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### Erratum

Reference 56 was originally listed as '[56] Michał Sobstyl, Mirosław Ząbek, Wojciech Gorecki, Grażyna Brzuszkiewicz-Kuzmicka. Twiddler's syndrome in a patient with tremor-dominant Parkinson's disease. A case report and literature review. *Neurologia i Neurochirurgia Polska* 2015; 49(6):467-471. <https://doi.org/10.1016/j.pjnns.2015.10.004>.'

The correct reference 56 is '[56] Tahirovic Elnur, Haxhibeqiri-Karabdic Ilirijana. Twiddler's syndrome: Case report and literature review. *Heart Views* 2018;19(1):27-31. Doi: 10.4103/heartviews.heartviews\_89\_17.'

# A Systematic Review and Meta-analysis of the Prevalence and Risk Factors in Cardiac Implantable Electronic Device Malfunction

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## Abstract

**Introduction:** Cardiac implantable electronic devices (CIED) include permanent pacemakers (PPMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. They treat several cardiac issues and are dependent on batteries; however, similar to any medical equipment, they can fail. The prevalence and risk factors for CIED malfunction must be understood for earlier detection and better patient outcomes.

**Material and methods:** A comprehensive search was conducted through electronic bibliographic sources (PubMed and Cochrane) until January 2023 in order to identify reviews, cohort studies and case reports pertaining to CIED. The primary outcome is the probability of CIED malfunction. The secondary outcome concerned significant risk factors. Two authors independently extracted articles by utilizing pre-established data fields. Using a random-effects model, the aggregated prevalence and 95 % confidence intervals (CIs) were computed.

**Results:** The meta-analysis comprised eight review articles, twenty-two retrospective studies, and thirty-seven case reports from the systematic review. The eight review articles contained a CIED malfunction of 4.03 % (random-effects model). The pooled prevalence of CIED malfunction in the meta-analysis of 22 retrospective studies was 0.41 percent (using a fixed-effects model) and 8.01 percent (using a random-effects model). Moreover, age, pre-existing cardiac conditions, CIED type, lead placement, and medical device interactions all contributed to an increase in the heterogeneity ( $I^2 = 98.90\%$ ) of the risk of CIED malfunction.

**Conclusion:** CIED malfunction is common and more likely to occur in elderly individuals and in certain types of CIED. Clinicians should focus on risk factors and closely monitor the patients with higher probability for CIED malfunction with short intervals.

**Keywords:** Pacemaker malfunction, Prevalence, Risk factors meta-analysis, Implantable cardiac devices, Cardiology

## 1. Introduction

Cardiac implantable electronic devices (CIEDs) has brought a significant shift in the field of cardiology, providing therapeutic interventions that aim to stabilize and restore normal cardiac rhythms. Despite the revolutionary nature of these devices,

they are not concised to functional abnormalities, a fact that has substantial implications for the well-being and overall quality of life of patients who rely on them. Having a thorough comprehension of the frequency and various risk factors linked to CIED malfunctions is crucial for healthcare professionals [1]. This knowledge plays a crucial role in the early

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detection of problems, guaranteeing the delivery of appropriate medical treatments, and ultimately, contributing to improved patient health results. The pacemaker (PM) serves as an exemplary illustration of electronic devices that are surgically implanted in the thoracic or abdominal areas to precisely regulate the electrical signals of the heart, thereby ensuring a consistent and stable rhythm of cardiac activity [2]. The aforementioned functions emphasize the crucial role of these devices within the broader context of cardiac care and the overall welfare of patients. It consists of a generator, one or more leads, and programming system. The generator contains a battery and circuitry that control the pacing mode and timing intervals. The leads are thin insulated wires that connect the generator to the heart [3]. These leads deliver electrical signals from the generator to the heart muscle, stimulating the heart to contract and maintain an appropriate rate. Despite their advanced technology, PMs can experience various types of malfunction. Common ways in which a PM may malfunction include lead dislodgement, lead fracture, over- or under-sensing of cardiac signals, inappropriate rate, battery depletion, and circuitry failure. These malfunctions can result in inadequate pacing, ineffective therapy, or complete device failure, leading to serious consequences such as bradycardia, syncope, or sudden cardiac death [4]. PM malfunction may arise from multiple underlying mechanisms. Lead-related issues, such as lead dislodgement or fracture, can disrupt the electrical connection between the generator and heart, leading to failure in pacing or sensing. Inappropriate pacing or failure to recognize aberrant rhythms can occur because of over- or under-sensing cardiac impulses, respectively. Battery depletion over time can cause a loss of device functionality, circuitry failure can impair the ability of the PM to deliver appropriate pacing signals and malfunction can have serious consequences for patients. Implantable cardioverter-defibrillators (ICD) may fail to detect abnormal heart rhythms or deliver appropriate shocks when needed, putting patients at risk of sudden cardiac arrest. Cardiac resynchronization therapy (CRT) device may fail to deliver synchronized electrical impulses to the heart, disrupting its normal rhythm and function. This can result in symptoms such as shortness of breath, chest pain, and fatigue and may require immediate medical intervention to correct malfunction and restore proper cardiac function [5]. When encountering cases of malfunctioning CIED, it is crucial to perform a comprehensive preoperative evaluation to ensure the well-being of patients who are undergoing surgical procedures. An exhaustive examination of the

#### Abbreviation

AAI	Single-Chamber Pacing (Atrial Pacing)
AF	Atrial Fibrillation
AV	Atrioventricular
AVB	Atrioventricular Block
BPM	Beats Per Minute
CI	Confidence Interval
CIED	cardiac implanted electronic device
CRT	Cardiac Resynchronization Therapy
DDD	Dual-Chamber Pacing (Dual-Chamber Demand)
DFT	Defibrillation Threshold Testing
EKG	Electrocardiogram
EGM	Electrogram
EP	Electrophysiology
ERI	Elective Replacement Indicator
HR	Heart Rate
ICD	Implantable Cardioverter-Defibrillator
ICU	Implantable Cardioverter-Defibrillator Unit
LA	Left Atrium
LRL	Lower Rate Limit
LV	Left Ventricle
MRI	Magnetic Resonance Imaging
ODO	Battery End of Life
P-wave	Sensing of Atrial Depolarization
PCI	Percutaneous Coronary Intervention
PM	Pacemaker
PMI	Pacemaker Implantation
PMT	Pacemaker-Mediated Tachycardia
RA	Right Atrium
RCT	Randomized Controlled Trial
R-wave	Sensing of Ventricular Depolarization
RV	Right Ventricle
RVOT	Right Ventricular Outflow Tract
SAR	Sensor-Augmented Rate Response
STEMI	ST-Elevation Myocardial Infarction
URL	Upper Rate Limit
VF	Ventricular Fibrillation
VOO	Ventricular Pacing Without Sensing
VT	Ventricular Tachycardia
VVI	Single-Chamber Pacing (Ventricular Pacing)

