clinical (p<.001) and overall summary scores (p<.001). b) Similar group differences in HRQOL between shock and no-shock groups were found at 24-months on the PCA (p=.01) and the KCCQ clinical (p=.01) and overall summary scores (p=.005). Receipt of an ICD shock resulted in significantly lower HRQOL and a higher number of reported symptoms over time.

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Manuel (2018) Canada	Qualitative study Semi-structured interviews	Total: n=5 Sex: 5 (100 %) female Age: range: 39–72 years	To gain a fuller understanding of the experiences of five women in the province of Newfoundland and Labrador (NL) who are living with an ICD.	<u>Living with the decision to have an ICD:</u> a) Decision based on the advice of the healthcare provider who they trusted; did not cause a lot of psychosocial distress b) Once perceived they had a cardiac condition that could be treated with ICD, they wanted it c) Recognition of the potential life-threatening cardiac condition was more difficult to deal with than making the decision to have the ICD <u>Creating modes of self-surveillance:</u> a) In a constant state of self-surveillance (always cognizant of bodily functions, looking for any physical signs of failing health, e. g. increase in pulse or palpitations) b) Lack of control (feeling of powerlessness and social isolation) c) Identification of factors that could lead to an ICD shock were collected as a repertoire of things to avoid (e. g. physical activity) <u>Finding a new normal:</u> a) Some were of frame of mind that if ICD fired it was simply doing what it was designed to do b) ICD provided a sense of solace and comfort that many had not felt for a long time c) Each firing of the ICD was a reminder of their illness d) Formal (e. g., healthcare providers) and informal supports (e. g., family, friends, and co-workers) were essential
Matlock (2017) USA	Qualitative study In-depth one-on-one interviews (open-ended questions)	Total: n=48 Sex: 16 (33.3 %) female Age: 27–79 (median 61.5) years Subgroups: ▪ Study 1 (2009): n=20 ▫ Sex: 8 (40 %) female	To explore the influence of cognitive bias on ICD decision making	<u>Cognitive Biases and Heuristics Consistently Observed</u> a) Patients recollected conversations where the clinician provided overemphasis of benefits. Deactivation was rarely discussed at all. b) Experiences such as battery changes and shocks appeared to be minimized. c) Strong default effect in favor of performing the ICD implantation. d) Halo effect around the clinician and the technology itself <u>Cognitive Biases and Heuristics Intermittently Observed</u>

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		▫ Age: 34–72 (median 61.5) years ▪ Study 2 (2013): n=28 ▫ Sex: 8 (25.8 %) female ▫ Age: 27–79 (median 61.5) years		a) Optimism bias was most prevalent among younger decliners who often saw themselves as healthier and less likely than others to need the device. b) Although data contained evidence of emotion at the time of decision making, it was difficult to determine to what degree the emotion influenced the decision making (affect heuristic). c) Among patients who accepted ICDs, the majority appeared to see themselves in a worsened state and who expressed the desire to receive the ICD as a way of improving their QoL or avoiding death. Among decliners, many saw themselves as healthy and viewed the ICD as unnecessary and a "risk" they did not wish to experience. d) Some patients anchored or relied heavily on the 1st piece of information they heard about the ICD, making their decision based on this "anchor" (anchor heuristic). Several patients who chose to have the device implanted anchored on the large size of the early devices. In comparison, the newer, smaller devices seemed to be more acceptable. e) Some patients readily recalled friends and family members who had died from cardiac events, which appeared to influence the patients' estimates of how likely they, too, might suffer a heart-related incident.
McEvedy (2018) Australia and USA	Cross-sectional survey Structured survey	Total: n=270 Sex: 196 (73 %) male Mean Age: 61 ± 14 years	(1) To describe patient knowledge regarding their ICD, (2) identify patient characteristics associated with insufficient ICD knowledge and (3) examine associations between ICD knowledge and willingness to discuss issues relating to ICD deactivation.	<u>Patient characteristics associated with insufficient ICD knowledge:</u> a) Using the 25th percentile as a cut-off point (to ≤ 4 out of 11 correct responses), 77 (29 %) participants were classified as having insufficient ICD knowledge. b) Compared to those with sufficient knowledge, insufficient ICD knowledge was associated with older age (mean: 66 vs 60 years, t=3.399, p=.001), being non-Caucasian and not having experienced ICD shock therapy. Insufficient ICD knowledge was also associated with MCI as measured by Montreal Cognitive Assessment score <24. A significant correlation between ICD knowledge and Montreal Cognitive Assessment scores persisted after controlling for age (partial r=0.232, p<.001). <u>Associations between ICD knowledge and willingness to discuss ICD deactivation issues:</u> a) Insufficient ICD knowledge was associated with greater unwillingness to discuss issues relating to ICD deactivation with clinicians.

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				b) The majority (93 %) of participants, including those with insufficient ICD knowledge, agreed with one or more of the suggested circumstances in which healthcare professionals might raise the issue of ICD deactivation. c) Three quarters (72 %) of participants agreed that deactivation issues should be raised in connection with ICD implantation, while the greatest number (82 %) said they would raise the question themselves if they felt the need to. Over half (55 %) agreed that ICD deactivation should be discussed routinely at ICD clinic appointments.
Merchant (2021) USA	Prospective study Medical records, device clinic records and RM database	Total: n=63 Sex: 42 (67 %) male Mean Age: 67.5 ± 14.3 years	To evaluate health status, trajectories in QoL and clinical outcomes, including cause of death, after the procedure of patients undergoing ICD generator exchange (GE).	<u>Health Status and QoL:</u> a) At the time of GE, SF-36 scores were significantly lower in domains of physical health (physical functioning: 62.3 ± 29.7; limitations due to physical health: 63.3 ± 42.4; energy/fatigue: 60.5 ± 19.4) compared to domains of emotional/social well-being (limitations due to personal/emotional problems: 82.8 ± 32.4; emotional well-being: 81.4 ± 18.1; social functioning: 81 ± 24.8) (p<.001 for each comparison between categories of physical health compared to categories of emotional/social well-being). b) Scores in domains of physical function and general health were significantly lower among patients with medical comorbidities. Among patients with diabetes, scores were significantly lower in physical functioning (40 ± 27.1 vs. 70.8 ± 26.3, p<.001), energy/fatigue (51.9 ± 17 vs. 63.8 ± 19.5, p=.031) and general health (51.2 ± 23 vs. 65.9 ± 20.6, p=.018). Similar for those with chronic obstructive pulmonary disease [physical functioning (34 ± 18.6 vs. 66 ± 29.0, p=.006); general health (37.1 ± 22.3 vs. 65 ± 20.2, p<.001)]. c) Among patients who completed SF-36 assessments at 12 months after GE (n=43) and 24 months post-procedure (n=23), scores in all 9 domains remained similar between baseline and both 12 and 24 month assessments. The pattern of lower scores in physical health domains compared to domains of emotional/social well-being persisted at 12 and 24 months. <u>Clinical Outcomes:</u> a) 4 patients (6 %) experienced appropriate ICD shocks during FUP. Of these, left-ventricular ejection fraction (LVEF) at the time of GE remained impaired in 3 (15 %, 23 %, 35 %) and had improved to 40 % in the remaining patient. None of the 4 had experienced appropriate ICD shocks prior to GE. The incidence of appropriate ICD shocks based on LVEF at the time of GE

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				was 3 out of 35 (9 %) among those with LVEF ≤ 35 %, 1 out of 18 (6 %) among those with improved LVEF (35 %–50 %) and 0 out of 6 among those with LVEF > 50 %. No inappropriate shocks occurred after GE. b) 17 hospitalizations occurred among 15 patients (24 %) during FUP, of which 8 hospitalizations were deemed to be primarily for cardiac causes (one for atrial fibrillation and 7 for HF). c) 5 patients (8 %) died during FUP. Kaplan- Meier estimates of survival after GE were 97 % at 1 year, 92 % at 2 years and 80 % at 3 years post-procedure. 2 deaths were attributed to progressive HF and one to a stroke
Miller (2019) Australien and USA	Cross-sectional study	Total: n=240 Sex: 57 (27.9 %) female Mean Age: 62 ± 13 years Subgroups: ▪ Inadequate health literacy Newest Vital Sign < 3: n=130 ▫ Sex: 34 (26.2 %) female ▫ Mean Age: 64 ± 13 years ▪ Adequate health literacy Newest Vital Sign ≥ 4: n=110 ▫ Sex: 33 (30 %) female ▫ Mean Age: 59 ± 14 years	To identify experiences and attitudes about discussions held with healthcare providers regarding EOL choices (GE and maintenance of defibrillation therapy) among ICD recipients; to determine the level of knowledge regarding ICD function at EOL among ICD recipients and compare knowledge by inadequate and adequate health literacy and to determine the association of health literacy with experiences, attitudes and knowledge regarding EOL choices among ICD recipients.	<u>ICD knowledge:</u> a) The percentage of incorrect answers on the ICD knowledge portion of the EOL-ICDQ ranged from 20 to 62 % per question. The overall ICD knowledge score in the total sample was 5.6 ± 3 (from a total possible of 11). The total score was higher in the adequate health literacy group compared to the inadequate health literacy group (6.4 ± 3 vs. 5 ± 2.8, p<.001). <u>GE:</u> a) Significant predictors of increased odds of answering yes to choosing to have GE in the context of terminal illness scenario were symptoms of anxiety, health literacy, and a positive history of shock. For every one-unit increase in anxiety or health literacy the odds of choosing GE increased by 14 % (p=.017) and 19 % (p=.046) respectively. For those who had a history of previous shock the odds of choosing GE were increased 2.156 times (p=.045). b) Predictors of decreased odds of answering yes to GE in the context of terminal illness scenario were self-reported minority status (non-Caucasian), symptoms of depression, and increased ICD knowledge. The odds of minorities choosing GE were 80.3 % (p=.018) less than their Caucasian counterparts. For every one-unit increase in depressive symptoms and ICD knowledge the odds of choosing GE were decreased by 15.8 % (p=.001) and 13.8 % (p=.046). c) For every one unit increase in health literacy (sole predictor) the odds of indecisiveness were increased by 19.4 % (p=.046).. For every one-unit increase in ICD knowledge (sole predictor) the odds of indecisiveness decreased by 20.4 % (p=.009). <u>Defibrillation therapy maintenance:</u>

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				a) The odds of women choosing to maintain defibrillation therapy were 2.288 times higher (p=.027) than that of their male counterparts (sole predictor female gender). b) For every one-unit increase in ICD knowledge (sole predictor) the odds of choosing to maintain defibrillation therapy were decreased by 11.4 % (p=.038). <u>Predictors of attitudes about the ICD at EOL:</u> a) ICD knowledge was a predictor of decreased odds of choosing GE, maintaining defibrillation therapy and indecisiveness regarding GE in terminal illness. b) Female gender; leaves women at increased risk of shocks in the active dying phase. c) psychological comorbidities ; by affecting the odds of choosing GE in the context of terminal illness. Anxiety increased these odds and depression lowered them.
Mirro (2018) USA	Cross-sectional study Survey	Total: ▪ Patients: n=128 ▫ Sex: 88 (68.8 %) male ▫ Age: mostly age 66 or older (58 %) ▪ Providers: n=48 ▫ Sex: 40 (83.3 %) female ▫ Age: range: 25–68 Subgroups: ▪ Group A (patient notification summary through patient portal): n=62 ▫ Sex: 40 (64.5 %) male	To measure the impact of sharing ICD RM data with patients via paper mailings or electronically through a patient portal on engagement, satisfaction, and healthcare utilization. We also surveyed providers' perceptions of the utility of this information and potential effects on clinical workload. <u>Intervention:</u> Randomization: Electronic intervention (Group A) or paper intervention (Group B). Electronic intervention group received ICD data	With regard to types of information desired, most patients wanted information about: Battery life status (87 %), date and time of ICD-related events (episodes) (83 %), heart rate and pacing (81 %), condition of lead wires (both pacing and shock coils) (78 %), number of shocks and/or antitachycardia pacing (77 %) and ICD therapy settings (63 %). <u>Patients' experiences with ICD data summary:</u> a) Group A expressed greater preference for their data summary than the standard of care letter than Group B ($F(1134)=5.95$, p=.0160, $\eta^2=.0425$). b) At baseline, Groups A and B expressed low levels of satisfaction with the amount of information they received through the current standard of care letter. Patient satisfaction related to amount of information increased in both groups after receiving the ICD data summary. Post hoc tests showed significant increases from baseline to 3-month (Group A and B: p<.0001) and baseline to 6-month (Group A: p<.0001; Group B: p=.0002), suggesting that satisfaction levels for both groups increased throughout the intervention. c) Group A found ICD data summary significantly easier to access through the patient portal compared to Group B (accessed through postal mail). d) Groups A and B found ICD data summaries easy to understand and useful.

