Evolution of the Cardiac Pace Maker and the Implants of Heart- A Narrative Review

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Abstract:
Pacemakers are adjustable electrical pulse generators that help regulate heart rhythms, emitting pulses typically lasting 0.5 to 25 milliseconds, with outputs of 0.1 to 15 volts and frequencies up to 300 pulses per minute. They are classified as either external for temporary use or internal for permanent implantation. Implantable cardioverter-defibrillators (ICDs), another type of cardiac implantable electronic device (CIED), were first developed in 1980. Modern ICDs include anti-bradycardia pacing functions, making them similar to pacemakers. Both devices use insulated lead wires with exposed tips implanted in the heart, controlled by a pulse generator and leads or electrodes (Puettel1, Malek2 and Ellison3.)

Introduction:
Permanent pacemakers are typically implanted via the transvenous route in a procedural suite or operating room, with patients either sedated or under monitored anaesthesia care, or general anaesthesia. (Van Gelder IC) (Mattsson G) The American Society of Anaesthesiologists issued a practice advisory in 2011 for managing patients with cardiac implantable electronic devices (CIEDs) during surgery. Key guidelines include conducting a focused history and physical examination to identify a CIED, reviewing medical records, chest x-rays, and ECGs, and palpating the device. It is essential to determine whether the device is a pacemaker or an ICD and to assess the patient's dependence on its pacing function. If electromagnetic interference is expected during surgery, suspend anti-tachyarrhythmia functions by reprogramming or using a magnet, and consider external defibrillator pads if the device is deactivated, placing them as far from the implant as possible. Intraoperative monitoring of device function is crucial, especially in procedures involving lithotripsy, MRI, electroconvulsive therapy, and radiation therapy. Postoperatively, monitor the patient's rhythm and device function, interrogate the device, and restore settings as needed (Stone ME).

ICDs save lives by preventing sudden death from ventricular arrhythmias, while pacemakers alleviate symptoms in bradyarrhythmia patients and cardiac resynchronization devices improve mortality and quality of life for heart failure patients (Goldberger Z.). However, extrinsic factors such as trauma, electromagnetic radiation, and lead...
displacement can cause ICDs and pacemakers to malfunction, leading to insufficient or incorrect therapy, often requiring device removal (Mark D Carlson 1). Increased survival rates, younger recipient ages, and more complex devices have heightened the risk of component failures (Andreas Schuchert 1 and group). Despite not adversely affecting lifestyle, CIEDs can cause anxiety and concerns about daily activities, often due to misinformation from non-professional sources. Without proper post-implantation information, patients may face uncertainty, restricted activities, or psychological issues. Studies show that psychoeducational interventions can reduce anxiety and depression, improve quality of life and physical outcomes, and decrease unplanned hospital admissions and calls to healthcare providers (Domingo Palacios-Ceña 1).

This review article aims to comprehensively elucidate the historical evolution, advancements, efficacy, and safety of traditional and newer pacemakers and implantable cardioverter-defibrillators (ICDs), in the management of cardiac complications.

Methods:

This narrative review includes articles which were systematically collected by performing Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). The two authors (Priyankkumar Patel and Jagbir Singh), assessed all eligible studies independently. A consensus was reached if there were any cases of disagreement between the authors. We searched through electronic database PubMed (articles published up to June 2024) and obtained a total of 2397 articles which included 609 articles for “Evolution of pacemaker”, 390 articles for “Evolution of ICDs”, 62 articles for “technological advancements of ICD”, 151 articles for “technological advancements of ICD”, 1020 articles for “safety and efficacy of pacemaker”, 22 articles for “engineering of pacemaker and ICD”, 4 articles for “Future challenges of pacemakers and ICDs” and 143 articles for “safety and efficacy of ICDs”. The screening process of the articles were based on the criteria as follows:

Inclusion Criteria
1. Peer-reviewed research articles published in scientific journals.
2. Review articles, meta-analyses, and systematic reviews addressing the topic of interest.
3. Randomized controlled trials (RCTs), observational studies, cohort studies, case-control studies, and cross-sectional studies.
4. Longitudinal studies with follow-up data on pacemaker and implantable cardioverter-defibrillator (ICD) outcomes.
5. Case reports and case series reporting unique or rare complications or outcomes.
6. Studies evaluating the efficacy, safety, or performance of Pacemakers and ICDs.
7. Investigations into new technological advancements, programming strategies, or device-related innovations in pacemaker and ICD therapy.