CIED system is essential, as it assists in identifying current operational abnormalities or potential risks that may affect patient outcomes. The management of patients exhibiting malfunctions in CIED requires an interdisciplinary approach, which entails the cooperation of various healthcare professionals such as cardiologists, electrophysiologists, cardiac surgeons, nurses, and technical personnel. Every individual within this consortium brings forth their distinct expertise and skills, thereby establishing a synergistic atmosphere that facilitates comprehensive evaluation, accurate diagnostic procedures, and prudent management strategies. This collaborative effort guarantees the prompt detection and resolution of device malfunctions, effectively reducing the likelihood of negative complications and simultaneously improving patient outcomes [6]. The

combined expertise and collaborative efforts of this interdisciplinary team are crucial in maintaining patient safety and improving the quality of the care delivered. The interprofessional team must assess the CIED settings, battery status, lead integrity, and underlying cardiac condition to make informed decisions regarding surgery, anesthesia, and appropriate perioperative monitoring strategies [7]. Being acquainted with the full scope, factors that contribute to, and the underlying mechanisms of malfunction in CIED is a crucial responsibility for healthcare professionals involved in the care of patients who have been implanted with these devices. In order to comprehensively perceive the malfunction of CIED, this study undertook a rigorous examination of existing scholarly works, aiming to encompass a comprehensive viewpoint of the matter under consideration. The aims of this work is to encompass the clarification of the consequences of malfunctioning CIED on patient outcomes, as well as emphasizing the utmost significance of a multidisciplinary team in effectively managing these complex complications. The comprehensive analysis has provided valuable insights that have the potential to enhance clinical methodologies, enhance patient safety, and drive the development of preventive measures to reduce the occurrence of CIED malfunctions. The contributions mentioned are of great value, as they have a crucial impact on enhancing the level of care and strengthening the ability of healthcare systems to overcome challenges related to medical devices [8].

## 2. Materials and methods

### 2.1. Research objectives

This systematic review has two objectives: To determine the prevalence of CIED malfunction and to identify the underlying risk factors of these device-related malfunctions. This academic effort seeks to add to the body of knowledge by exploring the complexities of CIED malfunctions. This will help improving clinical practices, improving patient care and safety for those with life-sustaining devices.

### 2.2. Search strategy

A comprehensive search was conducted in the PubMed and Cochrane databases using specified keywords and search terms. The search strategy was as follows: Databases: PubMed and Cochrane Keywords: “implantable cardioverter defibrillator [All

Fields] OR “Implantable Cardiac Device s [All Fields] OR “pacemaker, artificial [MeSH Terms] OR (“pacemaker [All Fields] AND “artificial [All Fields]) OR “artificial pacemaker [All Fields] OR “pacemaker [All Fields] OR “pacemakers [All Fields] OR “pacemaking [All Fields]) OR “CIED [All Fields] OR “cardiac implantable electronic device [All Fields] OR “cardiac resynchronization therapy [All Fields] AND (“malfunction [All Fields] OR “malfunction [All Fields] OR “malfunction [All Fields] AND (2010:2023[pdat]). The search was limited to articles published between 2010 and 2023 to ensure inclusion of recent research.

### 2.3. Study selection

This analysis's criteria were carefully chosen to ensure data relevance and quality. The parameters included (1) Data on cardiac implantable electronic device (CIED) malfunction prevalence and risk factors; (2) Publication in English to facilitate comprehensive analysis and interpretation; (3) Research on human subjects to ensure applicability and translatability to clinical practice; and (4) Publication within the temporal frame. This systematic review's integrity and scholarly rigor depended on these strict inclusion criteria.

### 2.4. Data extraction

All studies that met the inclusion criteria were included, and two independent reviewers (AS and FA) extracted data from these studies. To capture pertinent information from the selected studies, a data extraction sheet was drafted and the following data were extracted based on the all table heading.

### 2.5. Data analysis

The extracted data were descriptively analyzed. The prevalence rates and risk factors of CIED malfunction are summarized and presented in tabular or graphic forms. Additionally, the types of CIED malfunctions and their clinical consequences were summarized.

### 2.6. Quality assessment

The quality of the included studies was assessed using the Newcastle–Ottawa Scale for Studies. This assessment helped evaluate the methodological quality and potential biases of the included studies.

## 2.7. Data synthesis

Considering the heterogeneity of the included studies, narrative synthesis was performed to summarize the results. The data were categorized based on prevalence rates, risk factors, and CIED malfunction categories. Discussed are any common tendencies or patterns uncovered by the study depicts the PRISMA 2020 flowchart for new systematic review [Fig. 1], which includes database and registry searches. The research methods are recorded in Prospero (CRD42023385681).

## 3. Result

The proportions from eight separate studies were synthesized using meta-analysis, revealing a significant level of heterogeneity, as indicated by an I<sup>2</sup>

value of 92.77 %. The significant variation observed in the prevalence rates among the studies included in this analysis suggests the presence of potential disparities in the demographic characteristics of the study populations, methodological approaches employed, or other factors that may have influenced the outcomes. Despite the evident diversity, the combined percentage of positive cases, computed using a random-effects model, was determined to be 4.03 %. This inference suggests that, on average, the condition being examined affects approximately 4 % of individuals within the population being analyzed. It is crucial to emphasize that this numerical value represents a mean approximation, and the precise ratio of affirmative instances may vary depending on the particular attributes of the population being studied [Fig. 2]. It is noteworthy that the meta-analysis did not reveal any evidence of publication bias.

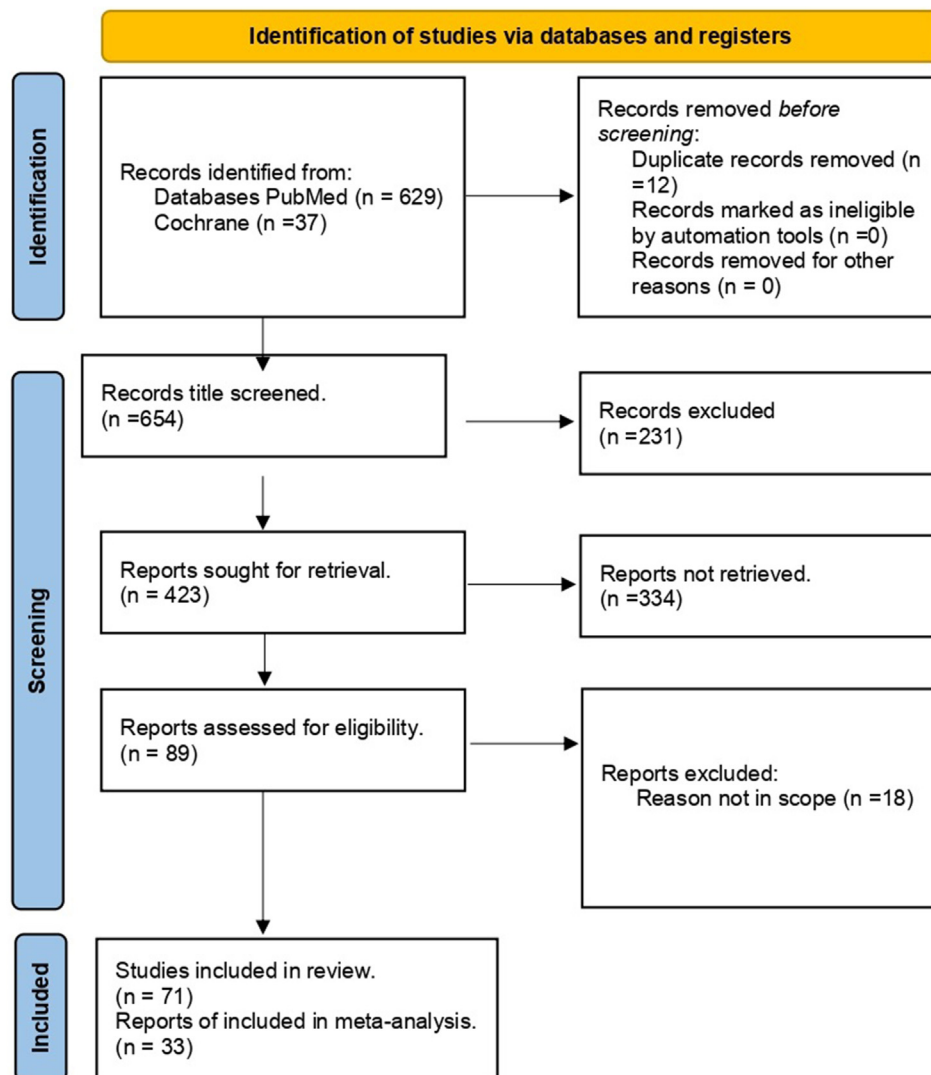


Fig. 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only.