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		▪ Group B (patient notification summary through letter): n=66 ▫ Sex: 48 (72.7 %) male	summary in patient portal, paper intervention group received printed ICD data summary in postal mail. Both groups received ICD data summary every 3–4 months. All participants received one-on-one training at enrollment using an example ICD data summary and were given handouts explaining how to access it in patient portal. Providers from the cardiology clinic took a survey at the end of the study.	e) Most participants in both groups did not want to have to contact their healthcare provider's office to understand ICD data summary. Workload measures: a) Healthcare visits to the hospital ($\chi^2(1)=0.18$, p=.67, OR=0.76), cardiology ($\chi^2(1)=3.39$, p=.07, OR=0.74), emergency room ($\chi^2(1)=2.10$, p=.15, OR=0.90), and Arrhythmia Diagnostic Clinic ($\chi^2(1)=0.55$, p=.46, OR=0.90) did not significantly increase from pre- to post-enrollment for the two groups. b) Over the course of the intervention, there was no significant increase (for both groups) in number of phone calls to cardiology clinic ($\chi^2(1)=3.43$, p=.06, OR=1.01) or messages to providers through the patient portal ($\chi^2(1)=1.46$, p=.23, OR=0.56). c) Analysis showed that number of ICD-related messages (χ^2 (1)=.04, p=.83, OR=1.11) and phone calls (χ^2 (1)=2.03, p=.15, OR=0.83) did not increase significantly from pre-to post-enrollment. Provider survey: a) Providers believed the ICD data summary was easy for patients to use and understand and useful in managing their health. Providers indicated that patients would value the information; they expressed concerns that patients could misinterpret medical information or it might be of little utility to patients due to lack of technical ability. c) Majority (83 %): ICD data summary allows for better patient-provider communication.
Murray (2021) UK	Mixed methods design Validated and adapted questionnaire and semi-structured survey	Total: n=139 Sex: 106 (76 %) male, 33 (24 %) female	To enable the efficient delivery of effective ICD support groups, by clarifying - patient perspectives of key challenges - patient interest in a support group	key ICD concerns: a) Total scores on the ICDC-B ranged from 0 to 32 (median=6, interquartile range =2–10) Emotional adjustment: a) Sense of gratitude, safety and reassurance (n=42) b) Increased anxiety and sense of vulnerability (n=15) c) Adjustment over time (n=10) Functional and role changes: a) Self-identity and role changes (n=5)

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			- topics deemed helpful to address in a support group - factors which affect patient inclination to attend a support group	b) Improved functioning and QoL (n=18) c) Physical discomfort (n=15) d) Practical adjustments (n=37) e) Minimal consequences (n=63) <u>Intention to attend a support group:</u> a) n=58 (42 %) would attend a support group for patients with ICDs. Indicating attendance was associated with more recent implantation (median=45 months), compared to not wanting to attend a support group (median=63 months, p<.03) b) Patients who would attend reported higher levels of ICD concerns (median ICDC total=6) than those who would not attend a support group (median ICDC total=4.7, p<.02). <u>Support group topics (endorsements):</u> a) Information about heart conditions (n=72/62 %), impact of an ICD on daily life (n=63/54 %), information about ICDs and how they function (n=63/54 %), coping with fear of shocks (n=62/53 %), emotional impact of having an ICD (n=47/41 %), how our psychological reaction affects adjustment (n=35/30 %), impact on sex life (n=27/23 %), impact on relationships and changed roles (25/22 %), body image concerns (24/21 %), impact on self-image (21/18 %)
Nagy (2019) USA, Israel, Canada, Italy, Denmark, Germany, France, Spain, Netherlands, Poland, Hungary,	Prospective, multicentre clinical trial (substudy of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization	Total: n=1791 Sex: 444 female Subgroups: ▪ CRT-D: n=1069 ▪ ICD-only: n=722	To assess the predictive value of baseline QOL questionnaire domains to predict long-term all-cause mortality, the combined endpoint of all-cause mortality or HF events, and HF events alone; as well as to ascertain any differences in the degree of left ventricular reverse remodelling to	<u>Patients with mobility issues at baseline (EQ-5D):</u> a) Patients with mobility issues at baseline had a significantly higher risk of death (29 % vs. 17 % at 7 years, p<.001), reached more frequently combined endpoint of HF/death (48 % vs. 33 % at 7 years, p<.001) and HF alone (38 % vs. 25 % at 7 years, p<.001) b) Multivariate Cox hazards regression analysis: after adjusting to relevant clinical covariates, issues within all domains of baseline EQ-5D questionnaire were significantly associated with long-term mortality (in all analyses p<.05); every 10 % increase in overall health status (visual analog scale) was associated with an 8 % lower risk of all-cause death (p=.006) and with a 6 % lower risk of HF/death (p=.002); HF events were only associated with issues in baseline mobility [HR=1.42, p<.001] or issues in usual activity (HR=1.35, p=.002)

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Switzerland and UK	Therapy (MADIT-CRT))		CRT-D by baseline QoL questionnaire parameters, in mild HF patients enrolled in MADIT-CRT	Patients in the first and second tertiles of KCCQ clinical summary score and KCCQ physical limitations score: a) Significantly higher cumulative probability of death and higher cumulative probability of HF/death or HF alone (all p<.001); 59 % and 36 % higher risk for long-term mortality, 71 % and 40 % higher risk of HF/death events and 77 % and 43 % higher risk of HF events alone, as compared to patients in the third tertile (all p<.05)
Nair (2021) Canada	Cohort study (substudy of BRUISE CONTROL-1 and 2 RCTs) Standardized and validated questionnaire	Total: n=1308 Sex: 950 (72.6 %) male Mean Age: 72.7 ± 9.7 years Subgroups: ▪ Pulse GE: n=654 ▪ De novo PM: n=327 ▪ ICD insertion: n=327	To identify factors associated with post-operative pain and develop a prediction score for post-operative pain (HeADSS score)	a) The presence of post-operative clinically significant haematoma, de novo surgery, female gender, younger age (<65 years) and lower body mass index (< 20 kg/m2) showed significant association with increased post-operative pain (these variables were evaluated in a multivariable logistic regression model) b) In the final risk prediction model, statistically significant predictors of increased post-operative pain: clinically significant haematoma, de novo surgery, female sex, age <65 years, and body mass index <20 kg/m2 (female sex as the reference group as it had the lowest risk)
Ng (2020) Canada	Cross-sectional study	Total: n=342 Sex: 82 % male Mean Age: 66 ± 13 years Subgroups: ▪ Aged < 65 years: n=126 ▫ Sex: 79 % male ▫ Age: 53 ± 11 years ▪ Aged > 65 years: n=216 ▫ Sex: 85 % male ▫ Age: 74 ± 6 years	To identify how patient age affects device acceptance and shock anxiety among ICD patients and to examine factors such as sex, previous shock history, and RM use on these parameters.	Age and HRQoL: a) Younger patients reported greater device-related distress (25 ± 20 vs 15 ± 19; p<.001), more body-image concerns (22 ± 25 vs 8 ± 18; p<.001), greater overall shock anxiety (17 ± 7 vs 14 ± 5; p<.001), higher scores on the mean consequence scale (1.6 ± 0.7 vs 1.3 ± 0.5; p<.001), mean triggers scale (1.7 ± 0.7 vs 1.5 ± 0.7; p=.004) and less total device acceptance (76 ± 15 vs 81 ± 15; p=.001) compared with older patients. b) Poor device acceptance was reported by 20 % of younger patients, compared with 10 % of older patients (p=.004). Sex and HRQoL: a) Male patients reported lower return-to-function scores compared with female patients (64 ± 26 vs 74 ± 24; p=.006). b) Younger male patients reported more body-image concerns (20 ± 23 vs 9 ± 18, p<.001) and greater device-related distress (26 ± 21 vs 15 ± 19; p<.001) compared with older male patients.

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				c) Younger female patients also reported more body-image concerns (26 ± 32 vs 4 ± 13; p<.001) and greater device-related distress (22 ± 17 vs 13 ± 18; p=.02) compared with older female patients. <u>RM and HRQoL:</u> a) Patients using RM (n=228; 75 %) reported greater positive appraisal (88 17 vs 77 27; p<.001) and total device acceptance (81 ± 14 vs 75 ± 18; p=.011) compared with those who do not use RM. b) Younger ICD patients using RM reported greater device-related stress (24 ± 20 vs 13 ± 18; p<.001), body-image concerns (22 ± 25 vs 6 ± 14; p<.001) and total device acceptance (76 ± 14 vs 83 ± 13; p<.001) compared with older ICD patients using RM. <u>Previous shock and HRQoL:</u> a) Patients with prior shocks reported higher scores in the mean consequences scale (1.6 ± 0.7 vs 1.3 ± 0.5; p<.001), mean triggers scale (1.7 ± 0.8 vs 1.4 ± 0.6; p=.006), and greater total shock anxiety (16.8 ± 6.8 vs 13.7 ± 4.9; p<.001) compared with patients with no previous shock. b) Stratified by age, younger patients with prior shocks reported greater device-related distress (24 ± 20 vs 14 ± 16; p=.004), more body-image concerns (22 ± 28 vs 7 ± 14; p=.001), and greater total shock anxiety (20 8 vs 15 5; p<.001) compared with older patients with prior shocks. c) Younger patients with no prior shocks also reported greater device-related distress (25 ± 21 vs 14 ± 19; p<.001), more body-image concerns (21 ± 24 vs 9 ± 19; p<.001), and greater total shock anxiety (16 ± 6 vs 13 ± 4; p<.001) compared with older patients with no prior shocks.
Paech (2020) Germany	Cross-sectional study	Total: n=136 Subgroups: ▪ Patients with PM: n=63 ▫ Sex: 29 (46 %) male, 34 (54 %) female	To examine depressive and anxiety symptoms as well as QOL of children with a PM and with ICD and to compare these to healthy peers.	<u>QOL (KIDSCREEN-10 questionnaire):</u> a) No significant differences in QOL when comparing patients with cardiac PM to healthy peers (n3; p=.41) b) Patients with an ICD had a significantly lower QOL than healthy controls (n3; p=.03) <u>Anxiety symptoms (Screen for Child Anxiety-Related Emotional disorders questionnaire):</u>

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		▫ Age: 44 (70 %) ≤ 14years, 19 (30 %) ≥ 15years ▪ Patients with ICD: n=23 ▫ Sex: 15 (65 %) male, 8 (35 %) female ▫ Age: 10 (44 %) ≤ 14years, 13 (55 %) ≥ 15years ▪ Healthy peers (LIFE study): n=50		a) Analysing the questionnaire self-report separating male from female patients, boys under the age of 15 years showed significantly higher anxiety symptoms compared to their older peers (p=.03) Self-perception/self-esteem (SPPC-D questionnaire): a) Female patients with a PM or an ICD showed a significantly lower physical appearance score compared to male patients with a PM or ICD (p=.02)
Patel (2020) USA	Cross-sectional survey	Total: n=344 Sex: 123 (36.3 %) female Mean Age: 62. 9 ± 12.8 years	To test patients' basic knowledge of their cardiac CIEDs and what information from their CIEDs they would find most useful for their daily lives.	Baseline knowledge: a) 63.2 % agreed or strongly agreed that they were knowledgeable about their device, while only 11 % disagreed or strongly disagreed with the statement Patient knowledge compared to device interrogation reports: a) 85.5 % of patients missed at least one basic question about devices with 51.2 % missing at least 2 of the 7 questions on the survey. b) Multiple-choice question that was answered most correctly was device manufacturer (91 %), while least correctly answered was battery life (59 %) Information desired by patients: a) Patients agreed or strongly agreed that each of the variables that a CIED could potentially provide would be useful for their knowledge. The variable that the most patients (strongly) agreed would be useful to know was battery life (83.6 %) while the least favorable to know for them was sensing/ impedance of leads (53.5 %)