Exclusion Criteria
1. Non-peer-reviewed sources, including editorials, commentaries, letters to the editor, and opinion pieces.
2. Grey literature, such as unpublished studies, dissertations, and patents.
3. Studies with insufficient data or methodology to assess outcomes of interest.
4. Studies not written in English or lacking translation services.
5. Studies focusing solely on pediatric populations or specific subgroups not representative of the broader patient population.
6. Studies examining non-implantable cardiac devices or non-invasive treatment modalities.
7. Research on investigational devices or therapies not yet approved for clinical use.
8. Studies lacking relevant outcome data or focusing solely on surrogate endpoints without clinical significance. However, after meticulous scrutiny, 2324 articles were deemed irrelevant to the focus of the review on screening as per inclusion criteria and exclusion considerations, consequently removed. Ultimately, 59 articles remained for detailed analysis, each deemed pertinent to the study's objectives.

![Prisma flow chart](image)

**Figure 1: Prisma flow chart**

**Results:**

**3.1 Historical evolutions:**

The history of the pacemaker began with independent efforts by Australian anaesthesiologist Mark Lidwell and American physiologist Albert Hyman. In 1928, Lidwell used an alternating current device to save a child in cardiac arrest by inserting a needle into the heart. Hyman, in 1932, developed a hand-cranked device called an "artificial pacemaker" to revive stopped hearts, though his work faced opposition and his device was not widely adopted. Significant advancements occurred in the early 1950s with the development of mains-powered portable pacemakers. These bulky, vacuum tube-filled devices, created by researchers like Wilfred Bigelow, John Callaghan, and John Hopps, were the first electronic pacemakers and used hypothermia experiments to improve cardiac surgery outcomes. Paul Zoll further advanced the field by developing an external tabletop pacemaker to treat heart block, which delivered electric pulses through chest electrodes, though it was painful for patients. By the mid-1950s, Aubrey Leatham and Geoffrey Davies in London developed the first demand circuit device, preventing "R on T"-induced ventricular fibrillation, and incorporated battery operation for portability. The first battery-operated wearable pacemaker, developed in 1957, marked a pivotal moment in medical history. Created by electrical engineer Earl Bakken in collaboration with cardiac surgeon C. Walton Lillehei at the University of Minnesota, this pacemaker was designed to address the limitations of existing AC-powered units, which were bulky, unreliable, and dependent on electrical outlets. Inspired by a transistorized metronome circuit from "Popular Electronics", Bakken developed a portable device powered by a 9.4-volt mercury battery.
battery. The initial prototype successfully paced a dog's heart and was soon applied to a young patient, saving her life. The evolution of pacemakers from the 1950s to the present day reflects significant advancements in technology and medical understanding. Initially, pacemakers were large, hand-made devices with basic functionality and limited battery life. The first implantable pacemaker, developed in 1958 by Wilson Greatbatch and Dr. William Chardack, was powered by nickel-cadmium batteries and required frequent recharging. Over the next few decades, pacemakers evolved rapidly. In the 1960s, the transition from external to transvenous leads allowed for less invasive procedures. The introduction of demand pacemakers in the 1970s enabled devices to sense and respond to the heart's activity, providing pacing only when necessary. Lead design improvements and the advent of the lithium-iodine battery significantly increased pacemaker longevity. The 1980s saw the development of steroid-eluting leads, which reduced inflammation and improved safety. Rate-responsive pacemakers emerged, adapting the pacing rate to the patient's activity level using internal sensors. By the 1990s, research by Soviet doctors Naum Lazarevich Gurvich and G.S. Yuniev led to the development of the first defibrillation waveforms and portable defibrillators. This era also saw the creation of the first portable external defibrillator by William Kouwenhoven and his team, culminating in a 45-pound device by 1961. The ICD concept was born in the 1960s when Michel Mirowski, an Israeli cardiologist, envisioned an implantable device to prevent sudden cardiac death. Collaborating with Morton Mower and other researchers, Mirowski developed a prototype ICD. In 1980, the first human ICD implantation was performed, marking a revolutionary step in cardiac care. The initial ICDs were large and required open-chest surgery, but advancements in technology rapidly improved their design. By the late 1980s, transvenous lead systems...
and smaller, more sophisticated devices allowed for less invasive implantation procedures. The 1990s brought further miniaturization and enhanced capabilities, such as the ability to deliver both pacing and defibrillation therapies. Today, ICDs are highly advanced, capable of continuous heart monitoring, delivering lifesaving shocks, and providing pacing for bradycardia and tachycardia. Modern ICDs are compact, reliable, and essential tools in preventing sudden cardiac death in high-risk patients. (N.) (Ivan Cakulev) (P M ZOLL).