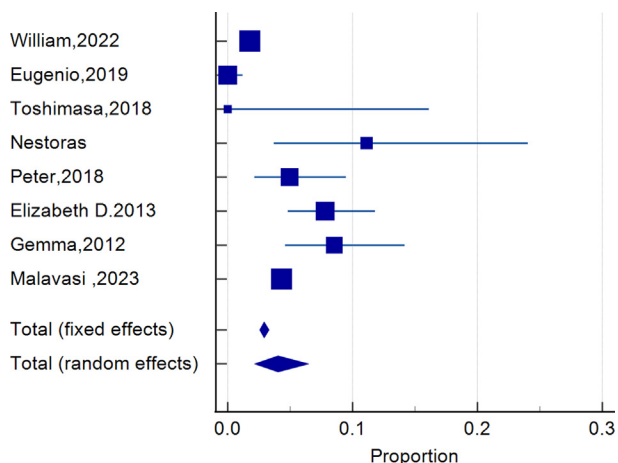


Fig. 2. A forest plot for the prevalence of pacemaker malfunctions in review studies.

This implies that the collection of studies included in this review is likely comprehensive and representative of the wider range of pertinent research, thus enhancing the dependability of the findings. When examining retrospective studies, the meta-analysis discovered that the combined prevalence of CIED malfunction was 0.41 % using a fixed-effects model and 8.01 % using a random-effects model. The significant heterogeneity observed ( $I^2 = 98.90\%$ ) highlights the existence of considerable variations in the populations studied, methodologies employed,

and other factors that contribute to the findings [Fig. 3]. Significantly, the analysis identified the presence of publication bias, suggesting a tendency to publish studies that yield statistically significant results rather than those with non-significant findings. This observation suggests the potential for an overestimation of the combined prevalence of the specific condition, as indicated in [Fig. 4]. Notwithstanding the difficulties arising from the considerable heterogeneity and the potential influence of publication bias, the findings of the meta-analysis indicate a relatively frequent prevalence of the CIED malfunction among the included studies. However, the wide range of prevalence estimates found in various studies, ranging from 0.00 % to 46.56 %, indicates that the actual prevalence of the condition may vary significantly depending on the specific population under investigation. This comprehensive analysis aims to explore the underlying causes of CIED malfunction, utilizing a wide range of studies to shed light on a variety of common and uncommon issues that affect these vital medical devices.

### 3.1. Summary of review studies

The research conducted by William Brandon revealed that a notable factor contributing to malfunction in cardiac implantable electronic devices

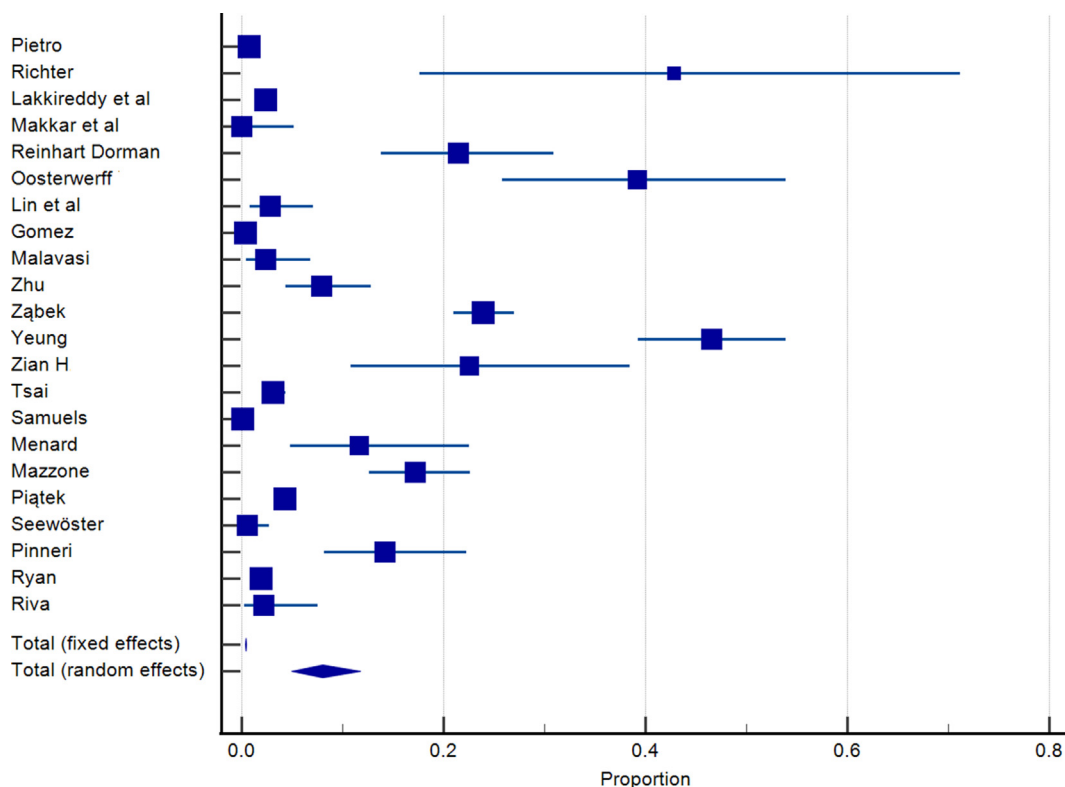


Fig. 3. A forest plot for the prevalence of pacemaker malfunctions in retrospective studies.

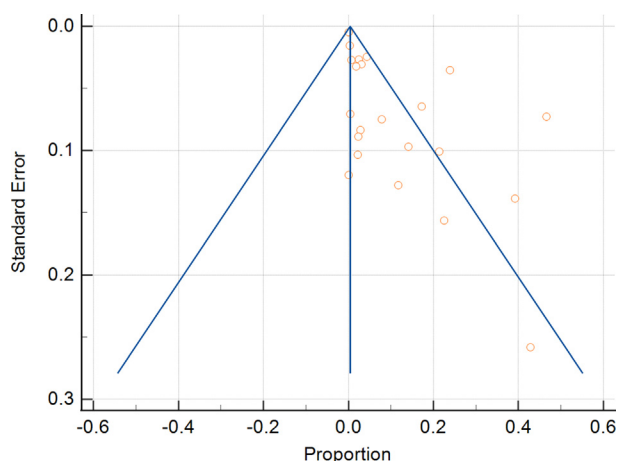


Fig. 4. A funnel plot present the publication bias in retrospective studies.