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Peplow (2018) UK	Prospective single-center study Structured questionnaire	Total: n=232 Subgroups: ▪ Day-case: n=101 ▫ Sex: 67 (66 %) male ▫ Mean Age: 66 ± 15 years ▪ Nonday-case: n=131 ▫ Sex: 89 (68 %) male ▫ Mean Age: 72 ± 12 years	To perform a single-center prospective audit of a day-case cardiac rhythm management device implantation service, including data on patient satisfaction.	Patients: a) In comparison to the nonday-case cohort, the day-case group were younger (p=.002) and less likely to have a complex transvenous device (CRT/ICD) (44 % vs 67 %; p<.001). b) The operator was more likely to use cephalic access in the day-case group (p=.01 for right atrial and p=.04 for right ventricular lead), though this is likely in part to reflect the increased use of CRT in nonday-case patients. Complications: a) No group difference in complications (day-case group: 12 (11.9%), nonday-case group 15 (11.3 %), p=.92). Lengths of stay and cost saving: a) Of 101 planned day-case patients, 93 (92 %) went home the same day, 5 (5 %) the next day, and 3 (3 %) stayed longer than one night. b) Of 131 nonday-case cohort, 116 (89 %) went home the next day as planned, 9 (7 %) stayed overnight for 2 days, and 6 (5 %) patients stayed beyond that. c) The total number of overnight bed days used was 12 in the day-case cohort (n=101) and 159 in the nonday-case group (n=131). Patient experience: a) Overall satisfaction was high with median scores of 5 (interquartile range 5–5), on a scale of 0–5, for each question. b) Majority of patients (n=98, 98 %) felt ready to go home on discharge, minority (n=5, 5 %) would have preferred an overnight stay.
Pike (2020) USA, Iran, Canada, UK, Sweden, Italy, Turkey,	Systematic qualitative review	Total: Studies: n=27 Patients: n=479 Sex: 328 male, 148 female, 3 not reported	To synthesize the best available qualitative evidence on the everyday life	Constant surveillance: a) rigorous attention to one's physical surroundings and biological functions b) In hope of avoiding the ICD firing by addressing precipitating factors that may cause a cardiac event Anticipating an ICD shock:

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Singapore, Spain and Australia		Age: range: 20–91 years	experiences of adults living with an ICD for cardiovascular disease.	a) ICD recipients knew that likelihood of ICD discharging was high b) The uncertain nature of when, where, how, and the outcome caused significant distress <u>Restricting activities:</u> a) ICD recipients based their level of physical activity on their perceived risk of the activity to cause the ICD to fire b) Many experienced a significant decline in their level of activity. This perception was informed by previous experiences, one's personal theories of risk and the advice of their health care provider <u>Quality of information:</u> a) ICD recipients unanswered questions about the operation influence their level of confidence to engage in ICD self-management b) Full explanation of the rationale for the ICD, how it works, its management and FUP care (e. g., battery replacement) in layman's terms by professionals is important, regardless of the recipients onus of seeking information. c) The delivery of consistent, accurate information is critical to instilling a sense of confidence in the health care professional's capability <u>Body image:</u> a) For some recipients, adjusting to the ICD lends itself to creative modes to keep it hidden or less visible from others b) Small reminders (e. g., itchy site) of ICD could not be erased easily c) Revealing having an ICD to others augmented feeling vulnerable <u>Living with an ICD:</u> a) Substantial distress as they struggle to embody the ICD as part of their everyday normal life. Accepting that the ICD was there to prevent SCD (while still being fearful of death) c) Experience of substantial psychosocial distress while coming to terms with the necessity of it to survive

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				d) Constant uncertainty of the future coupled with the lack of control over their lives that rendered the recipients vulnerable, sparked depression and caused them to reflect on their QoL with the ICD. Changing roles: a) Family members became overprotective and took over many household responsibilities. While ICD recipients understood that this was out of concern, some found it frustrating.
Pyngottu (2019) USA, Brazil, Netherlands and Germany	Systematic Review	Total: Studies: n=14 Patients: n=1872	To evaluate and summarize the current evidence on generic and disease-specific HRQoL and psychological adjustment in paediatric patients with a PM or an ICD	Patients with an ICD/PM and their parents showed lower HRQoL (generic scales) and similar disease-related HRQoL as pateints with severe CHD No significant diefference between PM patients and norms regarding anxiety and depression; whereas ICD patients experienced more depression and anxiety
Rao (2022) USA	Qualitative key informant study In-depth, semistructured interviews	Total: n=20 Sex: 11 (55 %) male, 9 (45 %) female Age: 6 (30 %) <65 years, 14 (70 %) ≥65 years	To explore drivers of patients' decision-making about ICDs in greater depth and to identify potential refinements or interventions to improve the SDM process	Patients´ Path to an ICD Decision: a) 18 of the 20 patients described a decision-making path that occurred over multiple visits, starting with learning about an ICD and its purpose and ending with a decision. Patients generally reported receiving input about the ICD from multiple clinicians and other sources of support. Some patients had multiple visits with their cardiologist and a visit with the electrophysiologist before they made a decision regarding ICD implantation. The encounters with nonelectrophysiologists were often critical to decision-making. Electrophysiologists played a heterogeneous role in these patients' ICD decisions Drivers of Patients' ICD Decisions: a) the numeric, probabilistic data regarding risks and benefits presented in the PDA b) Most patients' trust in their clinician's recommendation drove their decision (limited participation in decision). Some made their decision based on a misunderstanding of the purpose of ICD therapy The role of PDA in patients' ICD decisions:

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				a) Patients who had received the PDA, many reported it was rarely used during encounter, although some referenced the document afterward. If it was used by clinician, patients found it helpful. Some patients wished they had the PDA before meeting with the electrophysiologist <u>Patient experiences making an ICD decision:</u> a) 19 of 20 patients: did not feel pressured into their decision about an implantation b) Some patients requested support for emotional struggles associated with their decision. They desired specific information addressing aspects of living with an ICD (e. g. the sensation of an ICD shock). Some were surprised by size, location and bulkiness of the device c) Patients recommended strategies for clinicians to improve communication during the encounter. For example: acknowledging patient's concern, patient's lack of participation in the decision because of the amount of fear experienced, as well as the influence of procedure related fear e.g. of post-procedural recovery.
Rao (2022) USA	Natural experiment Surveys, administered by a single individual via telephone	Total: n=101 Sex: 40 (39.6 %) male Age: 51 <65 years, 50 ≥65 years Subgroups: ▪ Pre-mandate group (implantation prior 2/2018): n=45 ▫ Sex: 28 (62.22 %) male ▫ Age: 21 <65 years, 24 ≥65 years ▪ Post-mandate group (implantation after 2/2018): n=56	To better understand how mandated decision aid use has impacted relevant domains of patients' experiences and decisions	a) No significant differences in composite knowledge about ICDs, decision conflict, values-choice concordance or engagement in the decision-making process pre- and post-mandate b) Participants implanted pre-mandate were more likely to correctly identify the frequency of minor complications (66.7 % vs. 37.5 %, p=.012) c) Individual components of decision conflict scale were similar, though pre-mandate patients were less likely to report an understanding of the benefits of ICD (88.2 % vs. 94.6 %, p=.0456) d) 39 of 56 post-mandate patients (69.6 %) remembered receiving the decision aid. Of those who remembered the decision aid, n=36 (92.3 %) reported reading the decision aid prior to the procedure, n=35 (97.2 %) felt it helped them feel more comfortable with their decision, and n=34 (94.4 %) felt it helped improve discussions with their doctor

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		▫ Sex: 33 (41.07 %) male ▫ Age: 30 <65 years, 26 ≥65 years		
Rohani-Ghahari (2018) USA	Qualitative study Four focus groups	Total: n=24 Subgroups: ▪ patients: n=16 ▫ Sex: 10 male, 6 female ▫ Mean Age: 67.4 (range: 41–85, median=68) years ▪ informal caregivers: n=8 ▫ Sex: 2 male, 6 female ▫ Mean Age: 64.5 (range: 53–72, median=66) years	To understand patients' experiences and needs around CIED data delivery and education to support patient decision-making.	<u>Patient experiences with CIED and CIED RM:</u> a) Participants reported positive experiences with the CIED and the RM process. Patients attributed improvements in their heart condition to CRT-CIED and valued having clinicians reviewing their data. b) Dissatisfaction with RM interface design (e. g. bright device lights) c) Participants discussed concerns about traveling with a CRT-CIED along with RM and the ability to continue to transmit data. They desired a device that was portable and could transmit data wirelessly. d) Participants described the need for all of their healthcare providers, at any location, to have immediate access to their device data. Long lag time for receiving notification of an event hinders their understanding of the event, as it may lead to difficulty in recalling and linking that event to their experience (i. e., symptoms and activities). <u>Content for CIED alerts and data presentation:</u> a) Preference for content signifying the level of importance (e.g., a visual representation and meaningful use of color) along with simple warning words, instructions for action and simplified information instead of having to interpret numerical data on their own. c) Specific information as being critical to view, including battery status and whether the CRT-CIED was working effectively. d) Desire to receive CRT-CIED data for a specific time period to view trends in heart function. e) Patients: In the case of 'normal' reports, preferred to receive letters. Preferred digital display in general (e. g. on a smartwatch/-phone), as a means to view notification at a glance. <u>Opportunities for patient learning:</u>

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				a) After implantation of CRT-CIEDs, all participants reported being concerned about if and when they could resume their normal physical activities. b) Uncertainty about the safety of using/being near specific machinery due to magnetic field implications for the CRT-CIED. c) Need to better understand their device data and other related cardiac test results. d) Need for instructions and training material for emergencies/'abnormal' alerts. e) Concern that physicians have limited time during clinic visits and about asking too many questions during an office visit.
Sapp (2021) Canada	Multicentre before-and-after pilot study	Total: n=176 Subgroups: ▪ PM: n=76 ▫ Sex: 28 (37 %) female ▫ Mean Age: 63.4 ± 16.5 years ▪ ICD: n=100 ▫ Sex: 29 (29 %) female ▫ Mean Age: 62.5 ± 11.8 years	To evaluate the feasibility, safety and utilization of a remote-only patient management system, along with its effects on patient QOL and costs, which would reduce the need for in-clinic FUP at specialty sites for patients with CIEDs.	Safety: a) Composite end point (death, stroke, cardiovascular or device-related hospitalization) occurred in 12 (7 %) of 164 participants who completed the 12-month FUP, counting first event. Implementation and adherence: a) Of 176 patients, 153 (87 %) were adherent to RM FUP. Of these, 85 (85 %) of the 100 patients with a defibrillator and 68 (89 %) of the 76 patients with a PM had at least 1 remote transmission during the study and were considered adherent. Health care utilization: a) Among the 48 patients with defibrillators, there was a significant reduction in the proportion who had any type of in-clinic visit (36 [75 %] before v. 21 [44 %] after, p<.001), which was predominantly due to a significant reduction in visits to specialized sites (26 [54 %] v. 5 [10 %], p<.001). b) Among the 51 patients with PM, the proportion with in-clinic visits declined (42 [82 %] before v. 10 [20 %] after, p<.001), and the proportion with remote transmissions increased (2 [4 %] v. 43 [84 %], p<.001).
Schneider (2020) USA	Cross-sectional	Total: n=32 dyads (patients and their parent)	To describe the needs of pediatric ICD patients from both patient and par-	Most frequently endorsed needs by patients involve educational issues (e.g. understanding their diagnosis (34%) and medication (34%), lifestyle change due to ICD (31%))

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		Sex: Patients 28 % female, Parents 72 % female Mean Age (patients): 15.53 (SD=3.59, range: 8-21)	ent perspectives. The secondary purpose is to determine whether patient factors of gender, age, depression, and anxiety are associated with the likelihood of endorsing specific needs	Experiencing peer issues was more frequently endorsed by females (33% of females vs 4% of males; p=.026) Most frequently endorsed needs by parents involve family issues (e.g.: concern about child's frustration with parent's overprotectiveness (47%), child feeling depressed/ anxious (28%) Parents feeling overprotective were significantly younger
Schulz (2020) Germany	Randomized controlled trial	Total: n=118 Sex: 26 (22 %) female Mean Age: 58.8 ± 11.9 years Subgroups: ▪ UC: n=59 ▫ Sex: 15 (24.5 %) female ▫ Mean Age: 59.9 ± 10.8 years ▪ Web based intervention (WBI): n=59 ▫ Sex: 11 (18.6 %) female ▫ Mean Age: 57.6 ± 11.5 years	To examine the efficacy of a WBI integrated into routine care for improving HFA, depression, and mental QOL in ICD patients with increased psychosocial distress. Intervention: WBI: 6 weeks' access to a password-protected structured interactive internet programme for groups of 7–14 patients; additional content automatically unlocked each week; patients could enter feedback regarding usability and helpfulness of particular contents via ratings and text entries.	Primary outcomes: a) Changes from baseline in the composite primary outcome were similar in the WBI and UC groups, both at 6 weeks [parameter estimate (EST) -0.12, standard error (SE) 0.18, 95 % CI -0.23 to 0.47; p=.50; np^2=.001] and 1 year (EST -0.19, SE 0.18, 95 % CI -0.55 to 0.17; p=.29; np^2=.003). Secondary outcomes: a) WBI vs. UC differences emerged in the Hospital Anxiety and Depression Scale (HADS) depression component of the primary outcome. An EST of -2.98 points (SE 1.03, 95 % CI -5.00 to -0.96; p=.004; np^2=.032) results from a mean ± SD decrease from 8.1 ± 3.8 to 5.9 ± 3.8 points in the WBI group and an increase from 7.2 ± 3.8 to 8 ± 3.8 points in the UC group from pre-intervention to 1 year. The majority of this difference emerged between 6 weeks and 1 year (EST -2.43, SE 1.00, 95 % CI -4.40 to -0.47; p=.02; np^2=.026). b) The HADS anxiety subscale score decreased from 6.8 ± 4.6 to 6.5 ± 4.6 points in the WBI group and increased from 6.1 ± 4.6 to 7.7 ± 4.6 points in the UC group from 6 weeks to 1 year (EST -2.33, SE 1.07, 95 % CI -4.44 to -0.23; p=.03; np^2=.022). Questionnaire subscales: a) Exploratory analysis of FERUS subscales showed significant effects of WBI compared with UC from pre-intervention to 6 weeks for active and passive coping (p=.01; np^2=.018) and from 6 weeks to 1 year for social support (p=.048; np^2=.014).