### Table 1: Historical evolution

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Pacemaker</th>
<th>Implantable Cardioverter-Defibrillator (ICD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1928</td>
<td>Mark Lidwell uses an alternating current device to save a child</td>
<td>Jean-Louis Prévost and Frédéric Batelli demonstrate electrical shocks to manage ventricular fibrillation in animals</td>
</tr>
<tr>
<td>1932</td>
<td>Albert Hyman develops a hand-cranked &quot;artificial pacemaker&quot;</td>
<td></td>
</tr>
<tr>
<td>1950s</td>
<td>Development of mains-powered portable pacemakers</td>
<td>Research by Carl Wiggers and René Wégria on defibrillation</td>
</tr>
<tr>
<td>1952</td>
<td>Development of first electronic pacemakers</td>
<td>Claude Beck performs first successful human defibrillation during open-heart surgery</td>
</tr>
<tr>
<td>1957</td>
<td>Development of first battery-operated wearable pacemaker</td>
<td></td>
</tr>
<tr>
<td>1958</td>
<td>Wilson Greatbatch and Dr. William Chardack develop first implantable pacemaker powered by nickel-cadmium batteries</td>
<td></td>
</tr>
<tr>
<td>1960s</td>
<td>Transition from external to transvenous leads in pacemakers</td>
<td>Michel Mirowski envisions and develops prototype ICD</td>
</tr>
<tr>
<td>1970s</td>
<td>Introduction of demand pacemakers</td>
<td></td>
</tr>
<tr>
<td>1980s</td>
<td>Development of steroid-eluting leads</td>
<td>First human ICD implantation performed</td>
</tr>
<tr>
<td>1990s</td>
<td>Introduction of microprocessor-driven pacemakers</td>
<td>Further advancements in ICD technology</td>
</tr>
<tr>
<td>Post 2000s</td>
<td>Modern pacemakers incorporate bi-ventricular pacing and telemetry capabilities</td>
<td>Modern ICDs are compact, reliable, and capable of continuous heart monitoring</td>
</tr>
</tbody>
</table>

