

The Danish Pacemaker and ICD Register: Review of Clinical and Research Potential

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Abstract: The Danish Pacemaker and ICD Register (DPIR) was established in 1982 as a hardware registry and clinical quality database dedicated to cardiac implantable electronic device (CIED) therapy. It is among the most comprehensive and longest-running CIED registries in the world and has recorded over 200,000 CIED procedures in more than 133,000 individuals. Leveraging the Danish registry infrastructure, individual-level linkage to other national clinical and administrative registries via the unique personal identification number greatly expands its research potential. This review summarizes the development, database structure, variable content and quality, and the clinical and scientific impact of DPIR. Examples of data quality include complete national coverage of all CIED procedures, standardized data-entry fields that minimize variability across centers, mandatory reporting of core variables, and high concordance between registry entries and source documentation. Data from DPIR has informed clinical practice guidelines and supported clinical quality improvement in Denmark and internationally.

Keywords: pacemaker, cardiac resynchronization therapy, implantable cardioverter defibrillator, cardiac implantable electronic device, registry, clinical quality database, validation

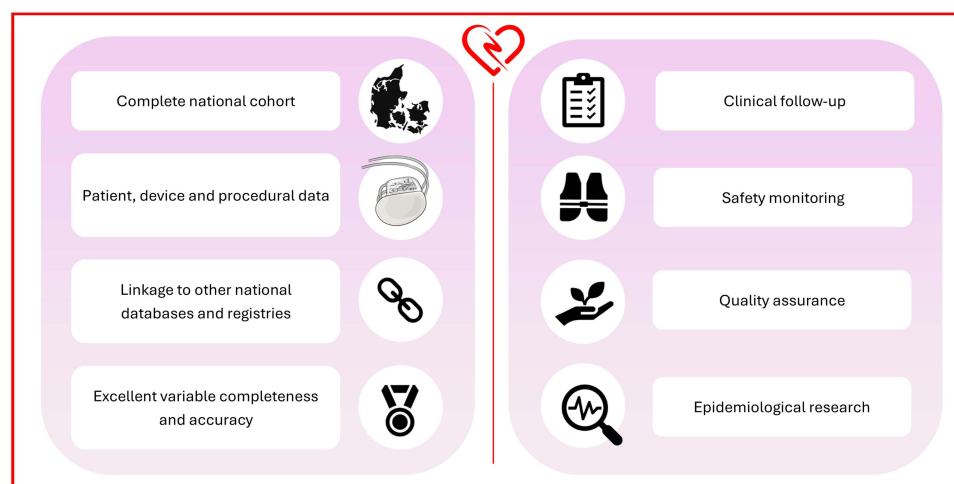
Introduction

Clinical registries are essential for surveillance and quality assurance in cardiovascular medicine. Established in 1982 as a hardware-oriented cardiac device registry and clinical quality database, the Danish Pacemaker and ICD Register (DPIR) has accumulated over 40 years of patient-, hardware-, and procedural data on cardiac implantable electronic device (CIED) therapy in Denmark.¹ It is among the largest, most comprehensive, and longest-running registries dedicated to CIED therapy worldwide. DPIR supports daily care, monitors safety, and offers valuable insights into long-term, real-world clinical practice. It has also been a valuable resource for epidemiological research. This review evaluates the content and data quality of DPIR, explores its research applications, and assesses its role in improving care for patients with CIEDs.

Organization

DPIR was established in 1982 by physicians from all Danish CIED implanting centers as a hardware-oriented cardiac device registry. Its objectives were later expanded to supporting daily care, documenting the quality of care associated with CIEDs,

Graphical Abstract



defining minimum standards of care, and identifying critical domains demanding careful attention.² More recently, DPIR was approved as an electronic medical record system. Implantable cardioverter defibrillator (ICD) implantations were included in 1989, and cardiac resynchronization therapy (CRT) devices in 1997. DPIR is located at Odense University Hospital and nested within the Arrhythmia Working Group of the Danish Society of Cardiology. The registry is funded by CIED manufacturers through a fee imposed on every device and lead sold in Denmark. In turn, the companies gain access to aggregated data from the registry.

In Denmark, pacemaker implantations are centralized to 10 public cardiology centers and one private hospital. Together, these centers serve the entire Danish population of approximately 6.0 million inhabitants (Figure 1). Five centers also perform ICD implantations, and four offer CRT. The distribution of centers across Denmark is determined by the Danish Health Authority. All centers report data to DPIR.

The DPIR Steering Committee is comprised of one physician from every public CIED implantation center (including the Chair) (10 individuals) and a Data Manager (11 members in total). Daily management is overseen by the Chair, the Data Manager, and one nurse technician. The nurse technician provides technical support and is not a member of the DPIR Steering Committee. Key clinical quality indicators and standards from DPIR are defined by the Danish Health Authority and presented in an annual report.¹ Data from DPIR can be provided for research purposes, but all research emanating from the registry must be pre-approved by the Steering Committee.

Setting

Healthcare in Denmark is universally tax-financed and freely available to all Danish residents.³ This includes CIED therapy. The Danish Civil Registration System (CRS) comprises a complete and ongoing cohort of Danish residents dating back to 1968.⁴ Registration occurs at birth or upon immigration by assignment of a unique ten-digit personal identifier, the Civil Personal Registration (CPR) number. The CPR number serves as a prerequisite for individual-level linkage across the vast network of Danish registries.^{3,4} The CRS is continuously updated with information on kinship, residency, migration, and vital status, enabling epidemiological research on complete populations with the potential for lifelong follow-up.⁴

Data Entry

All patients who undergo a surgical CIED procedure in Denmark are entered into DPIR using the CPR number, which enables individual-level linkage to other Danish registries. Entry occurs at first implantation and is completed, as a minimum, for all