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
			Based on this input, patients received automatic feedback (e.g. recommendation to discuss poorly understood content with other users or the psychologist). S.M.S. also initiated and moderated group discussions for each topic.	Evaluation of clinical significance: a) Reliable change index analysis showed that WBI vs. UC was associated with clinically significantly improved mental QoL in 5 patients (8.5 %) from pre-intervention to 1 year. In contrast, UC vs. WBI was associated with clinically significantly deterioration of mental QoL in 3 patients (4.7 %). Evaluation of web-based intervention content: a) 36 patients randomized to WBI indicate that the program was helpful (mean 3.1 ± 0.9) and usability was high (mean 3.1 ± 0.9). b) Support provided by the trained psychologist and reading contributions to the discussion board were considered particularly helpful. c) The WBI was considered a trustworthy and supportive place where patients could learn coping strategies, were inspired to try new things, and learned how to manage their illness. d) Topics rated as most helpful (score ≥2.5) were medical background information, information on what (not) to avoid with an ICD, understanding ICD shock therapy, psychological models regarding factors that contribute to development and persistence of anxiety, the two column-technique for dealing with cognitive error, and guidance for developing a resource-oriented problem-solving style.
Sears (2020) USA	Cohort study	Total: n=45 Sex: 63 % male Mean Age:62.4 (SD=11.7, range: 39–84)	To examine the impact of readily available mobile electrocardiogram (mECG) capability for a sample of ICD patients.	Anxiety: a) Patients who had an ICD longer reported significantly less cardiac anxiety at baseline, r2=.112, p=-.559, F(1, 43)=5.406, p=.025. b) Younger patients at implantation had greater baseline shock anxiety, r2=.097, p=-.153, F(1, 43)=4.604, p=.038. c) Shock anxiety was significantly higher at 30-day FUP (mean=18.4, SD=8.07) than at baseline (mean=15. 7, SD=6.39), t(44)=2.04, p=.05, d=0.38. ICD device acceptance: a) Significantly improved device acceptance at 30-day FUP (mean=75.3, SD=16.8) than at baseline (mean=70.5, SD=18.6), t(32)=2.54, p<.05, d=0.27.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				b) Significant negative relationship between multiple shocks and mECG use, rS(45)=-.320, p=.032. Indicating fewer ICD shocks were associated with more mECG use. mECG technology satisfaction a) ICD patients reported high and desirable levels of satisfaction with mECG technology (mean 4.4) on a 1 to 5 Likert scale.
Senn (2020) Germany	Qualitative Studie Leitfadengestützte Interviews	Total: Patientinnen und Patienten: n=10 Ärztinnen und Ärzte: n=3 Geschlecht: 1 Patientin Alter: 73 ± 8 Jahre	Zentrale Aspekte der („disease-related quality of life“) disease-related QOL dieses Patientenkollektivs (mit ICD) zu erfassen	Verständnis und Veränderung der disease-related QOL: a) Mehrheitlich langfristig kein Gefühl von starker Einschränkung b) Limitierender Faktoren: Grunderkrankung des Herzens, Alter oder Komorbiditäten c) Haupteinflussgrößen: Bewältigungsstrategien (Coping), Kohärenz Kohärenz: a) Verständnis der ICD-Funktionen in Abhängigkeit vom Vorwissen (Laie, Experte) als Voraussetzung für Wohlbefinden angeführt. b) Alle erkannten den Sinn der lebenserhaltenden Funktion als Alternative zum Tod. Sie empfanden mehr Sicherheit oder weniger Angst. c) Im Zeitverlauf wurde der ICD internalisiert oder als Teil des Selbst wahrgenommen. Generalisierte Widerstandfähigkeit: a) Eigenes medizinisches Wissen und Informationen über die Indikation und die Therapie waren förderlich. Informationsquellen: ärztliche Aufklärung, Broschüren, Internetrecherchen, Literatur oder Austausch mit Familie oder Freunden mit medizinischen Kenntnissen. b) Familie, Ehe- oder Lebenspartner waren eine Hilfe beim Umgang mit dem ICD ICD-assoziierte psychosoziale und physische Stressoren: a) Viele Patienten spüren ICD im Zeitverlauf nicht mehr; einige als störenden Fremdkörper b) Schock wird mit Schmerzen, Angst und Unsicherheit verbunden c) Einige Patienten stören sich langfristig an ästhetischen Veränderungen Individuelles Coping:

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				a) Eine positive Grundeinstellung oder die Aufrechterhaltung des positiven Selbstbildes wirkt unterstützend b) Patienten mit Schockerlebnissen und langer Krankheitshistorie attestieren sich gute Lebensqualität und fühlen keine Einschränkung c) Coping ist u. a. von Alterserscheinungen, Schicksalsschlägen oder körperlichen Einschränkungen durch Komorbiditäten abhängig
Spitzer (2017) Germany	Prospective, observational study Data from a large-scale registry (German DEVICE registry)	Total: n=2356 Subgroups: ▪ Discharged within 24 h: n=527 ▫ Sex: 461 (87.5 %) male ▫ Mean Age: 64.3+11.6 years ▪ Hospitalized for >24 h: n=1829 ▫ Sex: 1501 (82.1 %) male ▫ Mean Age: 64.5+13.6 years	To analyse the long-term safety of ICDs in patients discharged within 24 h or after 2–5-day hospitalization, respectively, after complication-free implantation, in circumstances of actual care.	FUP: The only significant difference between the groups was in rates of major adverse cardiovascular or cerebrovascular events, which were 5.2 % in the cohort of patients discharged within 24 h vs. 8.5 % in patients hospitalized post-procedure (p=.017). QoL: In both cohorts, improvements in QOL were reported for a majority of patients with highly similar distribution of patients reporting symptomatic improvements, unchanged or worsened in both cohorts.
Srivatsa (2020) USA	Cross-sectional study Mailed questionnaires	Total: n=34 Sex: 26 (76.5 %) male Mean Age: 63 ± 13.5 years (91.8 % over age 45) Subgroups: ▪ Remote group (R): n=21 ▪ Clinic group (C): n=13	To understand patient preferences in the pathways (clinic vs. RM) regarding their device care to make device appointments more satisfactory to patients and more clinically effective.	a) importance of different factors to respondents: I) ease of scheduling of appointments (83 %), II) convenience of device interrogation appointments (76 %), III) cost consideration (69%), IV) human contact (80 %), V) opportunity to ask questions (85 %), VI) accuracy of device interrogation (96 %) b) Regarding satisfaction of the pathways, between R and C groups, there was no difference in perception of convenience (4.2 vs. 4.3), ease of scheduling (4 vs. 4.2) or cost (3.9 vs. 4.0) c) Clinic visit was favored over RM FUP for opportunities to ask questions (3.6 vs. 4.3, p=.05) and human contact (3.2 vs. 4.3, p=.002)

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
Standing (2021) UK	Qualititative study Clinical observations interviews with patients, family members and clinicians	Total: Observations: n=38 Interview participants: n=80 Patients: n=44 Sex: 33 male and 11 female %male Age: range: 47–85 years Bereaved relatives: n=7 Clinicians: n=29	To explore the attitudes towards ICD deactivation and initiation of deactivation discussions among patients, relatives and clinicians.	<u>Current status of deactivation discussions:</u> a) Patients were not consistently engaged in deactivation discussions and when this did occur, the patient was often close to death b) Failure to deactivate ICD in timely manner could result in stressful and upsetting situations c) Bereaved relatives felt that deactivation was often poorly handled. Suggested reason for this was clinicians' apparent reticence to deactivate the ICD prior to the patient being in the last hours of life d) Some patients reported facing apparent resistance from clinicians when trying to express their preference for deactivation <u>Patients' perceptions of deactivation:</u> a) Deactivation was not necessarily viewed negatively, it was a means of avoiding unpleasant and unnecessary shocks. Knowledge that deactivation may be a possibility could offer a sense of control. b) For some patients the idea of deactivation was of concern. The device could become a source of comfort, which patients wished to keep activated as long as possible. <u>Responsibility for deactivation discussions and decisions:</u> a) HF nurses, cardiologists, physiologists, palliative and primary care clinicians may all have a role in both advance deactivation discussions and the ultimate decision to deactivate the ICD. None of these currently took primary responsibility for these tasks. <u>Timing of deactivation discussions:</u> a) Pre-implantation offers the first opportunity to introduce deactivation. Potential influence on a patient's decision was recognized. b) Most patients expressed a preference to be informed about deactivation prior to implantation, some clinicians were less convinced. c) Introducing deactivation pre-implantation was viewed as an 'illogical juxtaposition', which might give mixed messages and cause distress.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
				d) To discuss EOL was seen as inappropriate and potentially confusing. e) Both patients and clinicians indicated that deactivation should be an ongoing and evolving discussion, where the appropriateness of the ICD and how it fits with the patient's life is regularly reassessed.
Stoevelaar (2018) USA, Sweden, Canada, Denmark and New Zealand	Integrated review	Total: n=15 studies (n=13 reporting on incidence, n=3 reporting on impact)	To provide an overview of studies reporting on ICD shock incidence and impact in the last phase of life.	Incidence of ICD shocks: a) 7 studies reported on shock incidence (22–66 %) in final hour of life. 3 of these studies reported that 17–32 % of patients experienced shocks in the last month of life. 4 studies showed that in the last 24 hours of life, 3–32 % of patients experienced shocks. 2 studies showed that in the last hour of life, 8 % and 31 % of patients experienced shocks. Impact of shocks on patients: a) In one study, 76 % of physicians agreed they thought shocks are distressing to patients b) In one study, hospice administrators reported, 74 % of patients receiving shocks in the last phase of life were distressed by these Impact of shocks on relatives: a) In a survey study, 76 % of physicians agreed, that shocks at the EOL are distressing for the patients' loved ones. b) A study in hospices reported that 92 % of family members of patients receiving shocks found this distressing to witness. Impact of shocks on professional caregivers: a) Shocks were not only distressing for the hospice team to witness, but they must also deal with the patient's and their family's distress.
Streur (2020) USA	Secondary descriptive analysis Data from a randomized	Total: ▪ Patients: n=105 ▫ Sex: 76 (72 %) male, 29 (28 %) female	To (i) describe patient and partner sexual activity and related concerns from the time of an initial ICD implant through 12-month	a) ICD patients and partners report low levels of sexual activity at the time of an initial ICD implant, and sexual activity increases over a 12-month recovery period. b) Sexual concerns are highest immediately after an ICD implant and tend to resolve as time passes with return to sexual activity.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
	controlled trial (2009–2015) designed to compare 2 interventions for P-Only and for P+P after implant of an initial ICD	▫ Mean Age: 65.6 (SD=10.6) ▪ Partners: n=105 ▫ Sex: 30 (29 %) male, 75 (71 %) female ▫ Mean Age: 63.6 (SD=11.1)	FUP and (ii) identify factors predictive of return to sexual activity and fears associated with sexual activity. <u>Intervention:</u> P-Only: (i) booklet with other patients' experiences during 1st year of ICD recovery + discussion of managing recovery issues, (ii) 8 weekly Nurse Telephone Support call + additional FUP calls at 10 and 12 weeks, (iii) Nurse Pager providing access to research nurse 24/7 (iv) video produced by the manufacturer of each patient's ICD device. P+P Intervention : element I-IV plus integration of partner into intervention process through (i) 6 telephone-based partner group sessions, (ii) partner-focused booklet, (iii) partner access to Nurse Pager and (iv) 7 partner-focused video segments.	c) Common concerns related to resumption of sexual activity (e.g., fear of ICD firing inappropriately, fear of ICD not firing when needed) should be addressed in the early post-implant period, when concerns are most evident. d) Physical health is an important predictor of sexual activity after ICD implant placement. Addressing concerns and physical limitations may ease patient and partner fears, thereby helping patients and partners feel ready to resume sexual activity.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
Sweeting (2017) Australia	Two cross-sectional studies (Accelerometer data and survey study)	Total: n=218 Sex: 92 (59.4 %) male Mean Age: 53.3 ± 14 years Subgroups: ▪ Accelerometer study: n=63 ▫ Sex: 45 (71 %) male ▫ Mean Age: 49.1 ± 14.9 years ▪ Survey study: n=155 ▫ Sex: 92 (59.4 %) male ▫ Mean Age: 53.3 ± 14 years	To assess the physical activity levels amongst those with an ICD and whether the device impacts on amount of physical activity undertaken using an objective measure.	<u>Physical activity:</u> a) Survey study: 51 % of participants met physical activity guidelines of 150min/week (including walking). b) Accelerometer study: When considering only activity accumulated in bouts of ≥10 min, mean was 54 ± 71 min per week and only 14 % met physical activity guidelines. <u>Psychosocial factors (survey participants):</u> a) Mean scores for all depression anxiety stress subscales fell within the normal range for each group. <u>Factors associated with likelihood of meeting physical activity guidelines (survey participants):</u> a) The only psychosocial factor associated with meeting physical activity guidelines after adjusting for age was anxiety relating to triggers of an ICD shock (Florida Shock Anxiety Scale-Triggers subscale), with those more anxious being less likely to meet guidelines. b) Looking at those aged ≤40 years, individuals were more likely to have higher shock anxiety score (p=.01) and subscores (Triggers, p=.03; Consequences, p=.01). <u>Confidence to exercise (survey participants):</u> a) Univariate analysis identified factors associated with being more confident to exercise including fewer adverse events relating to device (6 % vs. 16 %, p=.05), better FPAS total (85.62 vs. 76.73, p<.001) and FPAS subscores (Return to function 79.20 vs. 69.77, p=.02, Device-related distress 11.23 vs. 20.50, p=.01, Positive appraisal 88.70 vs. 80.23, p=.02). Those who were more confident were more likely to meet physical activity guidelines based on international physical activity questionnaire (68 % vs. 35 %, p<.001) and undertake more minutes of moderate-vigorous physical activity (430min/week vs. 190min/week, p<.001).
van den Heuvel (2022) Australia	Longitudinal, prospective study	Total: n=40 Sex: 26 (65 %) male	To investigate the psychological functioning and HRQoL over time in patients with genetic heart	<u>Impact on psychological functioning:</u> a) Anxiety symptoms initially increased but gradually improved over time, compared to baseline, with a significant improvement in HADS anxiety score after 4 years (95 % CI -14.05 to -2.87, p=.017).