(CIEDs) was a deficiency in sensing, pacing, and capturing. This particular issue was observed in 1.7 % of the cases analyzed. Electrocardiography (ECG) serves as the primary method for detection, while the treatment approach involves addressing reversible factors and strategically employing temporary magnet placement to facilitate pacing. Frequently, it is necessary to engage in consultations with specialists in cardiology in order to refine the sensitivity settings of the device [9]. In a separate context, the study conducted by Eugenio provided a comforting finding, indicating that stun guns do not cause harm or result in lasting impairment to pacemakers or implantable defibrillators, even when used by individuals who have these devices [10]. The investigation conducted by Sinisa emphasized the importance of prioritizing the safety of patients with implanted cardiac implantable electronic devices (CIEDs) through the implementation of secure surgical and diagnostic practices. This study advocated for the adoption of thorough pre-operative assessments and careful preparation to mitigate potential risks. Furthermore, the research recommended refraining from utilizing nuclear magnetic resonance imaging in patients with standard pacemakers due to the identification of potential hazards [11]. The research conducted by Toshimasa shed light on the effective utilization of leadless pacemakers, as evidenced by the absence of any occurrences of device dislocation or malfunction over a period of 12 months [12]. In contrast, Pietro's study emphasized a heightened susceptibility to infection linked to leadless pacemakers, suggesting the inclusion of conventional cardiac implantable electronic devices (CIEDs) in the deliberation of implantation choices [13]. In the field of pediatrics, Nestoras discovered a notable prevalence of 11 % in lead malfunction, with ventricular

lead fractures being the primary cause. Notwithstanding this obstacle, the research confirmed that surgical procedures were carried out with minimal risk [14]. In contrast, Peter's research, which involved a sample of 162 hospitalized patients diagnosed with syncope, found that device and lead malfunction were not common causes. This highlights the importance of investigating other potential causes for syncope. Elizabeth D.'s study emphasized the usefulness of post-mortem CIED interrogations, revealing that they often provided valuable information related to device malfunction, as well as shedding light on the timing and mechanisms of mortality [16]. Please consult Table 1 for a comprehensive overview.

### 3.2. Summary of retrospective studies

The occurrence of malfunctions in Cardiac Implantable Electronic Devices (CIEDs) can be ascribed to a wide range of factors, including hardware malfunctions, software anomalies, environmental influences, and specific medical conditions. The specific causes of these malfunctions may differ depending on the type of CIED and the underlying medical conditions of the patient. The primary factor contributing to dysfunction in conventional CIEDs is hardware malfunctions, which include battery depletion, lead fractures, and damage to the device. Battery failure commonly occurs when the battery's power reserve is depleted. Fractures of the sternum can occur as a result of chronic mechanical stress or acute traumatic force applied to the thoracic area. The device may incur damages from different factors, including exposure to moisture or high temperatures [21–24,35]. Software-related problems have the potential to cause malfunctions in cardiac implantable electronic devices (CIEDs). The aforementioned concerns could arise due to disparities in programming or malfunctions within the software structure of the device, which could result in inadequate pacing procedures or erroneous heartbeat identifications [28]. Environmental factors can also impact the functionality of cardiac implantable electronic devices (CIEDs), as electromagnetic interference (EMI) emitted by external devices like magnetic resonance imaging (MRI) machines and cellular phones can pose potential risks. Electromagnetic interference (EMI) has the potential to disturb the functioning of the device, and in more extreme instances, can cause it to become non-functional [33,43]. Several medical conditions have been recognized as potential factors that may contribute to complications associated with cardiac implantable electronic devices (CIEDs). The



Table 1. Summary of the review study.

Author	Year	Title	No of Case	Prevalence	Cause of failure	Detection method	Treatment	Type of study	Quality assessment
William Brandon [9]	2022	Pacemaker Malfunction—Review of Permanent Pacemakers and Malfunctions Encountered in the Emergency Department	66 from 3743	1.7 %	Failure to Sense, Pace, Capture 3	ECG	Treat reversible causes Temporary magnet placement for pacing Cardiology consults to adjust sensitivity	Review	0.9
Eugenio [10]	2019	Electrical Stun Gun and Modern Implantable Cardiac Stimulators.	0 (No damage or permanent malfunction)	0 %	No damage or permanent malfunction was observed in either pacemakers or implantable defibrillators.	ECG	No risks resulted when the stun gun was used by a person wearing a pacemaker or an implantable defibrillator.	Review	0.5
Sinisa [11]	2011	Approach to patients with implanted pacemaker and scheduled surgical or diagnostic procedure.	3267		Risk is especially high if the procedure is performed in a body region close to the implanted pacemaker	ECG	Patients with implanted permanent pacemakers have no absolute contraindications for surgical treatment in any field of surgery. Adequate preoperative assessment and preparation, is a sufficient guarantee for safe diagnostic procedures and surgical treatment of patients with implanted pacemakers **Nuclear magnetic resonance is not recommended in patients with standard pacemakers	Review	0.5
Toshimasa [12]	2018	Leadless pacemaker implantation and concurrent atrioventricular junction ablation in patients with atrial fibrillation.	21	0 %	There was no device dislodgement or malfunction during the 12-month follow-up	ECG	Concurrent Micra implantation and AVJ ablation are feasible and appears safe	Review	0.5

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Table 1. (continued)

Author	Year	Title	No of Case	Prevalence	Cause of failure	Detection method	Treatment	Type of study	Quality assessment
Pietro [13]	2022	Leadless transcatheter pacemaker: Indications, implantation technique and periprocedural patient management in the Italian clinical practice.	7 from 782	0.0089 %	PM was the high-risk of device infection	ECG	The choice of implanting an L-PM rather than a conventional PM	Review	0.5
Nestoras [14]	2010	Long-term follow-up after steroid-eluting epicardial pacemaker implantation in young children: a single centre experience.	5 from 45	11 %	Five lead malfunction events were detected during the follow-up time, three of which were due to ventricular lead fracture	ECG	Operations were performed at a low risk.	Review	0.75
Peter [15]	2012	Pacing system malfunction is a rare cause of hospital admission for syncope in patients with a permanent pacemaker.	8 from 162	4.9 %	We found that in 162 patients with previously implanted PPM who were admitted to our hospital with syncope, device and lead malfunction were uncommon causes of hospital admission for syncope.	ECG	The attending physician might consider other potential causes of syncope, and may decide to evaluate for these causes in parallel with PPM interrogation	Review	0.5
Elizabeth D [16].	2021	Post mortem Interrogation of Cardiac Implantable Electronic Devices: A 15-Year Experience.	20 from 256	7.7 %	The potential malfunction was identified	CIED ECG	Post mortem CIED interrogation frequently contributes important information regarding critical device malfunction, pre-mortem abnormalities, mechanism, and time of death or patient identity	Review	0.5
Maria Lucia [17]	2016	Presence of 'ghosts' and mortality after transvenous lead extraction.	10 from 217	5 %	Device infections.	ECG	Transvenous lead extraction (TLE)	Review	0.5
Santiago [18]	2013	Reuse of pacemakers: comparison of short and long-term performance.	85 from 603	14 %	Reuse device	ECG, CXR	Pacemaker reuse is feasible and safe and is a viable option for patient with bradyarrhythmias.	Review	0.5

Gemma [19]	2012	Safety and effectiveness of transvenous lead extraction in octogenarians.	13 from 152	8.5 %	lead malfunction.	ECG, CXR	Transvenous lead extraction can be performed safely and successfully in octogenarians.	Review	0.5
Malavasi et al. [20]	2022	A systematic review and meta analysis on oncological radiotherapy in patient with cardiac implantable electronic device: prevalence and predictors of device malfunction in 3121 patients	135 from 3121	4.3 %	The use of neutron-producing energies and more complex devices (ICD/CRT-D)	ECG, CXR	No treatment	Systematic review and meta-analysis	0.25
Psaltikidis et al.	2021	Reuse of pacemakers and implantable cardioverter-defibrillators: systematic review, meta-analysis and quality assessment of the body of evidence.	6 from 1778	0.33 %	infection rates (OR 0.98; 95 % CI 0.60–1.60), device malfunction (OR 1.58; 95 % CI 0.56–4.48) or premature battery depletion (OR 1.96; 95 % CI 0.81–4.72) and no device-related deaths.	Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework	Device change	Systematic review and meta-analysis	0.5

Table 2. Summary of the retrospective study.