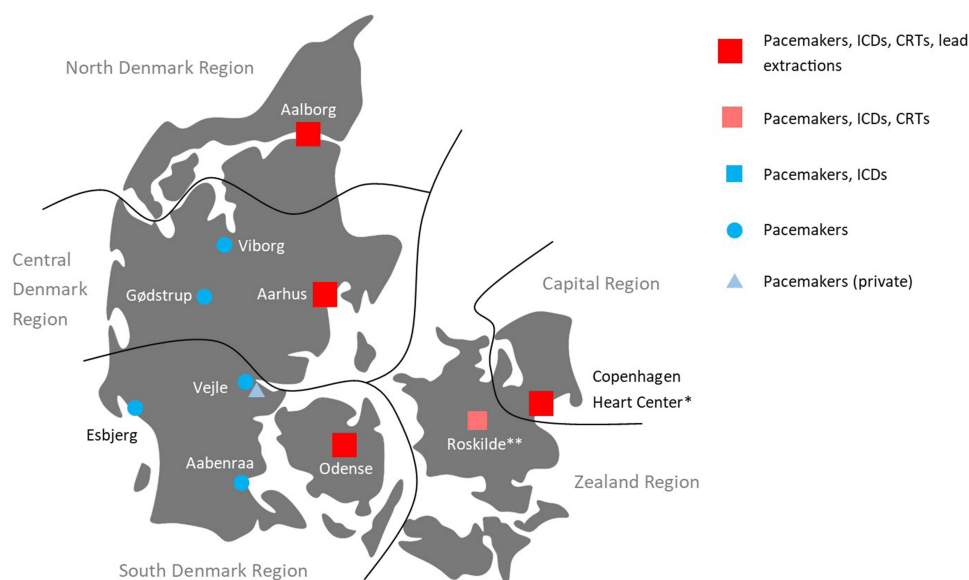


Figure 1 Overview of CIED centers: Four highly specialized university hospitals perform implantation of all CIED types as well as CIED extractions. One university center (Roskilde) performs pacemaker- and ICD implantations, while six centers implant pacemakers only. Pediatric CIED procedures are centralized at a single center in Copenhagen. *Also performs pediatric CIED implantations and extractions. **University Center.

Abbreviations: CIED, cardiac implantable electronic device; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator.

procedures involving hardware changes. The implanting physician or dedicated staff members perform the registration immediately after the procedure.

In 2007, DPIR became fully web based. This standardized the data collection procedure and enhanced its applicability as a clinical tool. Registered users can access the system, which enables physicians to view device-specific patient data across regions and over time, independently of electronic medical record systems. After implantation, in accordance with European Legislation for medical devices, patients are equipped with a patient ID (implant) card with information about the implanted device and leads, pacing mode, hardware model and serial numbers, and the date of implantation.

Data Content

DPIR records administrative patient data, clinical indication for CIED therapy, perioperative management, implanted hardware, procedure data, and implant-related complications. Indication for CIED therapy is provided only at first implantation. This includes information about cardiovascular diagnosis, prior percutaneous interventions or coronary artery bypass graft surgery, indication for CIED therapy, primary presenting symptom, New York Heart Association (NYHA) functional class, atrioventricular (AV) conduction status, QRS duration, and left ventricular ejection fraction (LVEF) (Table 1). A complete list of variables and their coding in DPIR per December 2025 is provided in [Supplementary Table 1](#).

Procedure data is provided for every intervention (Tables 1 and 2) and includes pre- and perioperative management and status (anesthetics, antibiotic prophylaxis, priority, body temperature, C-reactive protein, and leucocyte count, anticoagulant or antiplatelet therapy), procedure-specific information (procedure type, device type, procedure duration, fluoroscopy time and amount), and information about the implanted device (site of implantation, leads and locations, and hardware model). Many of these indicators were added to the registry in 1997.² For each case of CIED or lead removal, or lead abandonment, the reason for the explant procedure is documented. This is crucial for surveillance of serious device-related complications including CIED infections and lead-related complications. CIED infections typically warrant complete device extraction, whereas lead dysfunction often necessitates lead removal or abandonment. A separate sheet was added in 2007 to include complications for which hardware exchange or explant procedures are not necessarily indicated: superficial surgical site infections, pocket hematomas, central venous complications, deep venous thrombosis, pulmonary embolism, pneumothorax, hemothorax, pericardial effusion or tamponade, hardware complications, and stroke. Figure 2 presents the timeline of DPIR indicators, and Figure 3 shows the DPIR data structure.

Table 1 Completeness of Procedural Data Variables in the Danish Pacemaker and ICD Register

Indicator	Coverage	Completeness (%)		
		1982–2001	2002–2010	2011–2023
Patient ID	1982-	100	100	100
Institution	1982-	100	100	100
Periprocedural antibiotics	2009-	–	–	98
Procedure duration	2009-	–	–	98
X-ray duration	2009-	–	–	98
Amount of X-ray	2009-	–	–	98
Procedure priority	2009-	–	–	98
Predominant symptom	1982-	99	98	98
NYHA class	2006-	–	46	78
Left ventricular ejection fraction	2006-	–	50	88
Cardiac diagnosis	1982-	20	37	82
Indication for CIED therapy	1982-	98	97	99
AV conduction status at implant	2006-	–	–	26
QRS duration	2006-	–	–	99
Height	2010-	–	–	99
Weight	2010-	–	–	99
Body temperature at implant	2010-	–	–	99
C-reactive protein	2010-	–	–	99
Leucocytes	2010-	–	–	99
INR	2010-	–	–	99
Temporary pacemaker	2010-	–	–	99
Date	2010-	–	–	100
Site	2010-	–	–	93
Side	2010-	–	–	93
For shock electrodes				
ICD tested	2006-	–	99	91
Shock threshold	2006-	–	99	91
Reason for re-intervention	1982-	96	99	100
Reintervention procedure	1982-	100	100	100

Notes: Variables registered as “unknown” was also considered missing information. Smoking data was added to the registry in 2001 and discontinued in DPIR in 2016. Due to both low coverage and incompleteness, it was not made part of this table.

Abbreviations: AV, atrioventricular; CABG, Coronary artery bypass graft surgery; CIED, cardiac implantable electronic device; ICD, implantable cardioverter defibrillator; INR, international normalization ratio; NYHA, New York Heart Association; PCI, Percutaneous coronary intervention.

Quality Indicators

A set of quality indicators and standards for CIED therapy in Denmark was defined in accordance with recommendations from the European Society of Cardiology (ESC) Working Group for Cardiac Pacing Quality Indicators and the European Heart Rhythm Association (EHRA).⁵ This data is shared with the Danish Clinical Quality Program under The Danish Healthcare Quality Institute,⁶ and made publicly available in an annual report for transparency and accountability.¹ Key quality indicators in DPIR are surgical site infections resulting in CIED removal within 365 days of implantation (maximum 2%), early implant-related complications with major clinical impact or resulting in a CIED reoperation within 120 days of implantation (maximum 5%),⁷ venous access site (minimum 50% should apply the cephalic cut-down technique),⁸ and the annual number of procedures per operator (minimum 50 procedures per operator per year).^{7,9} Failure to meet the national standards elicits targeted efforts to identify, adjust, and remedy potential issues. This may occur locally or at a national level.