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
	Australian Genetic Heart Disease Registry, and/or the medical record	Mean age: 46.3 ± 4 years (range: 19.8–66.1)	diseases who receive an ICD, and identify risk factors for poor psychological functioning and HRQoL.	b) Participants with university-level education (HADS anxiety score 2.55 points lower, 95 % CI -4.98 to -0.11, p=.070) and male participants (HADS anxiety score 2.47 points lower, 95 % CI -4.96 to 0.00, p=.084) had fewer anxiety symptoms. c) Participants with comorbidities were predicted to have worse depression symptoms (HADS depression score 2.17 points higher, 95 % CI 0.04–4.27, p=.081) than participants without comorbidities. <u>Impact on HRQoL:</u> a) MCS gradually improved over time, with significant improvement after 2 years (95 % CI 3.27–26.97, p=.032). b) Over time a gradual improvement in PCS was observed, after an initial significant decrease at 3 months FUP (95 % CI -14.46 to -2.85, p=.013). c) Presence of comorbidities showed a significant effect on predicted PCS values, with participants with comorbidities scoring 8.99 points lower those without comorbidities (95 % CI -14.14 to -2.61, p=.014). <u>Shock anxiety:</u> a) Significant improvement in shock anxiety was observed at 4 years (95 % CI -19.76 to -3.87, p=.023), compared to the first measure (1–3 months) <u>Device acceptance:</u> a) FPAS scores improved over time, with a significant improvement after 6 months (95 % CI 4.81–27.89, p=.028), 1 year (95 % CI 8.13–35.34, p=.013) and 4 years (95 % CI 20.01–67.64, p=.005), compared to the first 3 months after ICD implantation.
Varghese (2019) Germany	Prospective, longitudinal cohort study with 5-year FUP	Total: n=423 Sex: 342 (80.9 %) male Age: 68 ± 11 years Age ≤50 years: 30 (7.1 %) Subgroups:	To analyze the incidence of PS in a large series of consecutive ICD implantations and the relation of PS to depression, anxiety, and	a) Non-ischemic etiology (OR: 3 [95 % CI: 1.3–6.7]; p=.007), longer duration since device implantation (105 ± 59 months versus 61 ± 42 months; p<.0001), and a positive history of adequate ICD shocks (OR: 59 [95 % CI: 17–205]; p<.0001) were related to the occurrence of PS b) Patients with a history of PS had significantly higher anxiety scores in the HADS scores (15 ± 5.7 versus 8.8 ± 7.4 points; p<.0001)

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
	Clinical and demographic data were obtained from the Australian Genetic Heart Disease Registry, and/or the medical record	▪ Phantom shock (PS): n=27 ▫ Sex: 22 (81.5 %) male ▫ Mean age: 66.2 ± 14.1 years; Age ≤50 years: 5 (18.5 %) ▪ No PS: n=396 ▫ Sex: 320 (80.8 %) male ▫ Mean age: 68.2 ± 11 years; Age: ≤50 years: 25 (6.3 %)	QOL as well as to education levels (predictors and consequences of PS)	c) Patients experiencing PS felt more frequently that the information provided to them before device placement was not sufficient (22.2 % versus 5 %; p=.004); d) They were also more frequently in need of psychological support after ICD implantation (25.9 % versus 3.3 %; p<.0001) and were more likely to have considered switching off their ICD in near EOL situations (59.3 % versus 29.5 %; p<.002)
Varghese (2020) Germany	Cross-sectional study Standardized self-completion survey questionnaire	Total: n=423 Sex: 342 (80.9 %) male Age: 68±11 years Subgroups: ▪ No ICD implantation regret: n=382 ▫ Sex: 306 (80.1 %) male ▫ Age: 69± 11 years ▪ ICD implantation regret: n=41 ▫ Sex: 36 (87.8 %) male ▫ Age: 63±13years	To analyze the incidence and identify predictors in a large series of recipients that regretted their decision after implantation and the relationship between this phenomenon to depression, anxiety and QOL, as well as to satisfaction with implantation of the device.	a) Peri-operative complications significantly increase the likelihood of regret following ICD implantation in this series. b) Patients with a history of inadequate shocks during FUP were more likely to feel regret. c) Inadequate ICD discharges have more psychological impact compared to adequate ICD shocks. d) Decision regret resulted in higher HADS score levels, a feeling of uncertainty after ICD implantation, more complaints relating to insufficient pre-implantation information, and a higher likelihood of considering switching off the ICD in near EOL situations.

Referenz (Jahr) Land	Design/ Datenquelle	Studienpopulation und Charakteristika	Ziel/Fragestellung/Intervention	Zentrale Ergebnisse
Wilson (2021) USA	Qualitative study Four focus groups	Total: n=24 Sex: 11 (45.8 %) male, 13 (54.2 %) female Age ▪ ≤65: 10 (41.7 %) ▪ 66–75: 9 (37.5 %) ▪ >75: 5 (20.8 %)	To understand the patients' knowledge of identifying information for their implanted devices and perspectives on sharing their implanted device information: (a) Are patients aware of identifying information for their implanted device including the unique device identifier? (b) Do patients want information on their implanted device shared? (c) What are the critical influences that guide their view?	<u>Lack of awareness of identifying information on implanted devices:</u> a) lack of details on the implanted devices and of clarity on what information was available to the patients b) some patients had implant cards with information such as device manufacturer and model, others never received a card c) general sentiment by participants that identifying information on their implanted device was documented somewhere within the health-care system and could be accessed as needed <u>Information on implanted devices is valuable:</u> a) Patients endorsed the value of having identifying information including the unique device identifier for their implanted devices available b) They acknowledged that unique device identifiers are important if a patient moves or existing relationships are no longer available <u>Perceived risks with sharing device information:</u> a) Patients perceived risk in sharing their implanted device information with insurance providers and the federal government b) Some patients described concern that insurance providers might use the information about their implanted device against them

AD = advance directive (Patientenverfügung); AVSH = automatic atrioventricular search hysteresis (Funktionsmodus von Herzschrittmachern); CBT = cognitive behavioral therapy (kognitive Verhaltenstherapie); CI = confidence intervall (Konfidenzintervall); CIED = cardiac implantable electric device (kardiales elektrisches Rhythmusimplantat); CRT = cardiac resynchronisation therapy (kardiale Resynchronisations-Therapie); CRT-D = cardiac resynchronisation therapy defibrillator (kardilae Resynchronisations-Therapie mit Defibrillatorfunktion); EOL = end of life (Lebensende); EST = estimate (Schätzung); FPAS = Florida Patient Acceptance Survey (Fragebogen zur Patientenakzeptanz); FUP = Follow-up; GE = generator exchange (Aggregatwechsel); HADS = Hospital Anxiety and Depression Scale (Angst- und Depressionsfragebogen); HF = heart failure (Herzinsuffizienz); HFA = heart focused anxiety (herzbezogene Angst); HHE = Heart Healthy Education (Edukationsprogramm zur Herzgesundheit); HRQOL = healt-related quality of life (gesundheitsbezogene Lebensqualität); ICD = implantable cardioverter defibrillator (Implantierbarer kardioverter Defibrillator); KCCQ = Kansas City Cardiomyopathy Questionnaire (Kardiomyopathie-Fragebogen); LVEF = linksventrikuläre Ejektionsfraktion; MCI = mild cognitive impairment (milde kognitive Beeinträchtigung); MCS = mental composite score (Score für mentale Komponenten des SF-36); MD = mean difference;

mECG = mobile electrocoardiogramm (mobiles Elektrokardiogramm); OR = Chancenverhältnis (odds ratio); P+P = Patient oder Patientin mit Partner oder Partnerin; "PCA = Erhebungsinstrument zur körperlichen Funktionsfähigkeit (Patient Concerns Assessment); PCS = Score für physische Komponenten des SF-36; PDA = Entscheidungshilfe für Patientinnen und Patienten (Patient Decision Aid); PedsQL = Fragebogen zur Lebensqualität von Kindern (Pediatric Quality of Life Inventory); PM = Herzschrittmacher (pacemaker); P-only = nur Patient /Patientin; PS = Phantomschocks ; QOL = Lebensqualität (Quality of Life); QOLT = Intervention zur Lebensqualität (Quality of Life Therapy intervention); RM = remote monitoring; SCA = plötzlicher Herzstillstand (sudden cardiac arrest); SCD = sudden cardiac death; SD = Standardabweichung (standard deviation); SDM = partizipative Entscheidungsfindung (shared decision making); S-ICD = subkutaner implantierbarer Defibrillator; TV-ICD = transvenöser implantierbarer Defibrillator; UC = übliche Versorgung (usual care); WBI = webbasierte Intervention