Author	Year	Title	No of Case	Prevalence	Cause of failure	Detection method	Treatment	Type of study	Quality assessment
Pietro [21]	2021	Causes of syncopal recurrences in patients treated with permanent pacing for bradyarrhythmic syncope: Findings from the SYNCOPACED registry.	10 from 1364	0.7 %	Pacing system malfunction, structural cardiac diseases, and tachyarrhythmias are rare mechanisms.	ECG	pacemaker or lead malfunction	Retrospective Cohort	0.75
Richter [22]	2018	Battery Malfunction of a Leadless Cardiac Pacemaker: Worrisome Single-Center Experience.	6 from 14	43 %	Battery malfunction 40 % of LCP in 3 years 6LCP \ 5CCP	Rhythm of 35 and 40 ppm	Cardiac pacing	Retrospective Cohort	0.75
Reinhart Dorman [23]	2014	High failure rate of the 5 French Sorin Hepta 4B pacemaker lead.	21 From 98	21 %	The most common complication was electrical dysfunction	ECG, CXR	The co-radial multifilar design, allowing a smaller diameter of the lead, may explain this finding.	Retrospective Cohort	0.5
Lakkireddy et al. [24]	2017	A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker. (MANUSCRIPT)	34 battery failure out of 1423 implanted LP	2.3 %	Battery failure due to: Increase in battery resistance caused by insufficient electrolyte availability at the cathode/anode interface.	Observation	1) In pacemaker dependent, device replacement was recommended or abandon the LP and add a conventional TVP.	Randomized Controlled Trial	0.75
Makkar et al. [25]	2012	Effect of radiation therapy on permanent pacemaker and implantable cardioverter-defibrillator function	69/CIED 50 of them (72 %) had pacemakers 19 (28 %) had ICDs	0 %	Radiation Therapy ⇒ CIED malfunction due to indirect RT exposure is uncommon	Interrogation	No treatment	Retrospective Cohort	0.75
Nakamura et al. [26]	2020	Effect of X-ray dose rates higher than 8 Gy/min on the functioning of cardiac implantable electronic devices	4 CIEDs- 3/4 CIEDs malfunctioned in the 6 MV FFF- 4/4 CIEDs malfunctioned 10 MV FFFWHEN THE DOSE RATE >8 Gy/min	100 %	Irradiation with X-ray dose >8 Gy/min caused a temporary interference	ECG during irradiation	Simultaneously returned to normal when stopping the irradiation	Retrospective Cohort	0.5

Oosterwerff [27]	2022	Experience with malfunctioning leadless pacemakers: Troubleshooting and management during medium-term follow-up	51 (2 excluded because of incomplete follow up 20 malfunctions)	42 %	Premature LP battery failure (18), malpacing/malsensing (1) and mechanical dislocation (1)	Observation	Implantation of another LP or a trans venous device was successfully performed in all 20 patients	Retrospective Cohort	0.25
Lin et al. [28]	2017	Frequency of pacemaker malfunction associated with monopolar electrosurgery during pulse generator replacement or upgrade surgery	4 of 142	2.8 %	Electro surgery (PG replacement or upgrade)	Continuous or ECG	Not mentioned	Retrospective study	0.5
Gomez [29]	2013	Malfunctions of implantable cardiac devices in patients receiving proton beam therapy: incidence and predictions	4228 PM + 14 ICD 6 malfunctions in 5 patients 2 PM and 3 ICD	0.42 %	Proton beam therapy (PBT) ⇒ All resets occurred in patients receiving thoracic PBT	Observation	Interrogation and reprogramming	Retrospective study	0.5
Malavasi [30]	2019	Radiotherapy-induced malfunctions of cardiac implantable electronic devices in cancer patients	126 patients (150 course of RT) 99 PM and 27 ICD (=126) 3 malfunctions (2 %)	2 %	Radiation Therapy	Observation	Reprogramming, no replacement	Retrospective study	0.25
Zhu [31]	2019	Inappropriate noise detection in Tendril family pacing leads.	14 from 178	8 %	Nose with Tendril family pacing leads	Muscle or diaphragm movement, electromagnetic interference, or noise from other sources	Recall affected device	Retrospective study	0.75
Zabek [32]	2018	Analysis of electrical lead failures in patients referred for trans venous lead extraction procedures.	192 from 804	23.8 %	Lead impedance below 200 Ohm or above 2000 Ohm 193 leads (96.5 %) Ineffective capture at maximum output pacing 161 leads (80.5 %) Sensing abnormalities (other than electromagnetic interference) 193 leads (96.5 %) Activation of Lead Integrity Alert 8 leads (4.0 %) Lead fracture detected on chest x-ray or fluoroscopy	ECG -CXR	Extraction	Retrospective study	0.75

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Table 2. (continued)

Author	Year	Title	No of Case	Prevalence	Cause of failure	Detection method	Treatment	Type of study	Quality assessment
Yeung [33]	2018	Radiotherapy for patients with cardiovascular implantable electronic devices: an 11-year experience.	47 %(88) of 189 of the patients had CIED malfunctions during or after radiotherapy	47 %	Loss of pacing output, followed by sensory issues and battery depletion.	ECG -CXR	Reprogramming or replacing the CIED	Retrospective study	0.75
Zian H [34].	2015	Sudden Death in Patients With Cardiac Implantable Electronic Devices.	9 from 40	22.5 %	Hardware flier and VF, VT then sudden death	ECG	Death	Retrospective study	0.75
Tsai [35]	2010	Prevalence of complications during implantation and during 38-month follow-up of 1060 consecutive patients with implantable cardioverter-defibrillators.	1060	3.3 %	Fractured leads requiring lead revision in 36 (3.4 %) patients, lead infection requiring antibiotics in 5 (0.5 %) patients, device replacement because of malfunction in 5	ECG CXR C&S	Treat reversible causes	Retrospective study	0.75
Samuels [36]	2021	Electromagnetic interference on cardiac pacemakers and implantable cardioverter defibrillators during endoscopy as reported to the US Federal Drug Administration.	45 from 43,759	0.01 %	Resulted in Injury 26 (58 %) \ No Injury		A total dose of 47.25 Gy applied in very close proximity to the cardiac resynchronization therapy pacemaker was carried out safely without jeopardizing the patient and any device malfunction during and after treatment within >1.5 years	Retrospective study	0.5
Menard [37]	2011	Radiotherapy for breast cancer and pacemaker	7 from 60	11.6 %	Therapeutic irradiation may cause pacemakers to malfunction due to the effects of ionizing radiation or electromagnetic interference.	ECG, CXR	All pacemakers were controlled before and after radiotherapy by the patient's cardiologist	Retrospective study	0.75
Mazzone [38]	2018	Safety and efficacy of the new bidirectional rotational Evolution® mechanical lead extraction sheath: results from a multi-center Italian registry.	41 from 238	17 %	The new bidirectional rotational mechanical lead extraction (LE) sheath in chronically implanted leads (>1-year-old leads).	ECG, CXR	The Evolution mechanical extraction sheath is an effective and safe tool for extracting chronically implanted leads.	Retrospective study	0.75