Table 2 Completeness of Lead- and Device-Specific Data

Indicator	Coverage	Completeness (%)		
		1982–2001	2002–2010	2011–2023
Patient ID	1982–	100	100	100
Manufacturer	1982–	100	99	99
Model	1982–	100	99	99
Serial number	1982–	100	99	99
Generator site	1982–	–	33	100
Previous Generator site	1999–	–	10	100
Lead type	1982–	100	100	100
Lead placement	1982–	100	100	100
Lead access site	1982–	<0.1	33	99
LV leads				
Placement in LAO projection	2003–	–	94	99
Placement in RAO projection	2003–	–	91	99
Contrast used	2003–	–	98	100
Phrenic nerve stimulation	2003–	–	98	100

Notes: Variables registered as “unknown” were also considered missing information.

Abbreviations: LAO, left anterior oblique; RAO, right anterior oblique.

Completeness and Validity

Materials and Methods

For this paper, we evaluated variable completeness (all variables) and the validity of 29 key variables in the DPIR (Table 3). Completeness was assessed as the proportion of available data in the registry relative to the total number of

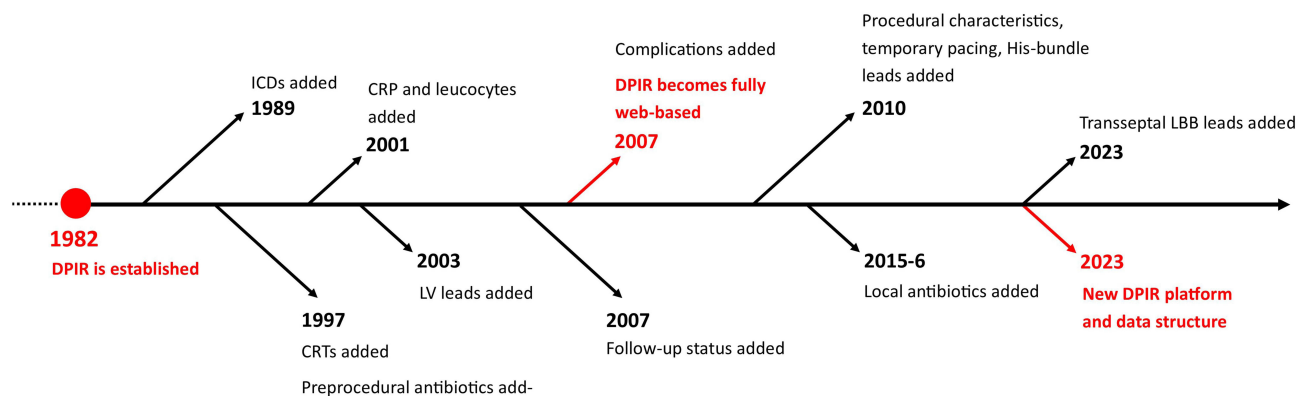


Figure 2 Timeline over important structural (red) and content (black) changes in the Danish Pacemaker and ICD Register (DPIR). Bold text highlights significant time points (bold black) and major structural changes (bold red) to the registry.

Abbreviations: CRP, C-reactive protein; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; LBB, left bundle branch; LV, left ventricular.

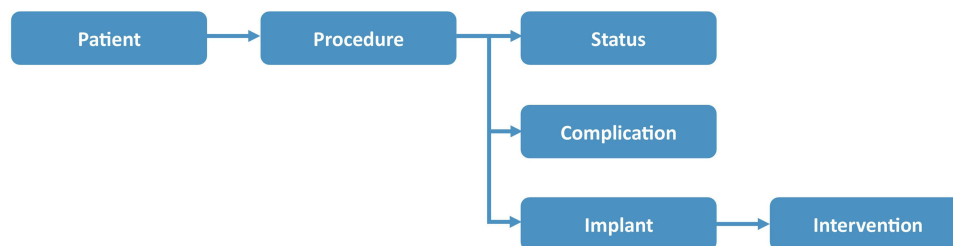


Figure 3 Data structure in the Danish Pacemaker and ICD Register (DPIR).

Table 3 Positive Predictive Values (PPVs) for Procedural Data Variables in the Danish Pacemaker and ICD Register (DPIR). Data Availability Refers to the Records with Information Present in the Database for a Given Variable, Reflecting Its Completeness

	Available	Confirmed	PPV	95% CI
Periprocedural antibiotics	598	562	94	92-96
Procedure priority	631	591	94	91-95
Procedure duration	157	153	97	94-99
Fluoroscopy duration	95	88	93	86-96
Fluoroscopy dose	88	78	89	80-94
Predominant symptom	465	443	95	93-97
NYHA functional class	162	158	98	94-99
Left ventricular ejection fraction	295	290	98	96-99
Cardiac diagnosis	483	475	98	96-99
Indication for CIED therapy	490	476	97	95-98
AV conduction status at implant	291	279	96	93-98
QRS duration	269	257	96	92-97
Height	451	444	98	97-99
Weight	451	443	98	97-99
Body temperature at implant	564	562	100	99-100
C-reactive protein	532	522	98	97-100
Leucocytes	465	463	100	98-100
INR	457	452	99	97-100
Temporary pacemaker	643	639	99	98-100
Site	42	37	88	75-95
Side	44	44	100	92-100
Lead/device type	1455	1454	100	100-100
Lead location	566	561	99	98-100
Lead anatomical position	607	607	100	99-100
Lead access site	548	539	98	97-99
Manufacturer	1349	1331	100	98-99
Generator site	667	663	99	98-100
Generator previous site	663	658	99	98-100
Type of re-intervention	194	192	99	96-100
Reason for re-intervention*	195	177	91	86-94

Notes: *Generators and leads. Variables height, INR, CRP, and QRS duration from Odense were not available for procedures performed prior to 2023 following the transition to a new electronic medical record system.