Anhang B.4: Orientierende Recherche

Erstautorin/ Erstautor	Jahr	Titel
Aktaş, MK	2021	Survival After Implantable Cardioverter-Defibrillator Shocks.
Alotaibi, S	2020	Remote monitoring of implantable cardiac devices in heart failure patients: a systematic review and meta-analysis of randomized controlled trials.
Auricchio, A	2017	Inappropriate shocks in single-chamber and subcutaneous implantable cardioverter-defibrillators: a systematic review and meta-analysis.
Beiert, T	2019	Increased mortality and ICD therapies in ischemic versus non-ischemic dilated cardiomyopathy patients with cardiac resynchronization having survived until first device replacement.
Birnie, DH	2019	Risk Factors for Infections Involving Cardiac Implanted Electronic Devices.
Brisben, AJ	2015	A New Algorithm to Reduce Inappropriate Therapy in the S-ICD System.
Burri, H	2021	EHRA expert consensus statement and practical guide on optimal implantation technique for conventional pacemakers and implantable cardioverter-defibrillators: endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), and the Latin-American Heart Rhythm Society (LAHRS).
Callum, K	2021	Remote monitoring of implantable defibrillators is associated with fewer inappropriate shocks and reduced time to medical assessment in a remote and rural area.
Ezzat, VA	2015	A systematic review of ICD complications in randomised controlled trials versus registries: is our 'real-world' data an underestimation?
Fleeman, BE	2019	Optimal Strategies to Reduce Inappropriate Implantable Cardioverter-defibrillator Shocks.
Fumagalli, S	2019	The influence of age on the psychological profile of patients with cardiac implantable electronic devices: results from the Italian population in a multicenter study conducted by the European Heart Rhythm Association.
Guédon-Moreau, L	2014	Decreased Delivery of Inappropriate Shocks Achieved by Remote Monitoring of ICD: A Substudy of the ECOST Trial.
Herman, D	2013	Deactivation of implantable cardioverter-defibrillators: results of patient surveys.
Hill, L	2018	Patient and Professional Factors That Impact the Perceived Likelihood and Confidence of Healthcare Professionals to Discuss Implantable Cardioverter Defibrillator Deactivation in Advanced Heart Failure.

Hindricks, G	2017	Daily remote monitoring of implantable cardioverter-defibrillators: insights from the pooled patient-level data from three randomized controlled trials (IN-TIME, ECOST, TRUST).
Holstiege, J	2018	Prävalenz der Herzinsuffizienz – bundesweite Trends, regionale Variationen und häufige Komorbiditäten.
Javaid, MR	2018	Improving rates of implantable cardioverter defibrillator deactivation in end-of-life care.
Kirkfeldt, RE	2014	Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark.
Kooiman, KM	2014	Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: implications for management.
Lawin, D	2020	Comparison of current German and European practice in cardiac resynchronization therapy: lessons from the ESC/EHRA/HFA CRT Survey II.
Lewis, KB	2014	Decision Making at the Time of ICD Generator Change: Patients' Perspectives.
Manolis, AS	2017	"Real life" longevity of implantable cardioverter-defibrillator devices.
Montgomery, JA	2018	Longevity of Cardiovascular Implantable Electronic Devices.
Mori, H	2021	Transvenous lead performance of implantable cardioverter-defibrillators and pacemakers.
Moss, AJ	2012	Reduction in Inappropriate Therapy and Mortality through ICD Programming.
Müller, A	2013	Empfehlungen zum Telemonitoring bei Patienten mit implantierten Herzschrittmachern, Defibrillatoren und kardialen Resynchronisationssystemen.
Munawar, DA	2018	Predicted longevity of contemporary cardiac implantable electronic devices: A call for industry-wide "standardized" reporting.
Olsen, T	2019	Incidence of device-related infection in 97 750 patients: clinical data from the complete Danish device-cohort (1982-2018).
Oudshoorn, N	2018	Hybrid bodies and the materiality of everyday life: how people living with pacemakers and defibrillators reinvent everyday routines and intimate relations.
Paratz, ED	2022	Postmortem Interrogation of Cardiac Implantable Electronic Devices. A 15-Year Experience.
Parthiban, N	2015	Remote Monitoring of Implantable Cardioverter-Defibrillators. A Systematic Review and Meta-Analysis of Clinical Outcomes.

Pasyar, N	2017	Changes in Daily Life of Iranian Patients with implantable Cardioverter Defibrillator: A Qualitative Study.
Providência, R	2015	Transvenous Implantable Cardioverter-Defibrillator (ICD) Lead Performance: A Meta-Analysis of Observational Studies.
Reddy, VY	2017	Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing: The SELECT-LV Study.
Riesinger, L	2019	Postmortem interrogation of cardiac implantable electrical devices may clarify time and cause of death.
Slotwiner, D	2015	HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices.
Trappe, H-J	2011	Aktuelle Schrittmacher- und Defibrillatortherapie.
Tseng, ZH	2015	Sudden Death in Patients With Cardiac Implantable Electronic Devices.
Udo, EO	2013	Pacemaker follow-up: are the latest guidelines in line with modern pacemaker practice?
Versteeg, H	2019	Effect of remote monitoring on patient-reported outcomes in European heart failure patients with an implantable cardioverter-defibrillator: primary results of the REMOTE-CIED randomized trial.
Waltenberger, J	2017	Verantwortlicher Umgang mit ICDs. Stellungnahme der Deutschen Gesellschaft für Kardiologie und ihrer Schwester-Gesellschaften.
Wilke, T	2013	Incidence and prevalence of atrial fibrillation: an analysis based on 8.3 million patients.
Willy, K	2022	The Impact of Cardiac Devices on Patients' Quality of Life—A Systematic Review and Meta-Analysis.
Wilner, B	2021	Remote Monitoring of Permanent Pacemakers and Implantable Cardioverter Defibrillators.
Winkler, S	2021	Is 24/7 remote patient management in heart failure necessary? Results of the telemedical emergency service used in the TIM-HF and in the TIM-HF2 trials.
Wintrich, J	2020	Handling of remote monitoring alerts according to the weekday of transmission: results from the OptiLink HF study.
Ziacchi, M	2017	Clinically guided pacemaker choice and setting: pacemaker expert programming study.

Anhang C: Experteninterviews

Anhang C.1 Leitfaden für Experteninterviews

A Einführung

- Vorstellung der eigenen Person (Hintergrund, IQTIG, Abteilung VE, Team)
- Anlass des Interviews:
  - Das IQTIG ist vom G-BA mit einer Weiterentwicklung des QS-Verfahrens zur Versorgung mit implantierten Herzschrittmachern und Defibrillatoren beauftragt. Dabei sollen nicht nur die Eingriffe, sondern auch die Nachsorge und sowohl der stationäre als auch der ambulante Sektor einbezogen werden.
  - Neben wissenschaftlicher Literatur und Datenanalysen binden wir über Interviews Expertinnen und Experten ein, die sich mit der Versorgungspraxis auseinandersetzen.
  - Das konkrete Ziel dieses Interviews ist es, Ihr praktisches und konzeptionelles Wissen in Bezug auf die medizinische Versorgung zu erschließen. Ihre persönlichen Erfahrungen sollen uns helfen, die Versorgungsabläufe besser zu verstehen sowie Qualitätsdefizite zu identifizieren.
- Allgemeine Erläuterungen zum Interview:
  - Die Dauer des Interviews wird ca. 90 Minuten betragen.
  - Ihre Kurzbeschreibung und die paraphrasierten Inhalte werden im Ergebnisbericht veröffentlicht.
  - Die Teilnahme am Interview ist freiwillig, es besteht jederzeit eine Rücktrittsmöglichkeit.
  - Hinweis: Es ist ein Leitfaden für mehrere Experten entwickelt worden – daher werden nicht zu allen Fragen Antworten erwartet.
- Fragen an die/den Interviewer/in bevor es losgeht?
- Aufnahme:
  - Bitte: Handy und Remote/Festnetz auszuschalten, um die Aufnahme nicht zu stören; Fenster schließen; Remoteoffice im Communicator deaktivieren
  - Besteht Einverständnis mit einer Tonbandaufzeichnung?
  - CAVE: Audiogerät anschalten! RECORD

B Implantation

B1 Wie kommt es zur Implantation eines Rhythmusimplantats? Welche Vorgeschichten sind in der Anamnese typisch? *Ggf. differenzieren zwischen HSM/Defi*

B2 Können Sie Defizite bzw. Verbesserungsmöglichkeiten für diesen Abschnitt der Versorgung beschreiben?

⇨ Info-Folie zeigen!

- *Verweis auf Qualitätsdimensionen*: Gibt es weitere Probleme, die Ihnen bei einem Blick auf die verschiedenen Qualitätsdimensionen einfallen?

⇨ Info-Folie zeigen!

- *Verweis auf QIs*: Gibt es Qualitätsdefizite, die bisher von der QS **nicht** erfasst werden?

B3 Wann erfolgt die Ersteinstellung des Aggregats bei der Implantation?

- Welche Besonderheiten gibt es bei der Ersteinstellung?
- Gibt es noch eine weitere Kontrolle vor der Entlassung aus der stationären Behandlung?
- Wie ist es, wenn der Eingriff ambulant durchgeführt wird? (Wiedereinbestellung, Verbandwechsel, Wundkontrolle)

B4 Welche Rollen spielen Belegärzte, Selektivverträge, ermächtigte Ärzte, Ambulanzen etc. bei den Eingriffen?

B5 Welche Auswirkungen erwarten Sie durch die Einführung eines Zweitmeinungsverfahrens für Herzschrittmacher und Defibrillatoren? Wie schätzen Sie den zukünftigen Nutzen der Indikationsindikatoren ein?

B6 Welche Typen von Rhythmusimplantaten sollten Gegenstand der QS sein?

- Die bereits jetzt in der stationären QS berücksichtigten oder noch weitere?
- Welche sollten ausgeschlossen werden?
- Gibt es bzw. sind technische Neuentwicklungen zu erwarten?

C Folgeeingriffe: Aggregatwechsel, Revision und Systemumstellung

C1 Können Sie Defizite bzw. Verbesserungsmöglichkeiten für diesen Abschnitt der Versorgung beschreiben?

- *Verweis auf Qualitätsdimensionen*: Gibt es weitere Probleme, die Ihnen bei einem Blick auf die verschiedenen Qualitätsdimensionen einfallen?
- *Verweis auf stationäre QIs*: Gibt es Qualitätsdefizite, die bisher von der stationären QS **nicht** erfasst werden?

C2 Welche Rollen spielen Belegärzte, Selektivverträge, ermächtigte Ärzte, Ambulanzen etc. bei den Eingriffen?

D Sektorenübergang

D1 Welche Teile der Versorgung mit Herzrhythmusimplantaten können ambulant, welche stationär durchgeführt werden?

D2 Können Sie Defizite bzw. Verbesserungsmöglichkeiten für die sektorenübergreifende Versorgung beschreiben?

- Wie laufen die Übergange von der stationären in die ambulante Versorgung (oder umgekehrt) ab? Gibt es Defizite?

E Nachsorge

E1 Haben Sie Patienten, die nicht zu Nachsorgeterminen kommen? Wie beurteilen Sie die Adhärenz/Compliance bei der Nachsorge?

⇨ *Info-Folien zeigen!*

E2 Sind auf dieser Folie alle erforderlichen Checks und Parameter aufgeführt?

- was fehlt?
- was könnte ggf. entfallen?

E3 Gibt es Besonderheiten bei neuartigen Aggregaten, z. B. Leadless Pacemaker, S-ICD?

E4 Gibt es Kriterien, nach denen sich eine korrekte Programmierung beurteilen lässt?

- Was könnte als Hinweis auf eine Fehlprogrammierung gewertet werden?
- Was unterscheidet gute von schlechten Nachkontrollen?

E5 Welche Rolle spielt der Schrittmacherausweis? Update?

E6 Welche Defizite bzw. Verbesserungsmöglichkeiten für die Nachsorge sehen Sie?

- *Verweis auf Qualitätsdimensionen*: Gibt es weitere Probleme in der Nachsorge, die Ihnen bei einem Blick auf die verschiedenen Qualitätsdimensionen einfallen?

E7 Werden unabhängig von Eingriffen (Erstimplantation und Folgeeingriffe) auch Nachkontrollen im Krankenhaus durchgeführt? Werden sie dokumentiert und abgerechnet?

E8 Welche Rollen spielen Belegärzte, Selektivverträge, ermächtigte Ärzte, Ambulanzen etc. bei den Nachkontrollen?