Piątek [39]	2016	Analysis of the incidence and causes of repeated surgical interventions in patients with early complications electrotherapy - 1 center experience from the period 2012–2015.	72 from 1673	4.3 %	Implantations of the leads with passive fixation and anti-coagulation therapy in perioperative period.	ECG, CXR	Used of the leads with active fixation and proper preparation of the patients requiring the antithrombic therapy.	Retrospective study	0.5
Seewöster [40]	2019	Cardiovascular magnetic resonance imaging in patients with cardiac implantable electronic devices: best practice and real-world experience.	1 from 200	0.05 %	Cardiovascular magnetic resonance (CMR) imaging has long been a contraindication for patients with a cardiac implantable electronic device (CIED).	ECG, CXR	With adherence to a standardized protocol and established exclusion criteria CMR imaging could safely be performed in patients with a CIED	Retrospective study	0.5
Richardson [41]	2014	Comparative outcomes of trans venous extraction of Sprint Fidelis and Riata defibrillator lead: a single center experience.	47 of 145	32.4 %	device-related endocarditis	Transthoracic (TTE) and trans esophageal (TEE) echocardiography	extraction	Retrospective study	0.75
Pinneri [42]	2013	Echocardiography-guided versus fluoroscopy-guided temporary pacing in the emergency setting: an observational study.	15 from 106	14 %	Comparing echocardiography-guided temporary pacemaker via the right internal jugular vein to standard fluoroscopy-guided temporary pacemaker via the femoral vein	ECG, CXR	Echocardiography-guided temporary pacemaker is a well-tolerated procedure that could allow reliable insertion of a temporary pacemaker	Retrospective study	0.75
Ryan [43]	2018	Oversensing of trans-thoracic excitatory stimuli in contemporary pacemakers.	18 from 959	1.8 %	The TIM electrical signal itself is over-sexed, causing device malfunction	ECG, CXR	Oversensing with pacing inhibition is apparent with the potential of adverse effects to patients	Retrospective study	0.5
Riva [44]	2018	Radiotherapy in patients with cardiac implantable electronic devices: clinical and dosimetric aspects.	2 from 93	2 %	The aim of this work was to evaluate RT-related malfunctions of CIED in a cohort of patients who underwent RT	ECG, CXR	A reprogramming of ICD when the patient reached a delivered dose to the tumor of 32 Gy, and an altered sensing function requiring replacement after 11 months from the end of RT	Retrospective study	0.75

optimal functioning of the device may be impaired by conditions such as infections and heart failure (29) (30). Please consult [Table 2](#) for a comprehensive analysis.

### 3.3. Summary of case report studies

Numerous case reports and empirical studies have shed light on the complex nature of cardiac implantable electronic device (CIED) failures, offering valuable understanding of the numerous challenges and complications involved in the management of patients with such devices. Liang has identified the mismanagement of atrial leads as a prominent factor contributing to malfunction of cardiac implantable electronic devices (CIED), resulting in the occurrence of excessive pacing [45]. Rizal's research shed light on the periodic malfunctioning of cardiac implantable electronic devices (CIEDs) as a result of Subclavian Crush Syndrome, which is caused by the sustained pressure exerted on the lead by the clavicle [46]. Rodriguez's investigation [47] identified potential inducers of malfunction in cardiac implantable electronic devices (CIEDs), namely interactions between pharmacological agents, metabolic disturbances, and high potassium levels. The occurrence of Twiddler's Syndrome, a condition in which patients engage in manipulation of the generator, was observed and documented by Mandal et al. and Tahirovic, highlighting the importance of educating patients about this critical issue [48,56]. The scholarly discussion by Obszanski et al. regarding the impact of lightning on cardiac implantable electronic devices (CIEDs) emphasized the importance of diligent surveillance and recognized the possibility of electrical burns occurring at the electrode interface [49]. The studies conducted by Wang, Upadhyay, and Tomoko [50,53,54] have reported instances of CIED malfunctions occurring alongside acute medical events, including hyperkalemia, proximal coronary artery occlusion, and exposure to radiation therapy. Torres-Ayala and Schernthaner emphasized the significance of anatomical anomalies in relation to the positioning of devices, which can result in potential malfunctions [55,63]. Venkatachalam's research underscored the significance of psychological variables and the complexities associated with the interpretation of CIED ECGs [51]. In aggregate, these case reports underscore the necessity of comprehensive patient education, meticulous surveillance, and timely intervention for reversible factors. This statement emphasizes the importance of medical professionals maintaining a high level of attentiveness

in their interpretation of electrocardiograms (ECGs) and taking proactive measures to address any potential complications that may arise. The collective knowledge gained from these various findings has the potential to improve the quality of patient care and reduce the occurrence of pacemaker malfunctions in different clinical settings. Please refer to [Table 3](#) for a comprehensive summary of these insights.

## 4. Discussion

The examination of three separate tables, which provide information on different aspects of malfunction in cardiac implantable electronic devices (CIEDs), offers a comprehensive and multifaceted understanding of the reasons and frequency of these failures in various clinical settings. This collection of studies sheds light on the intricate complexities associated with malfunctions in cardiac implantable electronic devices (CIEDs), offering valuable insights into the underlying causes and the resulting implications for patient care. [Table 1](#) provides a comprehensive analysis, encompassing a diverse range of studies that investigate the prevalence and underlying factors contributing to malfunctions in cardiac implantable electronic devices (CIEDs). This encompasses inquiries into matters pertaining to batteries, challenges associated with leads, and the influence of external factors such as radiation and electromagnetic interference. The table presented includes notable studies, such as the research conducted by William Brandon [9], which provide analysis on the complex and multifaceted aspects of CIED malfunction, encompassing a wide range of contributing factors. The study conducted by Santiago examines the reutilization of pacemakers and offers valuable insights into the potential impact of these practices on the performance of the devices. Taken together, these studies emphasize the need for a comprehensive comprehension of the various elements that contribute to malfunctioning of cardiac implantable electronic devices (CIEDs), including both internal device-related problems and external environmental factors. [Table 2](#) enhances the ongoing discussion by classifying research studies according to their diagnostic methodologies, emphasizing the crucial significance of diagnostic tools such as electrocardiography (ECG), chest X-rays, and other diagnostic modalities in the detection of malfunctions in cardiac implantable electronic devices (CIEDs). The research conducted by Nestoras [14] offers a comprehensive examination of the longitudinal surveillance of pediatric individuals who have been implanted with steroid-eluting epicardial



Table 3. Summary of all case report studies.