Abbreviations: AV, atrioventricular; CIED, cardiac implantable electronic device; INR, international normalization ratio; NYHA, New York Heart Association.

registered procedures (for procedural variables) or patients (for baseline demographics). Both true missing entries and entries recorded as “unknown” were classified as missing. Owing to major structural revisions of the DPIR over time, completeness was evaluated across three distinct periods: 1982–2001, 2002–2010, and 2011–2023. The time periods were chosen based on data availability. Only variables with full coverage within each period were included in the analysis. Medical records served as the reference standard.

Validity was assessed by three independent assessors (MHJPF, FNJ, FM) through medical record review in accordance with the definitions provided in [Supplementary Table 1](#). The validation sample was divided among three reviewers. In cases of uncertainty during data extraction or classification, the case was first discussed among the reviewers to reach consensus and, if needed, subsequently with an external reviewer (JBJ or JCO). Medical record review was performed for a combined total of 700 randomly selected procedures; pacemaker (PM), cardiac resynchronization therapy (CRT), and implantable cardioverter-defibrillator (ICD) from three implanting centers (two tertiary and one regional). We validated 300 PM, 200 CRT-P/D, and 200

single- and dual-chamber ICD procedures (100 of each device type per center) including a random selection of first implants and reintervention procedures. Another 200 lead extractions were separately validated focusing on reason for reintervention and mode of extraction only. Numeric variables were validated as integers, as fractional values were not uniformly reported. Lead type and position ($n=500$), and procedure duration and fluoroscopy amount ($n=200$) were validated only for a subset of patients. During follow-up, one center (Odense University Hospital) transitioned to a new electronic medical record system, resulting in reduced availability of certain variables for validation: height, weight, biochemistry, ECG characteristics, procedure duration and fluoroscopy amount. Accordingly, validation of these variables was limited to implantations performed after the transition. Data on left ventricular (LV) lead positioning and pacing thresholds were inconsistently reported across centers and available for only a very small subset of patients; consequently, these variables were not included in the validation analysis.

Positive predictive values (PPVs) were calculated as the proportion of DPIR data confirmed by medical record review with 95% confidence intervals (CIs) estimated using the Wilson score method. Missing data were excluded from the primary PPV analyses; however, sensitivity analyses were conducted using best-case (all missing considered confirmed) and worst-case (all missing considered unconfirmed) scenarios. For selected variables, analyses were further stratified by acute versus elective procedures to account for potential misclassification during off-hours.

All statistical analyses were performed in Stata 19 SE (StataCorp, USA). The study was approved by the DPIR Steering Committee. Access to patient medical records was granted for each participating center (Viborg, Aarhus, and Odense) and limited to entries within five years of approval in accordance with institutional guidelines (January 1, 2020, to December 31, 2025). In accordance with Danish law, informed consent and institutional review board approval was not required for this type of study. All data accessed for this study were handled in accordance with relevant Danish data protection and privacy regulations.

Completeness

Completeness results are presented in [Table 1](#) and [Table 2](#), and in [Supplementary Figure 1](#). Most variables exhibited high completeness ($>98\%$), whereas NYHA functional class (46–78%), left ventricular ejection fraction (LVEF) (50–88%), and baseline atrioventricular (AV) conduction at implant (26%) demonstrated lower completeness. Completeness was generally higher in more recent years, likely reflecting improvements following full digitalization of the registry. NYHA class was primarily reported for patients with clinically manifest heart failure, while AV conduction status was predominantly available for patients with an indication for bradycardia pacing.

Validity

All procedures were eligible for validation through medical record review. Positive predictive values (PPVs) are presented in [Table 3](#) and in [Supplementary Table 2](#), stratified by procedure priority. PPVs ranged from 86 to 100%. In total, 23 of 29 variables demonstrated PPVs $\geq 95\%$, including indication for cardiac implantable electronic device (CIED) therapy (97%, 95% CI 95–98%), lead type (100%, 95% CI 99–100%), and venous access site (98%, 95% CI 97–99%) - variables that have frequently been employed in research. Reason for reintervention, which is used to identify complications requiring a reintervention procedure, had a PPV of 91% (95% CI 86–94%). PPVs were consistent between acute and elective procedures ([Supplementary Table 2](#)). Overall, the PPVs remained high in both the best- and worst-case analyses ([Supplementary Table 3](#)), indicating robust validity under varying assumptions.

Limitations

Although the overall validity was excellent, results should be interpreted with caution for variables with small sample sizes due to a high proportion of missing data or low completeness, or variables with multiple non-mutually exclusive response options (eg., indication for CIED therapy, AV conduction, QRS duration, and reason for lead or generator reintervention; [Supplementary Table 1](#)). Furthermore, it was not the objective of this study to assess the causes of generator or lead removal or negative predictive values. Although the validation was conducted in only three centers across two regions, we have no reason to suspect that the findings are not generalizable to other Danish regions.¹⁰ In contrast, it is less certain whether our findings can be extrapolated to earlier time periods than 2020–2025. However,

Consistency with earlier validation of defibrillator leads,¹¹ supports the extrapolation of the observed high data quality to earlier periods.

Although complications are recorded in the DPIR, they were not assessed in this study due to underreporting of complications that do not require a CIED reintervention such as postoperative pneumothorax, superficial infections, or conservatively managed hematomas.⁷ An audit of complication registration in DPIR performed in 2009 revealed a sensitivity for complications of 43% (95% CI 39–47).¹² This limitation arises because DPIR is primarily a hardware-oriented registry. Primary data entry is performed immediately after implantation by the implanting physician or designated staff, whereas later or minor complications are often treated by non-electrophysiologists without access to the registry, leading to incomplete reporting. Exceptions are complications requiring device reinterventions, most notably definite CIED-related infections, in which case complete hardware removal is recommended,^{12–14} or lead-related reinterventions.^{12,15} These events are systematically recorded under reason for lead or device removal. However, cases of definite CIED infection in which device removal is deferred (eg., in frail or high-risk patients) remain subject to underreporting in the registry.