### 3.2 Technological advancements:

#### Pacemakers:

The development of pacemaker technology has undergone significant advancements since the late 1950s. Figure 2 describes the Emlqvist's circuit of the first implantable pacemaker. Initially, Rune Emlqvist designed a pacemaker utilizing silicon transistors for efficiency, powered by nickel-cadmium batteries that were recharged inductively through an external coil. In 1959, Wilson Greatbatch's accidental discovery led to the first implantable pacemaker, successfully tested on a dog by Drs. Chardack and Gage, and later implanted in humans, marking a pivotal moment in cardiac care. Early pacemakers faced challenges such as faulty batteries and unreliable leads. By the mid-1960s, transvenous leads replaced epicardial leads, simplifying implantation without thoracotomy. The introduction of
demand pacemakers allowed devices to sense and pace only when necessary. In the 1970s, the development of lithium-iodine batteries extended pacemaker longevity, while titanium casings replaced earlier materials for better durability. Programmable pacemakers, adjustable via radio-frequency telemetry, emerged, enhancing patient-specific treatment. The 1980s saw the innovation of steroid-eluting leads to reduce inflammatory response, and rate-responsive pacemakers that adjusted pacing rates based on patient activity. By the 1990s, microprocessor-driven pacemakers became sophisticated, offering automatic adjustment of pacing parameters and remote data transmission. The introduction of bi-ventricular pacing provided new treatment options for heart failure patients, improving cardiac function and survival. These technological advancements have made pacemakers more reliable, user-friendly, and effective, significantly improving the quality of life for patients with cardiac conditions.

**Figure 2: Circuit diagram of the first implantable pacemaker (O.)**

Pacemakers consist of a pulse generator, which houses the battery and electronics, and leads that extend from the generator to the myocardium to deliver a depolarizing pulse and detect intrinsic cardiac activity. The conductor cables and lead tip electrodes are insulated, with the leads either being concentric (a tube within a tube) or co-radial (side-by-side coils). Lead attachment to the myocardium can be active, with an electrically active helix at the tip for strength, or passive, with electrically inert tines. Short circuits can result in high impedance (due to fractures) or low impedance (from insulation breaches), depending on the disruption of conductor elements and insulation. Pacing begins when a voltage is applied between the electrodes (Siva K Mulpuru 1) (Sanne A Groeneveld 1 2). These devices are constructed entirely from FDA-approved biocompatible materials; however, they are non-biodegradable and remain in the patient's body indefinitely unless removed. While typically not harmful, the presence of outdated electrical implants in the tissue can sometimes be unnecessary and, if commonplace, may pose a risk to the patient's health (Agarwal S). They are broadly classified into single-chamber, dual-chamber, and biventricular pacemakers, each serving distinct purposes based on the specific cardiac conditions (Parsonnet).
Single-chamber pacemakers stimulate either the atrium or the ventricle and are the simplest form. They are often used in patients with atrial fibrillation or those who require minimal cardiac pacing. However, they may not maintain the natural coordination between atria and ventricles, which can affect cardiac efficiency. Dual-chamber pacemakers stimulate both the atrium and ventricle, ensuring synchronized contraction and maintaining atrioventricular (AV) synchrony. This coordination more closely mimics natural cardiac physiology, reducing symptoms like fatigue and shortness of breath and lowering the risk of atrial fibrillation and stroke. Biventricular pacemakers also known as cardiac resynchronization therapy (CRT) devices, are used in patients with heart failure. They stimulate both ventricles to improve the heart's pumping efficiency and coordinate contractions, significantly enhancing the quality of life and survival rates in patients with severe heart conditions. This is considered being advanced than the single-chamber pacemaker due to its dominant effect on sinus and AV synchrony (Dretzke J) (Sahu P).

Bradyarrhythmias can be effectively treated using a newer modality, transvenous pacemakers (TVPs), which are devices that have a pulse generator implanted subcutaneously and one or more transvenous electrodes that extend to the heart chamber(s). Technological advancements have introduced features such as rate responsiveness, where sensors adjust the pacing rate based on physical activity, and adaptive algorithms that tailor pacing to individual needs such as exercises towards personalized pacing (Mithilesh K DAS 1). Leadless pacemakers(LP), which integrate the generator and leads into a single unit, offer benefits such as reduced infection risk and complications related to lead placement (Shuyun Le). The novel LP device, that has a capsule like appearance, is implanted into the right ventricle through a femoral venous catheter that is placed percutaneously. It has an electrode system and a generator. Many of the lead- and generator pocket-related issues commonly associated with a TVP may be avoided by an LP by eliminating the requirement for a generator pocket and transvenous leads. While the LP was initially only recommended for right ventricular pacing, the development of atrioventricular synchronous pacing-capable LPs indicates that the uses of these innovative devices may increase (Chinitz L) (Steinwender C). Pacemakers in recent times have been developed to be programmed non-invasively by producing an X-Ray readable code (Puette1, Malek2 and Ellison3.).