E9 Welchen Stellenwert haben telemedizinische Nachkontrollen? Wie laufen sie ab?

F Ende der Therapie: Explantation, Tod des Patienten

F1 Wann ist eine endgültige Explantation indiziert? Wie häufig ist sie?

F2 Welche (palliativen) Maßnahmen sind bei absehbarem Tod des Patienten sinnvoll/erforderlich?

F3 Können Sie Defizite bzw. Verbesserungsmöglichkeiten für das Therapieende beschreiben?

- *Verweis auf Qualitätsdimensionen*: Gibt es weitere Probleme, die Ihnen bei einem Blick auf die verschiedenen Qualitätsdimensionen einfallen?

G Abschluss

G1 Welchen Stellenwert hat die gemeinsame Entscheidungsfindung (z. B. über Beginn, Weiterführung und Beendigung der Therapie durch die Implantate insbesondere bei Patientinnen und Patienten mit implantierten Defibrillatoren)?

G2 Gibt es Übertherapie/Untertherapie bzw. Überversorgung oder Unterversorgung?

G3 Welchen Stellenwert hat die Versorgung von Patienten und Patientinnen < 18 Jahre?

- Welche Besonderheiten gibt es bei Kindern und Jugendlichen?
- Welche Qualitätsdefizite bestehen bei der Versorgung von Kindern und Jugendlichen?

G4 Wollen Sie uns noch etwas mitgeben, was wir bisher nicht gefragt haben? Was ist Ihrer Ansicht nach noch wichtig, was wir bisher nicht thematisiert haben?

- *Gerät ausstellen!*
- Dank
- Wie geht es jetzt weiter: Interview wird transkribiert und ausgewertet. Abgabe als Bericht am 31. März 2023 an G-BA. Dann ggf. Weiterbeauftragung mit Indikatorenentwicklung und Machbarkeitsprüfung
- *Falls Formulare fehlen*: Erinnern: Erklärung Interessenkonflikte, Datenschutzerklärung, Vertraulichkeitserklärung?

Anhang C.2 Kurzbeschreibung Interviewpartnerinnen und -partner

Tabelle 1: Kurzbeschreibung der Teilnehmerinnen und Teilnehmer der Experteninterviews

ID (Nr.)	Berufliche und fachliche Qualifikation
1	**Interviewpartnerin bzw. -partner A** ▪ Fachärztin bzw. Facharzt für Innere Medizin ▪ Fachärztin bzw. Facharzt für Kardiologie ▪ Zusatzqualifikation „Interventionelle Kardiologie“ ▪ ambulant und belegärztlich tätig, Medizinisches Versorgungszentrum ▪ Region West ▪ Mitglied in diversen kardiologischen Institutionen ▪ Mitglied des Expertengremiums QS HSMDEF auf Bundesebene **Interviewpartnerin bzw. -partner B** ▪ Fachärztin bzw. Facharzt für Innere Medizin/Schwerpunkt Kardiologie ▪ Weitere Qualifikation „Spezielle Rhythmologie – Aktive Herzryhthmusimplantate“ (DGK) ▪ Zusatzqualifikation „Herzinsuffizienz“ (DGK) ▪ ambulant tätig, Medizinisches Versorgungszentrum ▪ Region West
2	▪ Fachärztin bzw. Fachärztin für Innere Medizin ▪ Weiterbildung im Fachbereich Kardiologie, Schwerpunkt Herzschrittmacherversorgung ▪ Region West ▪ Mitglied des Expertengremiums QS HSMDEF auf Bundesebene
3	▪ Pflegeexpertin bzw. -experte APN Herzinsuffizienz ▪ Pflegewissenschaftlerin bzw. -wissenschaftler ▪ stationär tätig ▪ Region West ▪ Mitglied des Expertengremiums QS HSMDEF auf Bundesebene
4	▪ Patientenperspektive
5	▪ Fachärztin bzw. Fachärztin für Innere Medizin (Kardiologie/Angiologie) ▪ Tätigkeitsschwerpunkt Invasivkardiologie und Rhythmologie ▪ ambulant tätig, Medizinisches Versorgungszentrum ▪ Region Ost ▪ Mitglied in diversen kardiologischen Institutionen
6	▪ Versorgungspraxis Kinder und Jugendliche ▪ Fachärztin bzw. Facharzt für Pädiatrie und Kinderkardiologie

ID (Nr.)	Berufliche und fachliche Qualifikation
	▪ Tätigkeitsschwerpunkte Kinderkardiologie, Herzrhythmusstörungen bei Kindern und Patientinnen bzw. Patienten mit angeborenen Herzfehlern, Herzschrittmacher- und ICD Implantationen bei Kindern und EMAH-Patientinnen und EMAH-Patienten (Erwachsene mit angeborenen Herzfehlern) ▪ stationär tätig ▪ Region Ost ▪ Mitglied in diversen kardiologischen Institutionen

Anhang D: GOP- und OPS-Kodes

Anhang D.1: Zuordnung der OPS-Kodes zu den GOP

Tabelle 1: Zuordnung der OPS-Kodes zu den GOP der Kategorie L

OPS	Bezeichnung	GOP vertragsärztlich	GOP belegärztlich
5-378.01	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregatentfernung: Schrittmacher, Einkammersystem	31211	36211
5-378.02	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregatentfernung: Schrittmacher, Zweikammersystem		
5-378.07	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregatentfernung: Ereignis-Rekorder		
5-378.81	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Kupplungskorrektur: Schrittmacher, Einkammersystem		
5-378.82	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Kupplungskorrektur: Schrittmacher, Zweikammersystem		
5-399.7	*Andere Operationen an Blutgefäßen: Entfernung von venösen Katheterverweilsystemen (z.B. zur Chemotherapie oder zur Schmerztherapie)*		
5-399.d	*Andere Operationen an Blutgefäßen: Entfernung einer implantierbaren Medikamentenpumpe (z.B. zur Chemotherapie oder zur Schmerztherapie)*		
5-377.1	Implantation eines Herzschrittmachers, Defibrillators und Ereignis-Rekorders: Schrittmacher, Einkammersystem	31212	36212
5-377.2	Implantation eines Herzschrittmachers, Defibrillators und Ereignis-Rekorders: Schrittmacher, Zweikammersystem, mit einer Schrittmachersonde		
5-378.18	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Sondenentfernung: Schrittmacher		
5-378.21	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenentfernung: Schrittmacher, Einkammersystem		
5-378.22	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenentfernung: Schrittmacher, Zweikammersystem		

OPS	Bezeichnung	GOP vertragsärztlich	GOP belegärztlich
5-378.2c	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenentfernung: Defibrillator mit Einkammer-Stimulation, ohne atriale Detektion		
5-378.2d	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenentfernung: Defibrillator mit Einkammer-Stimulation, mit atrialer Detektion		
5-378.2e	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenentfernung: Defibrillator mit biventrikulärer Stimulation, ohne Vorhofelektrode		
5-378.2f	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenentfernung: Defibrillator mit biventrikulärer Stimulation, mit Vorhofelektrode		
5-378.31	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Sondenkorrektur: Schrittmacher, Einkammersystem		
5-378.41	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Lagekorrektur des Aggregats: Schrittmacher, Einkammersystem		
5-378.42	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Lagekorrektur des Aggregats: Schrittmacher, Zweikammersystem		
5-378.51	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregatwechsel (ohne Änderung der Sonde): Schrittmacher, Einkammersystem		
5-378.52	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregatwechsel (ohne Änderung der Sonde): Schrittmacher, Zweikammersystem		
5-399.5	*Andere Operationen an Blutgefäßen: Implantation oder Wechsel von venösen Katheterverweilsystemen (z.B. zur Chemotherapie oder zur Schmerztherapie)*		
5-399.b0	*Andere Operationen an Blutgefäßen: Implantation oder Wechsel einer implantierbaren Medikamentenpumpe (z.B. zur Chemotherapie oder zur Schmerztherapie): Medikamentenpumpe mit konstanter Flussrate*		
5-399.b1	*Andere Operationen an Blutgefäßen: Implantation oder Wechsel einer implantierbaren Medikamentenpumpe (z.B. zur Chemotherapie oder zur Schmerztherapie): Programmierbare Medikamentenpumpe mit kontinuierlicher Abgabe bei variablem Tagesprofil*		

OPS	Bezeichnung	GOP vertragsärztlich	GOP belegärztlich
5-399.b2	*Andere Operationen an Blutgefäßen: Implantation oder Wechsel einer implantierbaren Medikamentenpumpe (z.B. zur Chemotherapie oder zur Schmerztherapie): Medikamentenpumpe mit integrierter elektronischer Okklusionsüberwachung*		
5-399.c	*Andere Operationen an Blutgefäßen: Revision einer implantierbaren Medikamentenpumpe (z.B. zur Chemotherapie oder zur Schmerztherapie)*		
5-378.32	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Sondenkorrektur: Schrittmacher, Zweikammersystem	31213	36213
5-377.30	Implantation eines Herzschrittmachers, Defibrillators und Ereignis-Rekorders: Schrittmacher, Zweikammersystem, mit zwei Schrittmachersonden: Ohne antitachykarde Stimulation	31214	36214
5-377.31	Implantation eines Herzschrittmachers, Defibrillators und Ereignis-Rekorders: Schrittmacher, Zweikammersystem, mit zwei Schrittmachersonden: Mit antitachykarder Stimulation		
5-378.61	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenwechsel: Schrittmacher, Einkammersystem		
5-378.71	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Sondenwechsel: Schrittmacher, Einkammersystem		
5-378.b3	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Systemumstellung Herzschrittmacher, Zweikammersystem auf Herzschrittmacher, Einkammersystem		
5-378.b6	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Systemumstellung Herzschrittmacher, biventrikuläre Stimulation [Dreikammersystem] auf Herzschrittmacher, Einkammersystem		
5-378.b7	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Systemumstellung Herzschrittmacher, biventrikuläre Stimulation [Dreikammersystem] auf Herzschrittmacher, Zweikammersystem		
5-378.62	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Aggregat- und Sondenwechsel: Schrittmacher, Zweikammersystem	31215	36215
5-378.72	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Sondenwechsel: Schrittmacher, Zweikammersystem		

OPS	Bezeichnung	GOP vertragsärztlich	GOP belegärztlich
5-378.b0	Entfernung, Wechsel und Korrektur eines Herzschrittmachers und Defibrillators: Systemumstellung Herzschrittmacher, Einkammersystem auf Herzschrittmacher, Zweikammersystem		

Anhang D.2: Zuordnung der OPS-Kodes 5-377.** zu den Devices

*Tabelle 2: Zuordnung der OPS-Kodes (Version 2020) 5-377.** (ohne Ereignis-Rekorder; isolierte Sondenimplantationen und Zusatzkodes wurden bei der Zuordnung nicht berücksichtigt) zu den Devices*

Zuordnung	OPS	Bezeichnung
HSM	5-377.1	Implantation eines Herzschrittmachers mit Einkammersystem
	5-377.2	Implantation eines Herzschrittmachers mit Zweikammersystem und einer Schrittmachersonde
	5-377.30	Implantation eines Herzschrittmachers mit Zweikammersystem und 2 Schrittmachersonden ohne antitachykarde Stimulation
	5-377.31	Implantation eines Herzschrittmachers mit Zweikammersystem und 2 Schrittmachersonden mit antitachykarder Stimulation
	5-377.k	Implantation eines intrakardialen Impulsgenerators
Defibrillatoren	5-377.50	Implantation eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-377.51	Implantation eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-377.6	Implantation eines Defibrillators mit Zweikammer-Stimulation
	5-377.j	Implantation eines Defibrillators mit subkutaner Elektrode
CRT	5-377.40	Implantation eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-377.41	Implantation eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode
	5-377.70	Implantation eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-377.71	Implantation eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode

Anhang D.3: Zuordnung der OPS-Kodes 5-378.** zu den Folgeeingriffen

*Tabelle 3: Zuordnung der OPS-Kodes (OPS 2022) 5-378.** (ohne Ereignisrekorder; Sondenentfernungen; Zusatzkodes wurden bei der Zuordnung nicht berücksichtigt) zu den Folgeeingriffen*