Temporal Trends in Implant Activity

DPIR has captured the (near) totality of CIED therapy in Denmark for over 40 years, accumulating more than 200,000 CIED procedures across more than 133,000 individuals. Per February 27, 2024, 52,039 persons were living with a CIED in Denmark. As shown in Figures 4 and 5, the annual number of CIED procedures has been steadily increasing as has the number of high-complexity CIED device implantations and reoperation procedures (battery changes, upgrades, downgrades, lead-related interventions and device removals), which are associated with higher complication rates.^{7,16}

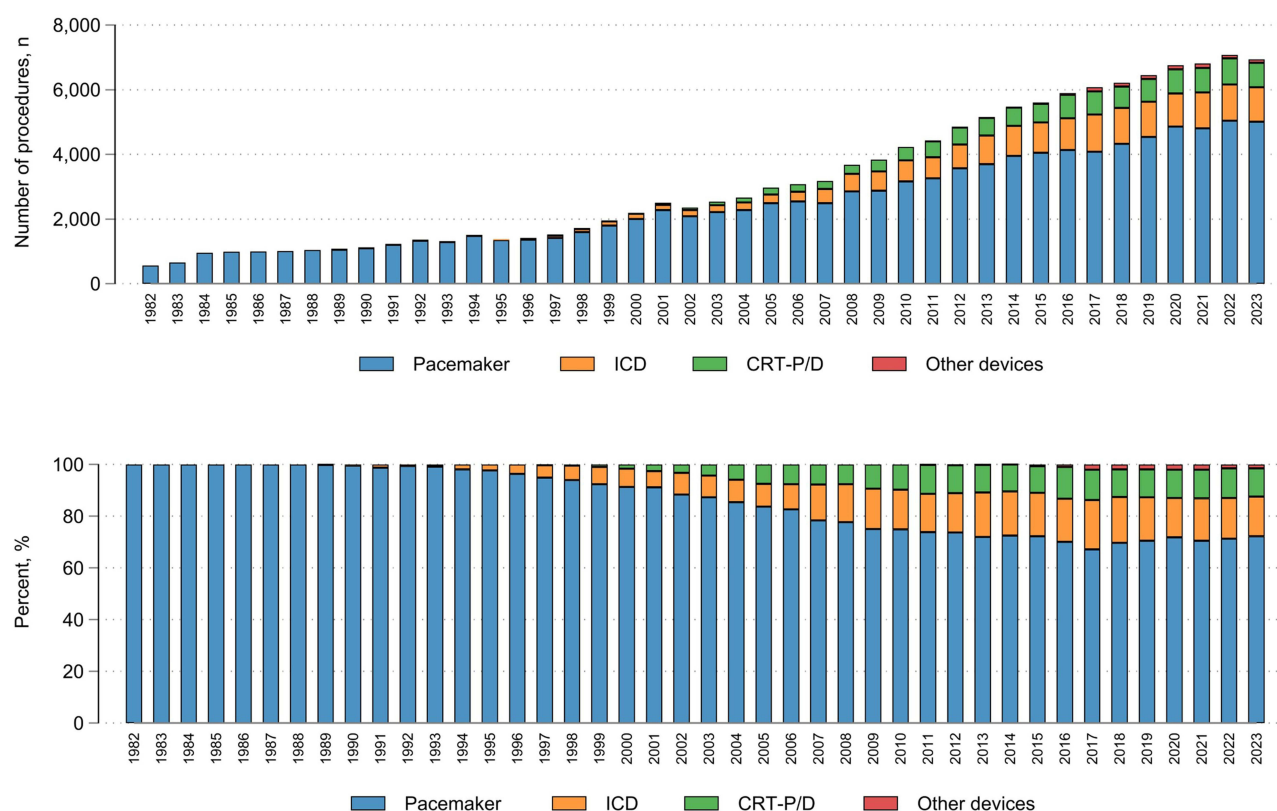


Figure 4 Implant activity 1982–2023 per device type excluding lead interventions only. Colors indicate device type (pacemaker, ICD, CRT or other device type). CRT-P/D = cardiac resynchronization therapy pacemaker/defibrillator.

Abbreviations: ICD, implantable cardioverter defibrillator; PM, pacemaker.

Research Potential

The near-optimal epidemiological framework served as the basis for a wide range of research using DPIR data. Below are examples of how research emanating from DPIR influenced clinical care for patients with CIEDs.

Prevalence and Prevention of CIED-Related Complications

CIED implantation carries a risk of serious complications, including infection, lead dysfunction, cardiac perforation, tamponade, and pneumothorax. Randomized controlled trials are often underpowered to adequately assess such events, and few prospective CIED registries match DPIR in completeness, accuracy, and long-term follow-up.

To understand the risks and predictors of CIED-related adverse events, a previous study identified all patients undergoing a CIED procedure between May 2010 and April 2011 in Denmark using DPIR ($n=5,918$).⁷ Detailed information about minor and major complications occurring within six months of the procedure were collected from medical chart review in all patients.⁷ Early implant-related complications occurred in approximately 9.5% of patients (higher than previously assumed) while major complications (defined by severe clinical impact or reoperation) were observed in 5.6%. Complication risks were higher among women, underweight patients, those receiving complex devices, and in procedures performed at low-volume centers (<750 procedures/year) or by low-volume operators (<50 procedures/year).

Subsequent analyses of 28,860 Danish patients examined specific risks for pneumothorax¹⁷ and lead-related complications.⁸ Procedural factors were the strongest independent predictors, and subclavian venous access was associated with a markedly increased risk of pneumothorax (odds ratio (OR) 7.8, 95% confidence interval (CI) 3.0–10.8), discouraging the use of intrathoracic venous puncture.^{16,18}

Data from DPIR enabled researchers to identify complete populations of CIED recipients and thereby determine complication rates at the population level. These studies established contemporary benchmark rates for future reference and, through risk-factor assessments, helped define quality indicators for CIED therapy. For example, annual operator and center volume, and systematic reporting of CIED-related adverse events, were included as recommended indicators for the quality and outcomes of cardiac pacing by EHRA,⁵ and they informed the EHRA consensus document on optimal implantation technique for pacemakers and ICDs.¹⁹ Standardized registration is essential for identifying and addressing undesirable patterns of care.

CIED Infections

Given the clinical and economic burden of CIED infections,²⁰ they have been studied extensively using data from DPIR. Complete CIED removal is recommended in case of definite CIED infection,^{13,14} and because DPIR is highly hardware oriented, infections are well-documented in the registry. Two population-based cohort studies originating from DPIR examined the incidence of CIED infections and their associated risk factors; first in 2011 in 46,299 pacemaker patients (1982–2007),²¹ and later in 2019 in 97,750 patients with pacemakers, ICDs or CRTs (1982–2018).²²

The overall incidence of CIED infections after first pacemaker implantations was 2.04/1000 device years (DY) for pacemakers implanted between 1982 and 2018.²² Infection rates were highest for higher complexity devices, and considerably higher after CIED reoperation procedures; as high as 18.94/1000 DY for CRT-D reoperations. These findings underscored the significance of device and procedure complexity for the risk of infection.