Author	Year	Title	No of Case	Cause of failure	Detection method	Treatment	Type of study	Quality assessment
Liang [45]	2021	Pacemaker malfunction? What is the mechanism?	1	Atrial lead understanding leading to over pacing	X-ray	Pacemaker removal	Case report	0.5
Rizal [46]	2020	Intermittent Pacemaker Malfunction Caused by Continuous Compression of the Lead by the Clavicle (Subclavian Crush Syndrome).	1	Several syncopal events from Subclavian crush syndrome	ECG ventricular asystole	Trans venous temporary pacemaker insertion	Case report	0.5
Rodriguez [47]	2011	Pacemaker malfunction induced by a pharmacy-metabolic “perfect storm” a brief report.	1	Antiarrhythmic drugs, hyperkalemia, 3 syncopal episodes within 24 h	Electrocardiograph	Hyperkalemia correction, the device was reprogrammed	Case report	0.75
Mandal et al. [48]	2012	A Rare Case of Very Early Pacemaker Twiddler's Syndrome.	1	Twiddler's syndrome: It occurred early within the first 48 h	CXR, PM interrogation and fluoroscopy	Insertion of prophylactic temporary pacemaker	Case report	0.5
Obszanski et al. [49]	2019	Lightning-induced pacing system malfunction: a case report	1	Lightning-induced: 1) Electrical burn at the endocardial–electrode interface2) Sudden elevation of the pacing threshold	ECG, echo and interrogation	Transcutaneous lead extraction and implantation of a new DDD system	Case report	0.5
Wang [50]	2014	[Hyperkalemia-induced failure of pacemaker capture and sensing: a case report].	1	Acute hyperkalemia, ventricular escape rhythm, associated with failure of pacemaker capture and sensing	ECG, WBW	Treat reversible causes	Case report	0.5
Venkatachalam [51]	2011	Common pitfalls in interpreting pacemaker electrocardiograms in the emergency department	3	Sometime psychological cause ECG not enough	ECG, understanding cycle	Treat reversible causes	Case report	0.5
Umei [52]	2018	Pacemaker malfunction after acute myocardial infarction in a patient with wrap-around left anterior descending artery supplying the right ventricular apex.	1	Cardiopulmonary arrest occurred due to the elevation of the pacing threshold because of pacemaker malfunction.	ECG	The pacemaker was upgraded to an implantable cardioverter-defibrillator	Case report	0.5
Upadhyay [53]	2011	The stunned atrial lead: Transient malfunction of a permanent atrial pacer lead following acute myocardial infarction.	1	Proximal right coronary artery occlusion caused transient loss of sensing and capture of the atrial lead	ECG	Percutaneous coronary intervention (PCI), leading to return of lead function over time.	Case report	0.5

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Table 3. (continued)

Author	Year	Title	No of Case	Cause of failure	Detection method	Treatment	Type of study	Quality assessment
Tomoko [54]	2016	Pacemaker malfunction associated with proton beam therapy: a report of two cases and review of literature-does field-to-generator distance matter.	2	Proton beam therapy (PBT)	Daily programmer analysis	reprogrammed	Case report	0.5
Torres-Ayala [55]	2014	Radiography of cardiac conduction devices: a pictorial review of pacemakers and implantable cardioverter defibrillators.	1	Anatomic positioning	CXR,	Treat reversible causes	Case report	0.5
Tahirovic [56]	2018	Twiddler's Syndrome: Case Report and Literature Review.	1	Pacemaker implantation usually caused by patient manipulation with a generator.	ECG	Treat reversible causes	Case report	0.5
Suksaranjit [57]	2014	Pacemaker stimulus amplitude alteration without loss of capture: an unusual ECG finding in cardiac tamponade from pacemaker lead perforation.	1	Pacemaker lead perforation into the pericardial space typically results in loss of capture	ECG	Treat reversible causes	Case report	0.5
Stuart [58]	2020	Erosive Twiddler's Syndrome: A Severe Case with Externalization of the Pacemaker.	1	Pacemaker malfunction in the setting of the device leads dislodgment due to physical manipulation.	ECG	Treat reversible causes	Case report	0.5
Siroky [59]	2020	Shortness of breath and palpitations in an elderly man: Bad device behavior or malfunction	1	unnecessary dyssynchronous	ECG	generator change	Case report	0.5
Simpson [60]	2010	Pacemaker laser lead extraction and implantation of dual-chamber implantable cardioverter defibrillator via Mustard baffle in complete transposition of great arteries.	1	Unnecessary dyssynchronous ventricular pacing.	ECG	reprogrammed	Case report	0.5
Sideris [61]	2022	Trans venous extraction of cardiac rhythm device leads: a report of the experience from a single referral center in Greece.	1	The malformation results in two parallel circulations	ECG	Generator replacement or upgrades	Case report	0.5

Senior [62]	2021	Cardiac implantable electronic device malfunction due to twiddler's syndrome in a patient with bipolar affective disorder.	1	Cause received neutron-producing beams.	ECCG	Systematic remote CIED monitoring	Case report	0.75
Schernthaner [63]	2020	Safe application of extensive radiotherapy to a cardiac resynchronization device.	1	Merkel cell carcinoma near the location of a cardiac resynchronization therapy pacemaker.	ECCG, CXR	device was extracted without complication	Case report	0.5
Miglioranza [64]	2013	A new view of an unusual pacemaker complication: role of three-dimensional transthoracic echocardiography.	1	Severe tricuspid regurgitation due to entrapment of the anterior leaflet of the valve by a permanent pacemaker lead	ECCG, CXR	The necessity of repositioning the lead if severe regurgitation or tricuspid valve malfunction are demonstrated.	Case report	0.5
Mazzone [65]	2021	Late presentation of recurrent syncope after permanent pacemaker implantation due to Lead-Header malposition.	1	Showing that the ventricular lead is not fully inserted into the header and the terminal pin is not seen past the distal set screw (black arrow)	ECCG, CXR	The device was reprogrammed to asynchronous mode (DOO at 80 ppm) and the patient was transferred to our hospital for lead extraction	Case report	0.5
Mihailidis [66]	2014	Malfunctions of implantable cardiac devices in patients receiving proton beam therapy: incidence and predictions. In regard to Gomez et al.	42	The incidence of device malfunctions among patients undergoing PBT.	ECCG, CXR	We recommend that proton beam therapy be avoided for patients who are "pacing-dependent" and those with tumors in close proximity to the device.	Case report	0.5
Rocco [67]	2022	Reel syndrome: a rare presentation of a rare cause of cardiac resynchronization malfunction.	1	Reel syndrome is a rare cause of pacemaker lead displacement		The importance of an early diagnosis and discussing the underlying mechanism, management and prevention.	Case report	0.75
Pan [68]	2013	Runaway pacemaker protection—or a problem?	1	This case describes unexpected lengthening of the paced cycle length in 2 SJM pacemakers caused by malfunction of the RAP circuit.	ECCG, CXR	Resetting of the RAP circuit was suspected and confirmed, and the problem was resolved noninvasively	Case report	0.5

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Table 3. (continued)

Author	Year	Title	No of Case	Cause of failure	Detection method	Treatment	Type of study	Quality assessment
Salahuddin [69]	2016	The pacemaker-twiddler's syndrome: an infrequent cause of pacemaker failure.	1	She admitted to repeatedly manipulating the pacemaker generator in her left pectoral region.	EKG, CXR	Lead repositioning is required, however proper patient education and counselling against further manipulation is paramount to long-term management.	Case report	0.5
Ramírez [70]	2011	Twiddler syndrome: report of one case.	1	Pacemaker dysfunction was demonstrated due to sensing and pacing failure, associated with left pectoral muscle rhythmic contraction.	EKG, CXR	We have presented a case of the Twiddler's syndrome that is unique because it was first misdiagnosed as neurological disease.	Case report	0.5
Paweł T [71].	2017	Atrioventricular synchronized in the background of ventricular noise and undersensing.	1	Ventricular lead failure was confirmed through observation of ventricular lead impedance >2000 Ω, fluctuations in ventricular sensing in electrograms (EGMs), and variable pacing thresholds, especially during forceful movements of left upper limb.	EKG	The patient underwent successful transvenous ventricular lead extraction. New ventricular lead was implanted and pacemaker replacement was performed.	Case report	0.75
Panagiotis N [72].	2011	Dual-chamber pacemaker malfunction mimicking atrial capture by the ventricular electrode.	1	There was a significant delay between the atrial capture and atrial depolarisation and systole, as well as a loss of ventricular capture because of an acute increase in the threshold.	EKG, CXR	Normal pacemaker function and pacing EKG were restored through modification of the pacemaker's functional parameters.	Case report	0.5
Brian [73]	2015	Inappropriate mode switching clarified by using a chest radiograph.	1	Pacemaker interrogation revealed a high number of short duration mode switching episodes.	CXR	A review of the chest radiograph is advised on a case of inappropriate mode switching when the atrial electrogram reveals a nonphysiologic etiology. **The patient will require a generator	Case report	0.5