Zuordnung	OPS	Bezeichnung
Explantation Aggregat	5-378.01	Aggregatentfernung eines Herzschrittmachers mit Einkammersystem
	5-378.02	Aggregatentfernung eines Herzschrittmachers mit Zweikammersystem
	5-378.05	Aggregatentfernung eines Defibrillators mit Zweikammer-Stimulation
	5-378.0a	Aggregatentfernung eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.0b	Aggregatentfernung eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.0c	Aggregatentfernung eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-378.0d	Aggregatentfernung eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-378.0e	Aggregatentfernung eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.0f	Aggregatentfernung eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.0g	Aggregatentfernung eines Defibrillators mit subkutaner Elektrode
	5-378.21	Aggregat- und Sondenentfernung eines Herzschrittmachers mit Einkammersystem
	5-378.22	Aggregat- und Sondenentfernung eines Herzschrittmachers mit Zweikammersystem
	5-378.25	Aggregat- und Sondenentfernung eines Defibrillators mit Zweikammer-Stimulation
	5-378.2a	Aggregat- und Sondenentfernung eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.2b	Aggregat- und Sondenentfernung eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.2c	Aggregat- und Sondenentfernung eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-378.2d	Aggregat- und Sondenentfernung eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-378.2e	Aggregat- und Sondenentfernung eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode

Zuordnung	OPS	Bezeichnung
	5-378.2f	Aggregat- und Sondenentfernung eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.2g	Aggregat- und Sondenentfernung eines Defibrillators mit subkutaner Elektrode
	5-378.2h	Entfernung eines intrakardialen Impulsgenerators
Revision Sonde	5-378.31	Sondenkorrektur eines Herzschrittmachers mit Einkammersystem
	5-378.32	Sondenkorrektur eines Herzschrittmachers mit Zweikammersystem
	5-378.35	Sondenkorrektur eines Defibrillators mit Zweikammer-Stimulation
	5-378.3a	Sondenkorrektur eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.3b	Sondenkorrektur eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.3c	Sondenkorrektur eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-378.3d	Sondenkorrektur eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-378.3e	Sondenkorrektur eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.3f	Sondenkorrektur eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.3g	Sondenkorrektur eines Defibrillators mit subkutaner Elektrode
	5-378.3h	Lagekorrektur eines intrakardialen Impulsgenerators
Revision Aggregat	5-378.41	Lagekorrektur des Aggregats eines Herzschrittmachers mit Einkammersystem
	5-378.42	Lagekorrektur des Aggregats eines Herzschrittmachers mit Zweikammersystem
	5-378.45	Lagekorrektur des Aggregats eines Defibrillators mit Zweikammer-Stimulation
	5-378.4a	Lagekorrektur des Aggregats eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.4b	Lagekorrektur des Aggregats eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.4c	Lagekorrektur des Aggregats eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-378.4d	Lagekorrektur des Aggregats eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion

Zuordnung	OPS	Bezeichnung
	5-378.4e	Lagekorrektur des Aggregats eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.4f	Lagekorrektur des Aggregats eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.4g	Lagekorrektur des Aggregats eines Defibrillators mit subkutaner Elektrode
Aggregatwechsel	5-378.50	Aggregatwechsel eines Herzschrittmachers
	5-378.51	Aggregatwechsel eines Herzschrittmachers mit Einkammersystem
	5-378.52	Aggregatwechsel eines Herzschrittmachers mit Zweikammersystem
	5-378.55	Aggregatwechsel eines Defibrillators mit Zweikammer-Stimulation
	5-378.5a	Aggregatwechsel eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.5b	Aggregatwechsel eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.5c	Aggregatwechsel eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-378.5d	Aggregatwechsel eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-378.5e	Aggregatwechsel eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.5f	Aggregatwechsel eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.5g	Aggregatwechsel eines Defibrillators mit subkutaner Elektrode
Aggregat- und Sondenwechsel	5-378.60	Aggregat- und Sondenwechsel eines Herzschrittmachers
	5-378.61	Aggregat- und Sondenwechsel eines Herzschrittmachers mit Einkammersystem
	5-378.62	Aggregat- und Sondenwechsel eines Herzschrittmachers mit Zweikammersystem
	5-378.65	Aggregat- und Sondenwechsel eines Defibrillators mit Zweikammer-Stimulation
	5-378.67	Aggregat- und Sondenwechsel eines Defibrillators mit Ereignis-Rekorder
	5-378.6a	Aggregat- und Sondenwechsel eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.6b	Aggregat- und Sondenwechsel eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode

Zuordnung	OPS	Bezeichnung
	5-378.6c	Aggregat- und Sondenwechsel eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-378.6d	Aggregat- und Sondenwechsel eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-378.6e	Aggregat- und Sondenwechsel eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.6f	Aggregat- und Sondenwechsel eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.6g	Aggregat- und Sondenwechsel eines Defibrillators mit subkutaner Elektrode
	5-378.6h	Wechsel eines intrakardialen Impulsgenerators
Sondenwechsel	5-378.71	Sondenwechsel eines Herzschrittmachers mit Einkammersystem
	5-378.72	Sondenwechsel eines Herzschrittmachers mit Zweikammersystem
	5-378.75	Sondenwechsel eines Defibrillators mit Zweikammer-Stimulation
	5-378.7a	Sondenwechsel eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.7b	Sondenwechsel eines Herzschrittmachers mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.7c	Sondenwechsel eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion
	5-378.7d	Sondenwechsel eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-378.7e	Sondenwechsel eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.7f	Sondenwechsel eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.7g	Sondenwechsel eines Defibrillators mit subkutaner Elektrode
Kupplungskorrektur	5-378.81	Kupplungskorrektur eines Herzschrittmachers mit Einkammersystem
	5-378.82	Kupplungskorrektur eines Herzschrittmachers mit Zweikammersystem
	5-378.85	Kupplungskorrektur eines Defibrillators mit Zweikammer-Stimulation
	5-378.8a	Kupplungskorrektur eines Herzschrittmachers mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.8b	Kupplungskorrektur eines Herzschrittmacher mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.8c	Kupplungskorrektur eines Defibrillators mit Einkammer-Stimulation ohne atriale Detektion

Zuordnung	OPS	Bezeichnung
	5-378.8d	Kupplungskorrektur eines Defibrillators mit Einkammer-Stimulation mit atrialer Detektion
	5-378.8e	Kupplungskorrektur eines Defibrillators mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.8f	Kupplungskorrektur eines Defibrillators mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.8g	Kupplungskorrektur eines Defibrillators mit subkutaner Elektrode
	5-378.8j	Kupplungskorrektur eines kardialen kabellosen Stimulationssystems
Systemumstellungen	5-378.b0	Systemumstellung eines Herzschrittmachers mit Einkammersystem auf einen Herzschrittmacher mit Zweikammersystem
	5-378.b1	Systemumstellung eines Herzschrittmachers mit Einkammersystem auf einen Herzschrittmacher mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.b2	Systemumstellung eines Herzschrittmachers mit Einkammersystem auf einen Herzschrittmacher mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.b3	Systemumstellung eines Herzschrittmachers mit Zweikammersystem auf einen Herzschrittmacher mit Einkammersystem
	5-378.b4	Systemumstellung eines Herzschrittmachers mit Zweikammersystem auf einen Herzschrittmacher mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.b5	Systemumstellung eines Herzschrittmachers mit Zweikammersystem auf einen Herzschrittmacher mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.b6	Systemumstellung eines Herzschrittmachers mit biventrikulärer Stimulation auf einen Herzschrittmacher mit Einkammersystem
	5-378.b7	Systemumstellung eines Herzschrittmachers mit biventrikulärer Stimulation auf einen Herzschrittmacher mit Zweikammersystem
	5-378.b8	Systemumstellung eines Herzschrittmachers auf einen Defibrillator mit Einkammer-Stimulation ohne atriale Detektion
	5-378.b9	Systemumstellung eines Herzschrittmachers auf einen Defibrillator mit Einkammer-Stimulation mit atrialer Detektion
	5-378.ba	Systemumstellung eines Herzschrittmachers auf einen Defibrillator mit Zweikammer-Stimulation
	5-378.bb	Systemumstellung eines Herzschrittmachers auf einen Defibrillator mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.bc	Systemumstellung eines Herzschrittmachers auf einen Defibrillator mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.bd	Systemumstellung eines Herzschrittmachers auf einen Defibrillator mit subkutaner Elektrode

Zuordnung	OPS	Bezeichnung
	5-378.be	Systemumstellung eines Herzschrittmachers auf einen intrakardialen Impulsgenerator
	5-378.c0	Systemumstellung eines Defibrillators mit Einkammer-Stimulation auf einen Defibrillator mit Zweikammer-Stimulation
	5-378.c1	Systemumstellung eines Defibrillators mit Einkammer-Stimulation auf einen Defibrillator mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.c2	Systemumstellung eines Defibrillators mit Einkammer-Stimulation auf einen Defibrillator mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.c3	Systemumstellung eines Defibrillators mit Zweikammer-Stimulation auf einen Defibrillator mit Einkammer-Stimulation ohne atriale Detektion
	5-378.c4	Systemumstellung eines Defibrillators mit Zweikammer-Stimulation auf einen Defibrillator mit Einkammer-Stimulation mit atrialer Detektion
	5-378.c5	Systemumstellung eines Defibrillators mit Zweikammer-Stimulation auf einen Defibrillator mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.c6	Systemumstellung eines Defibrillators mit Zweikammer-Stimulation auf einen Defibrillator mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.c7	Systemumstellung eines Defibrillators mit biventrikulärer Stimulation auf einen Defibrillator mit Einkammer-Stimulation ohne atriale Detektion
	5-378.c8	Systemumstellung eines Defibrillators mit biventrikulärer Stimulation auf einen Defibrillator mit Einkammer-Stimulation mit atrialer Detektion
	5-378.c9	Systemumstellung eines Defibrillators mit biventrikulärer Stimulation auf einen Defibrillator mit Zweikammer-Stimulation
	5-378.ca	Systemumstellung eines Defibrillators auf einen Herzschrittmacher mit Einkammersystem
	5-378.cb	Systemumstellung eines Defibrillators auf einen Herzschrittmacher mit Zweikammersystem
	5-378.cc	Systemumstellung eines Defibrillators auf einen Herzschrittmacher mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.cd	Systemumstellung eines Defibrillators auf einen Herzschrittmacher mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.ce	Systemumstellung eines Defibrillators auf einen Defibrillator mit subkutaner Elektrode
	5-378.cf	Systemumstellung eines Defibrillators mit subkutaner Elektrode auf einen Defibrillator mit Einkammer-Stimulation ohne atriale Detektion
	5-378.cg	Systemumstellung eines Defibrillators mit subkutaner Elektrode auf einen Defibrillator mit Einkammer-Stimulation mit atrialer Detektion

Zuordnung	OPS	Bezeichnung
	5-378.ch	Systemumstellung eines Defibrillators mit subkutaner Elektrode auf einen Defibrillator mit Zweikammer-Stimulation
	5-378.cj	Systemumstellung eines Defibrillators mit subkutaner Elektrode auf einen Defibrillator mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.ck	Systemumstellung eines Defibrillators mit subkutaner Elektrode auf einen Defibrillator mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.cm	Systemumstellung eines Defibrillators auf einen intrakardialen Impulsgenerator
	5-378.d0	Systemumstellung eines intrakardialen Impulsgenerators auf einen Herzschrittmacher mit Einkammersystem
	5-378.d1	Systemumstellung eines intrakardialen Impulsgenerators auf einen Herzschrittmacher mit Zweikammersystem
	5-378.d2	Systemumstellung eines intrakardialen Impulsgenerators auf einen Herzschrittmacher mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.d3	Systemumstellung eines intrakardialen Impulsgenerators auf einen Herzschrittmacher mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.d4	Systemumstellung eines intrakardialen Impulsgenerators auf einen Defibrillator mit Einkammer-Stimulation ohne atriale Detektion
	5-378.d5	Systemumstellung eines intrakardialen Impulsgenerators auf einen Defibrillator mit Einkammer-Stimulation mit atrialer Detektion
	5-378.d6	Systemumstellung eines intrakardialen Impulsgenerators auf einen Defibrillator mit Zweikammer-Stimulation
	5-378.d7	Systemumstellung eines intrakardialen Impulsgenerators auf einen Defibrillator mit biventrikulärer Stimulation ohne Vorhofelektrode
	5-378.d8	Systemumstellung eines intrakardialen Impulsgenerators auf einen Defibrillator mit biventrikulärer Stimulation mit Vorhofelektrode
	5-378.d9	Systemumstellung eines intrakardialen Impulsgenerators auf einen Defibrillator mit subkutaner Elektrode