A key strength of DPIR is its ability to track detailed device histories for each patient across centers and administrative regions.³ When linked with other Danish national health registries, DPIR has facilitated identification of high-risk patient subgroups,^{23–25} enabling the development of targeted preventive strategies. For example, pocket infections were shown to occur more frequently after CRT reoperations,²³ and subsequent analyses using DPIR demonstrated that prophylaxis with an antibiotic-eluting envelope was associated with a reduced infection risk in this population.^{20,26} As healthcare systems face increasing financial constraints, systematic data collection is essential to guide the targeted use of preventive strategies in patients at highest risk.²⁷

Lead Performance

In December 2011, the U.S. Food and Drug Administration (FDA) issued a Class I recall for the 7- and 8-French Riata defibrillator leads (St. Jude Medical) after multiple reports of conductor externalization and lead failure.²⁸ Hardware

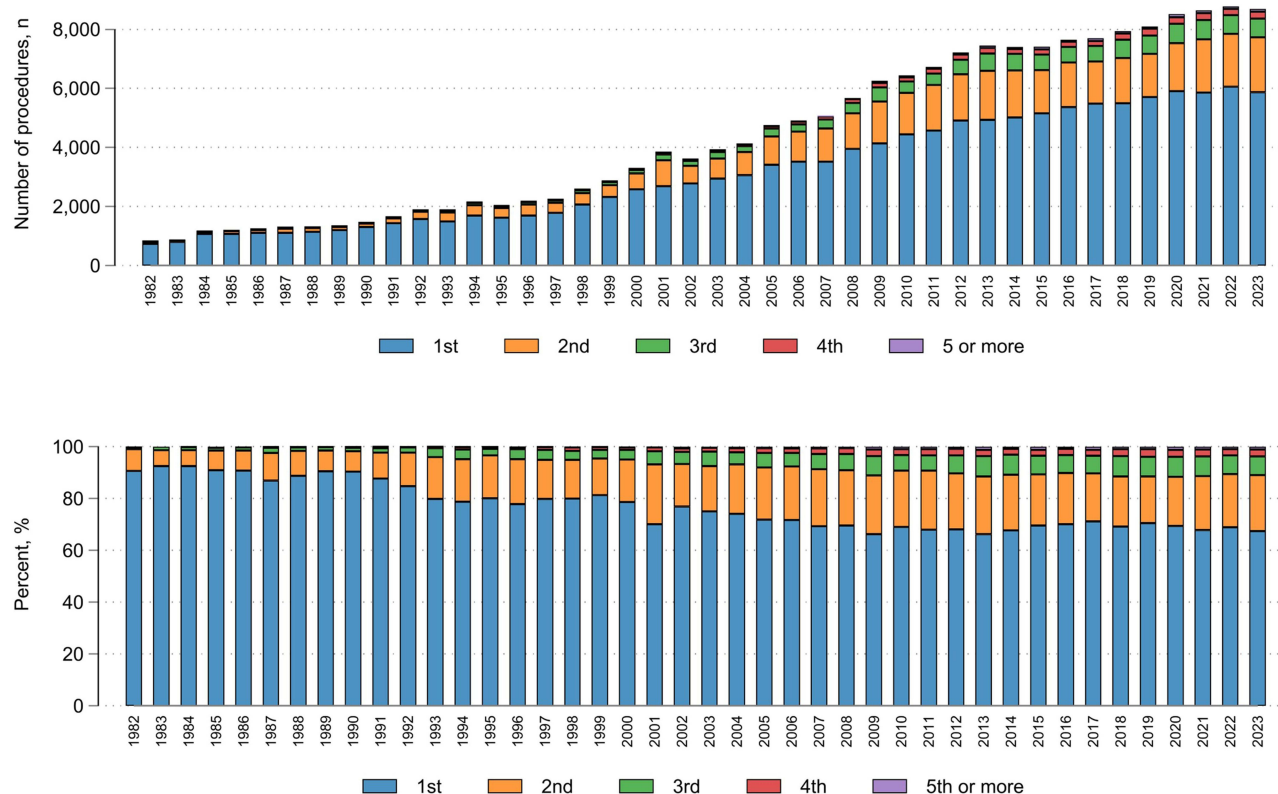


Figure 5 Total number of procedures performed in 1982–2023. Colors indicate registration type (first, second, third, fourth or more than fifth registration).

recalls pose serious risks to patients and must be addressed promptly through correction, monitoring, or device removal.²⁹

DPIR maintains accurate hardware registrations, which enabled rapid identification of all 299 patients implanted with the recalled Riata leads. This facilitated retrospective chart review, organization of an examination program to assess the prevalence of externalized leads, and long-term follow-up of patient outcomes.^{30,31} DPIR thus served both as a clinical instrument for addressing urgent patient safety issues, and as a provider of patient data for investigating the mechanisms, prevalence, and risk factors for conductor externalization and electrical failure. The resulting studies demonstrated that the prevalence of lead externalization in the Danish cohort was comparable to international findings, that the degree of externalization increased over time, that its anatomical distribution differed between single- and dual-coil leads, and that externalized leads were associated with an elevated long-term risk of electrical abnormalities. Subsequent studies have used the registry to examine lead-related outcomes in other subpopulations of patients with CIEDs to identify causes of failure and prevent future adverse events.^{15,32,33}

More recently, several new pacing and ICD modalities have been introduced, including conduction system pacing (CSP), leadless pacemakers, and subcutaneous and extravascular ICDs. The long-term durability and extractability of these systems remain uncertain, particularly for CSP, an emerging modality that has been widely adopted beyond controlled trial settings.^{34,35} DPIR began recording His-bundle lead placements in 2009 and added left bundle branch area (LBBA) lead placements in 2023. These updates will enable monitoring and longitudinal assessment of CSP lead performance and outcomes within the Danish healthcare setting.

Perspectives

Clinical registries are essential for independent monitoring of clinical performance and quality of care, and for documenting the prevalence and impact of cardiovascular disease on outcomes of CIED therapy. With a population now exceeding 133,000 individuals with CIEDs, combined with the ability to link individual-level data to numerous national databases in

Denmark,³ the research potential of DPIR is extensive. Maintaining a registry with high completeness and validity, however, requires a strong organizational structure, perseverance, and adaptability from all participating centers.