ICDs:
The first-generation implantable ICDs from the 1980s were pioneering devices designed to recognize and terminate ventricular fibrillation (VF) by delivering high-energy shocks (M Mirowski). These early ICDs comprised a pulse generator encased in a titanium can, housing a battery, a capacitor for charge storage and delivery, a microprocessor, and integrated circuits for sensing, data capture, and therapy control. Despite their groundbreaking nature, these devices had significant limitations. They could not detect unstable ventricular tachycardias (VTs) that could degenerate into VF, and lacked programmability, necessitating separate pacemakers for backup bradycardia pacing, leading to potentially dangerous interactions (Swerdlow CD). The ICDs contained cylindrical aluminum electrolytic capacitors and silver vanadium pentoxide batteries, which facilitated rapid charge times and high-voltage shock delivery (Holley). The microprocessor was responsible for basic functions such as sensing cardiac rhythms and triggering therapy delivery. The lead system for these early ICDs was also quite primitive. It comprised a spring patch and an apical cup that required open chest surgery for placement. The leads had a coaxial design, featuring a layered structure with
conductors separated by insulation layers. The electrodes were positioned epicardially, which limited the ability to detect and treat arrhythmias effectively and made the implantation procedure highly invasive and risky, associated with significant morbidity and mortality. However, these components contributed to the large size of the devices. Implantation required a thoracotomy, as the leads, including a spring patch and apical cup, were placed abdominally. These early ICDs primarily used waveform analysis based on the rate of R waves to detect VF. Due to this basic detection method, inappropriate shocks were common, as the devices often misclassified supraventricular tachycardias with rapid ventricular response as VF (van Welsenes GH). The introduction of transvenous leads in 1988 marked a significant advancement, allowing for implantation via less invasive procedures performed in electrophysiology laboratories. Second-generation ICDs, introduced in the late 1980s to early 1990s, marked a significant advancement over their predecessors. These had the capability of pacing bradycardia and were minimally programmable devices which were smaller, eliminating the need for thoracotomy by utilizing transvenous leads. The electronic components included improved microprocessors and integrated circuits, which provided minimal programmability and the ability to pace bradycardia eliminated the need of external pacemaker. These devices also had limited telemetry functions for battery monitoring and recording the number of delivered shocks. The lead design featured the coaxial lead, which had a layered structure. This design comprised a tip conductor, ring conductor, and defibrillation conductor, all insulated by layers. The coaxial design ensured reliable sensing and pacing, critical for detecting arrhythmias and delivering therapy. (Cannom DS) (Kroll MW)

Third-generation ICDs feature advanced electronic and lead components that significantly enhance their functionality and reliability. The electronic system includes lithium-silver vanadium manganese oxide batteries, which extend service life, and microprocessors integrated with advanced sensing and rhythm discrimination algorithms. These devices support extensive programmability and telemetry, allowing for precise therapy adjustments. The introduction of antitachycardia pacing (ATP) technology is pivotal, enabling low-energy shocks and pacing therapies to terminate ventricular tachycardias without high-energy shocks, thereby improving patient comfort and reducing battery drain. The leads in third-generation ICDs utilize a multi-lumen design, incorporating parallel conductors within a single insulating body. This construction enhances durability and minimizes lead size while providing reliable pacing and defibrillation. (G H Bardy 1) (Gradaus R). Third-generation ICDs and modern ICDs have seen significant advancements in algorithms and efficacy. These devices utilize sophisticated detection algorithms that analyze the rate, onset, and morphology of cardiac rhythms. Third-generation ICDs introduced programmable cycle length-related zones, enabling precise discrimination between ventricular tachycardia (VT) and supraventricular tachycardia (SVT). The inclusion of antitachycardia pacing (ATP) in third-gen ICDs allows for low-energy interventions, reducing the need for high-energy shocks and extending battery life. Modern ICDs build on these advancements with enhanced algorithms capable of real-time analysis and adaptive learning. They use dual-chamber sensing to improve rhythm discrimination further and reduce inappropriate shocks. The integration of data capture and telemetry enables continuous monitoring and remote adjustments, optimizing therapy delivery. These technical improvements in algorithms and sensing capabilities have significantly increased the efficacy of ICDs in preventing sudden cardiac death by
ensuring timely and accurate therapeutic interventions (van Welsenes GH).