Brittany [74]	2019	Atrial pacing every other beat: Is it pacemaker malfunction?	1	The ECG shows a monomorphic wide QRS rhythm at a rate of 62 bpm.	ECG	Her ICD Brady parameters were changed to an LRL of 70 ppm with an AV Delay of 200–300 ms to suppress the spontaneous idioventricular rhythm.	Case report	0.5
Adam [75]	2019	Continuous veno-venous hemodialysis and suspected pacemaker malfunction on telemetry monitoring.	1	Given persistent hypotension and bradycardia after cessation of amiodarone, a temporary transvenous pacemaker was placed, programmed to VVI mode of function and base rate of 80 BPM.	ECG	The pacemaker was programmed to VVI mode at 30 BPM and CVVH was turned back on	Case report	0.75
Sang Min [76]	2016	Inappropriate high-rate pacing with maximal output due to runaway pacemaker malfunction in a temporary device.	1	Malfunction of temporary pacemaker.	ECG	She was safely discharged several days later after successful insertion of a permanent pacemaker	Case report	0.5
Simon [77]	2010	Recurrent ventricular tachycardia in the post-operative period: the danger of malfunctioning epicardial pacing wires.	1	An unusual cause of recurrent ventricular arrhythmias sec-	ECG	Treatment was to switch off and remove the malfunctioning	Case report	0.75
Rabia [78]	2018	Reel Syndrome: An Atypical Cause for Inappropriate Shocks in a Patient with Automated Implantable Cardioverter Defibrillator (AICD).	1	Reel syndrome is a variant of Twiddler's syndrome, which is a rare complication of pacemaker implantation	ECG, CXR	Studies are being done to prevent the Twiddler and Reel syndrome from occurring via anchoring of the leads	Case report	0.75
Bhavisha [79]	2021	Temporary device malfunction of an MR conditional cardiac resynchronization defibrillator when undergoing MRI without appropriate re-programming: a case report.	1	Temporary device malfunction of an MR	ECG, CXR	Whilst MRI in patients with implantable cardiac devices is safe, strict protocols must be followed requiring robust multidisciplinary communication.	Case report	0.5
Giacomo [80]	2013	The managed ventricular pacing algorithm can be misinterpreted as pacemaker malfunction.	1	Pacemaker malfunction	ECG, CXR	The presence of a very short AV interval of 80 ms following the loss of	Case report	0.5
Goyal [81]	2022	Pacemaker Malfunction Due to Electric Blanket: A Rare Case of Electromagnetic Interference	1	Discontinuing the use of the electric warming blanket,	ECG, CXR	pacemaker was reprogrammed to DDDR mode which resulted in resolution of symptoms	Case report	0.75

pacemakers. This study sheds light on the occurrence of lead malfunction that has been identified during the subsequent monitoring of these patients. In contrast, the research conducted by Peter (15) provides a comprehensive understanding of the infrequency of pacing system malfunctions as a contributing element to hospital admissions resulting from syncope in individuals with permanent cardiac implantable electronic devices (CIEDs). The aforementioned findings highlight the crucial significance of precise and prompt detection mechanisms in ensuring the protection and welfare of patients. **Table 3** adopts a retrospective perspective, examining the frequency and underlying causes of malfunctions in cardiac implantable electronic devices (CIEDs) within the context of actual clinical settings. In this context, scholarly investigations, exemplified by the works of Lakkireddy et al. [24] and Yeung [33], provide valuable perspectives on the complexities associated with the management of battery failures, the subtleties surrounding leadless pacemakers, and the potential complications arising from radiation therapy. The retrospective assessment highlights the importance of continuous monitoring of device performance and highlights potential issues that may arise during the device's operational lifespan. After analyzing the conversations held at these tables, it is evident that the malfunction of CIEDs (Cardiac Implantable Electronic Devices) is a multifaceted problem influenced by various factors such as the design of the device, individual patient attributes, and external interventions. The prevalence estimates demonstrate a wide range, which is indicative of the varied patient demographics and methodological approaches employed in different studies. The meta-analysis that was conducted, which accounted for these variations, indicates a prevalence rate of approximately 4 % for malfunctions in cardiac implantable electronic devices (CIEDs) among the general population. This discussion emphasizes the importance of maintaining continuous vigilance in monitoring the performance of CIEDs (Cardiac Implantable Electronic Devices). It advocates for conducting regular evaluations and conducting a comprehensive assessment of potential risk factors. Moreover, it underscores the crucial significance of early detection of malfunctions, as demonstrated by research conducted by Samuels (36) on electromagnetic interference during endoscopic procedures, and Tsai (35) on the range of complications during both the implantation process and subsequent follow-up periods.

## 5. Conclusion

In conclusion, the compilation of studies that is represented in these tables offers a comprehensive understanding of the factors that contribute to malfunction in cardiac implantable electronic devices (CIEDs), as well as the prevalence of such malfunctions. This highlights the significance of ongoing research efforts and careful monitoring to enhance patient safety and improve the technology that goes into CIEDs. Commonly, complications related to leads and electrical dysfunctions are considered to be the primary causes of malfunctions in cardiac implantable electronic devices (CIEDs). The findings of the meta-analysis provide a significant source of knowledge that can be used to both improve patient care and inform clinical practice. These findings have the potential to serve as an essential foundation for the development of comprehensive guidelines that are centered on the cautious management of malfunctions in cardiac implantable electronic devices (CIEDs). Despite the undeniable efficacy of cardiac implantable electronic devices (CIEDs) in the therapeutic management of a wide variety of cardiac conditions, one of the most significant difficulties is still the problem of device malfunction. These malfunctions can be caused by a wide variety of factors, some of which are internal to the device, such as inherent complexities in its design, and some of which are external, such as interference from electrical currents or exposure to radiotherapy. However, the emergence of technological advancements such as leadless cardiac implantable electronic devices (CIEDs), along with improved post-implantation management techniques and comprehensive pre-operative risk assessments, offers the possibility of reducing these risks. In this endeavor, the adoption of a patient-centric approach is of the utmost importance because it entails customizing the approach to accommodate the unique characteristics and clinical conditions of each individual patient. This is something that must be done. This guarantees that the management of these essential devices, as well as their functionality, are optimized.

## Author contributions

Conception and design of Study: AS, AA. Literature review: ABS, FAA, NSA, FAA, AA. Acquisition of data: AS, AA, MA. Analysis and interpretation of data: AS, NSA. Research investigation and analysis:

MA, FAA. Data collection: ABS, FAA, NSA, FAA, AA. Drafting of manuscript: AS, AA, MA. Revising and editing the manuscript critically for important intellectual contents: AS, AA, MA. Data preparation and presentation: AS, ABS, FAA. Supervision of the research: MA. Research coordination and management: AS.

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### Data availability

All data used in this systematic review are publicly available through the referenced literature sources or databases. No additional datasets were generated for this study.

### Ethical approval

As this systematic review does not involve primary data collection from human participants, ethical approval was not required. The review adheres to the guidelines and principles of evidence synthesis and analysis.

### Informed consent

As this study does not involve human participants, informed consent was not applicable.

### Use of previously published material

The data and findings presented in this systematic review are based on previously published studies and literature sources. Proper attribution and citations have been provided for all referenced works.

### Conflicts of interest

The authors declare that they have no conflicts of interest related to this systematic review. There were no financial or non-financial interests that could have influenced the conduct or reporting of this study.

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