Beyond fostering numerous registry-based studies, the association of Danish CIED implanting centers has enabled several investigator-initiated national randomized controlled trials in clinical electrophysiology and device therapy, including the DANISH trial,³⁶ the DANPACE³⁷ and DANPACE II³⁸ trials, and the ongoing DANISH-CRT trial.³⁹ As demonstrated by the Western Denmark Heart Registry⁴⁰ and the SWEDEHEART Registry,^{41,42} clinical registries may also serve as platforms for RCTs. Registry-based RCTs leverage the existing infrastructure for randomization, data collection, and follow-up to provide pragmatic answers to key clinical questions, while substantially reducing the costs and time compared with conventional RCTs.

Conclusion

Maintaining clinical registries is labor-intensive but essential to preserve both scientific integrity and economic sustainability in cardiac electrophysiology and device therapy. DPIR comprises a complete, continuously updated cohort of patients with CIEDs, including detailed data on patients, hardware, and procedures. For more than 40 years, it has supported CIED therapy in Denmark, making it an invaluable tool both in clinical practice and for epidemiological research. Completeness is high, and most variables demonstrate excellent validity for research purposes. Through a wide range of population-based investigations, the registry has played a key role in shaping clinical decision-making in Denmark and beyond.

Abbreviations

AV, atrioventricular; CI, confidence interval; CIED, cardiac implantable electronic device; CPR, Civil Personal Registration; CRS, Civil Registration System; CRT, cardiac resynchronization therapy; CRT-P/D, cardiac resynchronization therapy pacemaker/defibrillator; CSP, conduction system pacing; DPIR, The Danish Pacemaker and ICD Register; EHRA, European Heart Rhythm Association; ESC, European Society of Cardiology; FDA, Food and Drug Administration; ICD, implantable cardioverter defibrillator; LBB, left bundle branch; LV, left ventricular; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; PPV, positive predictive value; RCT, randomized controlled trial.

Data Sharing Statement

Data is available upon reasonable request to the corresponding author.

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Disclosure

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References

1. The Danish Pacemaker and ICD Register Annual Report 2022. Report. The Danish Pacemaker and ICD Register; 2023.
2. Møller M, Arnsbo P, Asklund M, et al. Quality assessment of pacemaker implantations in Denmark. *Europace*. 2002;4(2):107–112. doi:10.1053/eupc.2002.0234

3. Schmidt M, Schmidt SAJ, Adelborg K, et al. The Danish health care system and epidemiological research: from health care contacts to database records. *Clin Epidemiol.* 2019;11:563–591. doi:10.2147/CLEP.S179083
4. Schmidt M, Pedersen L, Sorensen HT. The Danish Civil Registration System as a tool in epidemiology. *Eur J Epidemiol.* 2014;29(8):541–549. doi:10.1007/s10654-014-9930-3
5. Aktaa S, Abidin A, Arbelo E, et al. European Society of Cardiology Quality Indicators for the care and outcomes of cardiac pacing: developed by the Working Group for Cardiac Pacing Quality Indicators in collaboration with the European Heart Rhythm Association of the European Society of Cardiology. *Europace.* 2022;24(1):165–172. doi:10.1093/europace/eurab193
6. Sundhedsvæsnets Kvalitetsinstitut. Available from: <https://www.sundk.dk/>. Accessed April 24, 2026.
7. Kirkfeldt RE, Johansen JB, Nohr EA, Jorgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. *Eur Heart J.* 2014;35(18):1186–1194. doi:10.1093/eurheartj/ehz511
8. Kirkfeldt RE, Johansen JB, Nohr EA, Moller M, Arnsbo P, Nielsen JC. Risk factors for lead complications in cardiac pacing: a population-based cohort study of 28,860 Danish patients. *Heart Rhythm.* 2011;8(10):1622–1628. doi:10.1016/j.hrthm.2011.04.014
9. Sundhedsstyrelsen. Pacemakere, ICD'er og andre avancerede pacemakersystemer. Sundhedsstyrelsen; 2014.
10. Henriksen DP, Rasmussen L, Hansen MR, Hallas J, Pottsgård A. Comparison of the Five Danish Regions regarding demographic characteristics, healthcare utilization, and medication use—A descriptive cross-sectional study. *PLoS One.* 2015;10(10):e0140197. doi:10.1371/journal.pone.0140197
11. Kristensen AE, Larsen JM, Nielsen JC, et al. Validation of defibrillator lead performance registry data: insight from the Danish Pacemaker and ICD Register. *Europace.* 2017;19(7):1187–1192. doi:10.1093/europace/eur226
12. Kirkfeldt RE. *Complications After Cardiac Implantable Electronic Device Implantations in Denmark*. Aarhus University; 2013.
13. Blomstrom-Lundqvist C, Traykov V, Erba PA, et al. European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections—endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS). *Eur J Cardiothorac Surg.* 2020;57(1):e1–e31. doi:10.1093/ejcts/ezz296
14. Glikson M, Nielsen JC, Kronborg MB, et al. 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). *Europace.* 2021;42(35):3427–3520.
15. Frausing MHJP, Nielsen JC, Johansen JB, et al. Lead complications after cardiac surgery in patients with cardiac implantable electronic devices. *Eur J Cardiothorac Surg.* 2022;62(2). doi:10.1093/ejcts/ezac318
16. Frausing MHJP, Kronborg MB, Johansen JB, Nielsen JC. Avoiding implant complications in cardiac implantable electronic devices: what works? *Europace.* 2021;23(2):163–173. doi:10.1093/europace/eurab221
17. Kirkfeldt RE, Johansen JB, Nohr EA, Moller M, Arnsbo P, Nielsen JC. Pneumothorax in cardiac pacing: a population-based cohort study of 28,860 Danish patients. *Europace.* 2012;14(8):1132–1138. doi:10.1093/europace/eus054
18. Benz AP, Vamos M, Erath JW, Hohnloser SH. Cephalic vs subclavian lead implantation in cardiac implantable electronic devices: a systematic review and meta-analysis. *Europace.* 2019;21(1):121–129. doi:10.1093/europace/euy165
19. Burri H, Starck C, Auricchio A, et al. 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). *Europace.* 2021;23(7):983–1008. doi:10.1093/europace/eurab367
20. Frausing MHJP, Johansen JB, Afonso D, et al. Cost-effectiveness of an antibacterial envelope for infection prevention in patients undergoing cardiac resynchronization therapy reoperations in Denmark. *Europace.* 2023;25(6):1–9. doi:10.1093/europace/eurad159
21. Johansen JB, Jorgensen OD, Moller M, Arnsbo P, Mortensen PT, Nielsen JC. Infection after pacemaker implantation: infection rates and risk factors associated with infection in a population-based cohort study of 46299 consecutive patients. *Eur Heart J.* 2011;32(8):991–998. doi:10.1093/eurheartj/ehq497
22. Olsen T, Jorgensen OD, Nielsen JC, Thogersen AM, Philbert BT, Johansen JB. Incidence of device-related infection in 97 750 patients: clinical data from the complete Danish device-cohort (1982–2018). *Eur Heart J.* 2019;40(23):1862–1869. doi:10.1093/eurheartj/ehz316
23. Olsen T, Jorgensen OD, Nielsen JC, et al. Risk factors for cardiac implantable electronic device infections: a nationwide Danish study. *Eur Heart J.* 2022;43(47):4946–4956. doi:10.1093/eurheartj/ehac576
24. Frausing MHJP, Nielsen JC, Johansen JB, et al. Cardiac surgery in patients with cardiac implantable electronic devices and risk of device infections: a nationwide nested case-control study. *J Interv Card Electrophysiol.* 2022;66(4):897–904. doi:10.1007/s10840-022-01236-7
25. Frausing MHJP, Nielsen JC, Johansen JB, et al. Rate of permanent cardiac implantable electronic device infections after active fixation temporary transvenous pacing: a nationwide Danish cohort study. *Heart Rhythm.* 2022;3(1):50–56. doi:10.1016/j.hrthm.2021.11.008
26. Frausing MHJP, Nielsen JC, Johansen JB, et al. Rate of device-related infections using an antibacterial envelope in patients undergoing cardiac resynchronization therapy reoperations. *Europace.* 2022;24(3):421–429. doi:10.1093/europace/eurab207
27. Frausing MHJP, Nielsen JC, Westergaard CL, et al. Economic analyses in cardiac electrophysiology: from clinical efficacy to cost utility. *Europace.* 2024;26:1–11. doi:10.1093/europace/eurab031
28. Class 1 device recall Riata ST silicone insulated leads: US Food and Drug Administration; 2011 [cited November 19, 2025]. Available from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=105847>. Accessed April 24, 2026.
29. Hauser RG, Swerdlow CD. What electrophysiologists should know about cardiac implantable electronic device recalls. *Heart Rhythm.* 2024;21(6):958–961. doi:10.1016/j.hrthm.2024.02.039
30. Larsen JM, Riahi S, Nielsen JC, et al. Nationwide fluoroscopic screening of recalled Riata defibrillator leads in Denmark. *Heart Rhythm.* 2013;10(6):821–827. doi:10.1016/j.hrthm.2013.02.010
31. Larsen JM, Nielsen JC, Johansen JB, et al. Prospective nationwide fluoroscopic and electrical longitudinal follow-up of recalled Riata defibrillator leads in Denmark. *Heart Rhythm.* 2014;11(12):2141–2147. doi:10.1016/j.hrthm.2014.07.003
32. Larsen JM, Hjortshøj SP, Nielsen JC, et al. Single-coil and dual-coil defibrillator leads and association with clinical outcomes in a complete Danish nationwide ICD cohort. *Heart Rhythm.* 2016;13(3):706–712. doi:10.1016/j.hrthm.2015.11.034