### Table 2: Advancement of technology in ICDs and Pacemaker

<table>
<thead>
<tr>
<th>Era</th>
<th>Development</th>
<th>Pacemakers</th>
<th>ICDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1950s</td>
<td>Initial designs</td>
<td>Rune Elmqvist's silicon transistor pacemaker, nickel-cadmium batteries recharged inductively</td>
<td>First implantable ICDs designed to recognize and terminate VF, large size requiring thoracotomy</td>
</tr>
<tr>
<td>1960s</td>
<td>First implantable devices</td>
<td>Wilson Greatbatch's implantable pacemaker, transvenous leads replaced epicardial leads, demand pacemakers</td>
<td>No significant updates</td>
</tr>
<tr>
<td>1970s</td>
<td>Battery and casing improvements</td>
<td>Lithium-iodine batteries extended longevity, titanium casings for durability</td>
<td>No significant updates</td>
</tr>
<tr>
<td>1980s</td>
<td>Programmable pacemakers and new lead technology</td>
<td>Programmable pacemakers with RF telemetry, steroid-eluting leads, rate-responsive pacemakers</td>
<td>Introduction of transvenous leads, second-generation ICDs with minimal programmability and bradycardia pacing</td>
</tr>
<tr>
<td>1990s</td>
<td>Microprocessor-driven devices</td>
<td>Advanced microprocessor pacemakers, automatic pacing adjustment, remote data transmission, biventricular pacing (CRT)</td>
<td>Third-generation ICDs with ATP technology, lithium-silver vanadium manganese oxide batteries, multi-lumen leads</td>
</tr>
<tr>
<td>2000s</td>
<td>Leadless pacemakers and improved ICD algorithms</td>
<td>Leadless pacemakers reducing infection risk, novel LP devices with synchronous pacing, X-ray readable code for non-invasive programming</td>
<td>Advanced detection algorithms, dual-chamber sensing, real-time analysis, remote monitoring, and telemetry</td>
</tr>
</tbody>
</table>

### 3.3 Outcomes and Risk Assessment:

Pacemakers, including traditional transvenous pacemakers (TVPs) and newer leadless pacemakers (LPs), have proven efficacy and safety in managing bradyarrhythmias. TVPs, which have been the standard for decades, are effective in maintaining heart rhythm but come with risks such as lead-related complications, including infection, dislodgement, and tricuspid valve (TV) regurgitation due to the lead traversing the valve (Ludwig S) (Ranasinghe I). Several studies show that at 90 days, TVPs are systematically linked to a 7.76% to 12.4% risk of major problems, with lead and generator-related issues accounting for over half of these cases. TVPs have a 1% to 2% annual risk of problems in the long run, which are primarily caused by infection and lead failure. By the time they are three years old, around one in six patients with a TVP have a major complication and treating these consequences is quite expensive (Udo EO) (Cantillon DJ). LPs, particularly the Micra device, offer a promising alternative by eliminating the lead and pocket-related complications associated with TVPs.

A study by Ngo L et al., indicates that LPs have a high implantation success rate and a favourable safety profile. LPs are associated with a lower incidence of complications compared to TVPs, with Micra devices showing 51% lower odds of complications at 90 days and 1 year post-implantation. Early data suggest that LPs
have good electrical performance, with over 90% of devices maintaining adequate pacing capture thresholds for up to one year. Quality of life improvements have been noted with LPs, with patients experiencing better physical and mental health outcomes compared to those with TVPs. Although the absence of a lead crossing the TV should theoretically reduce TV regurgitation, studies have shown mixed results, with some suggesting comparable rates of regurgitation to TVPs (Ngo L) (Beurskens NEG) (Salau E). Two studies show incidences of cardiac perforation and LP dislodgement (Vamos M) (Wang Y). In addition to having a good safety profile of LPs, no efficacy statistics are available for periods longer than two years, so it's unclear how long the gadget will continue to function. The Nanostim LP experienced an unanticipated early battery failure between 2.3 and 4.0 years following implantation (Lakkireddy D).

Adverse events (AEs) associated with implantable cardioverter-defibrillators (ICDs) span various device- and lead-related complications, infections, thrombosis, and inappropriate shocks. In a systematic review on the Adverse events of ICD by Rebecca P et al reported that, device malfunctions and mechanical complications were relatively rare, with malfunction rates around 1.6% and mechanical complications at 4.2%. Lead-related issues, such as malfunctions, fractures, and dislodgements, also contributed significantly to AEs, with lead malfunctions and fractures occurred 2.4% and 3.4% of cases, respectively. Infections were another critical concern, affecting 1.2-2.7% of patients, with some cases requiring lead or device removal.

Inappropriate shocks were a significant AE, affecting 3-21% of patients over 1-5 years (&). These shocks were often due to lead migration, supraventricular tachycardia (SVT), and T-wave over-sensing. Strategic programming and patient selection, including pre-implantation ECG screening and exercise testing, reduced the risk of inappropriate shocks. Subcutaneous ICDs (S-ICDs) offer a higher safety profile by avoiding lead complications associated with transvenous ICDs (TV-ICDs), but still present issues like T-wave over-sensing and myopotential interference (Tran HH) (Jonathan Buber). A Meta-analytic Study by Zhiyong Q et al., have shown that inappropriate shocks can increase trauma and mortality risk among patients (Zhiyong Qian 1 2). Recent programming strategies, such as higher detection rates and longer detection intervals, have been effective in reducing inappropriate therapies and improving outcomes (Tran HH).

The efficacy of implantable cardioverter-defibrillators (ICDs) is well-established for preventing sudden cardiac death, particularly in patients with ventricular fibrillation (VF) and hypertrophic cardiomyopathy (HCM). Studies have shown that ICDs, including subcutaneous (S-ICDs) and extravascular (EV-ICDs), exhibit high shock efficacy and sensitivity for ventricular arrhythmias. Defibrillation threshold testing (DFT) for S-ICDs has demonstrated a shock efficacy of 98% and a detection sensitivity of up to 100% for VF. The proximity of EV-ICDs to the heart allows for lower energy requirements for defibrillation and effective asystole support pacing (Crozier) (Charles D Swerdlow 1) (Tran HH).

In HCM patients, S-ICDs have proven effective in converting VF and safe over a 5-year follow-up period. These devices were often implanted in patients with low to intermediate sudden cardiac death (SCD) risk scores. Appropriate shocks were delivered at a rate of 0.6 per 100 person-years, similar to transvenous ICDs (TV-ICDs). Inappropriate shocks, a notable concern, occurred at a rate of 1.2 per 100 person-years, but advancements such as the Smart-Pass algorithm have reduced these incidents (Rella). The overall efficacy and safety profile of ICDs, coupled with strategic programming and modern
algorithms, underline their critical role in managing high-risk cardiac patients and preventing SCD (Tran HH).

Table 3: Comparison of Traditional Transvenous Pacemakers (TVPs), Leadless Pacemakers (LPs), Traditional ICDs, and Subcutaneous/Extravascular ICDs