33. Brandt NH, Kirkfeldt RE, Nielsen JC, et al. Single lead atrial vs dual chamber pacing in sick sinus syndrome: extended register-based follow-up in the DANPACE trial. *Europace*. 2017;19(12):1981–1987. doi:10.1093/europace/euw364
34. Frausing MHJP, Bæk AL, Kristensen J, Gerdes C, Nielsen JC, Kronborg MB. Long-term follow-up of selective and non-selective His bundle pacing leads in patients with atrioventricular block. *J Interv Card Electrophysiol*. 2023;66(8):1849–1857. doi:10.1007/s10840-023-01488-x
35. Burri H. Complications with left bundle branch area pacing. *Heart Rhythm*. 2022;19(5):735–736. doi:10.1016/j.hrthm.2022.01.032
36. Køber L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. *N Engl J Med*. 2016;375(13):1221–1230. doi:10.1056/NEJMoa1608029
37. Andersen HR, Thuesen L, Bagger JP, Vesterlund T, Thomsen PE. Prospective randomised trial of atrial versus ventricular pacing in sick-sinus syndrome. *Lancet*. 1994;344(8936):1523–1528. doi:10.1016/S0140-6736(94)90347-6
38. Kronborg MB, Frausing M, Malczynski J, et al. Atrial pacing minimization in sinus node dysfunction and risk of incident atrial fibrillation: a randomized trial. *Eur Heart J*. 2023;44(40):4246–4255. doi:10.1093/eurheartj/ehad564
39. Kronborg MB, Frausing M, Svendsen JH, et al. Does targeted positioning of the left ventricular pacing lead towards the latest local electrical activation in cardiac resynchronization therapy reduce the incidence of death or hospitalization for heart failure? *Am Heart J*. 2023;263:112–122. doi:10.1016/j.ahj.2023.05.011
40. Schmidt M, Maeng M, Madsen M, Sørensen HT, Jensen LO, Jakobsen CJ. The Western Denmark Heart Registry: its influence on cardiovascular patient care. *J Am Coll Cardiol*. 2018;71(11):1259–1272. doi:10.1016/j.jacc.2017.10.110
41. Jernberg T, Attebring MF, Hambræus K, et al. The Swedish Web-system for enhancement and development of evidence-based care in heart disease evaluated according to recommended therapies (SWEDEHEART). *Heart*. 2010;96(20):1617–1621. doi:10.1136/hrt.2010.198804
42. Fröbert O, Lagerqvist B, Olivecrona GK, et al. Thrombus aspiration during ST-segment elevation myocardial infarction. *N Engl J Med*. 2013;369(17):1587–1597. doi:10.1056/NEJMoa1308789

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