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Traditional Transvenous Pacemakers (TVPs)</th>
<th>Leadless Pacemakers (LPs)</th>
<th>Traditional ICDs</th>
<th>Subcutaneous ICDs (S-ICDs) &amp; Extravascular ICDs (EV-ICDs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>Effective in managing bradyarrhythmias</td>
<td>Effective with lower complications compared to TVPs</td>
<td>Prevents sudden cardiac death, particularly in VF and HCM patients</td>
<td>High shock efficacy, effective in converting VF, asystole support pacing</td>
</tr>
<tr>
<td>Safety Profile</td>
<td>Risks include lead-related complications, infections, and tricuspid valve regurgitation</td>
<td>Lower incidence of complications, good electrical performance</td>
<td>Device malfunctions, mechanical complications, lead-related issues, infections</td>
<td>Higher safety profile, avoids lead complications, but issues like T-wave over-sensing</td>
</tr>
<tr>
<td>Complications</td>
<td>7.76% to 12.4% risk of major problems at 90 days, 1% to 2% annual risk long-term</td>
<td>Cardiac perforation, dislodgement, no long-term efficacy data</td>
<td>Malfunction rates around 1.6%, lead malfunctions 2.4%, infections 1.2-2.7%</td>
<td>T-wave over-sensing, myopotential interference, inappropriate shocks</td>
</tr>
<tr>
<td>Patient Outcomes</td>
<td>Risk of major complications in one in six patients by three years</td>
<td>Better physical and mental health outcomes compared to TVPs</td>
<td>Inappropriate shocks affect 3-21% of patients over 1-5 years</td>
<td>Safe over 5 years, similar appropriate shock rate as TV-ICDs, reduced inappropriate shocks</td>
</tr>
<tr>
<td>Technological Advancements</td>
<td>Rate-responsive pacing, adaptive algorithms</td>
<td>Leadless designs, synchronous pacing in LPs, non-invasive programming</td>
<td>ATP, advanced sensing, and discrimination algorithms</td>
<td>Smart-Pass algorithm reduces inappropriate shocks</td>
</tr>
<tr>
<td>Clinical Indications</td>
<td>Symptomatic bradycardia from AV block or SSS</td>
<td>Similar indications, emerging for broader applications</td>
<td>High-risk cardiac patients, particularly with VF and HCM</td>
<td>Patients with low to intermediate SCD risk scores</td>
</tr>
<tr>
<td>Cost and Treatment</td>
<td>Expensive to treat complications</td>
<td>Initial costs offset by fewer complications</td>
<td>Costs associated with managing AEs and inappropriate shocks</td>
<td>Reduced costs with lower complication rates</td>
</tr>
</tbody>
</table>

3.4 Electromagnetic Interference:
An electronic device's inability to function as a result of electromagnetic fields produced by outside sources is known as electromagnetic interference, or EMI. Device faults, either temporary or permanent, may result from this interference. Patients with implanted cardioverter-defibrillators
ICDs) and pacemakers should be especially concerned about electromagnetic fields (EMI) since these life-saving devices can be negatively influenced by these fields. Modern PMs and ICDs are not completely immune, even though they are housed in hermetically sealed titanium or stainless steel with insulative coatings, and they use bandpass filters and bipolar leads to lessen sensitivity. Strong electromagnetic fields can still impair their functionality, putting dependent patients at grave danger (Napp).

Various medical and non-medical procedures and devices can interfere with pacemaker function due to EMI. Transthoracic DC cardioversion can cause PM malfunction, such as reversion to backup mode and generator failure; placing paddles 15 cm away or using an anterior-posterior approach can mitigate risks. Radiofrequency (RF) catheter ablation can lead to sensing and pacing failures, especially with unipolar leads, so PMs should be checked pre- and post-procedure, and RF application duration and distance minimized. Electrocautery’s RF current can inhibit or trigger inappropriate pacing; using bipolar electrocautery, limiting application duration, and programming the PM to asynchronous mode can reduce risks. MRI interferes with PM function due to strong electromagnetic fields, causing reed switch activation and potential electrode heating; recommendations include using lower magnetic fields, thorough pre- and post-MRI PM checks, and monitoring vital signs. Radiotherapy’s high-energy radiation can damage PM circuitry; shielding the PM, minimizing radiation exposure, and close monitoring are critical. Extracorporeal shock wave lithotripsy can damage the PM if aimed directly at it; maintaining a distance of at least 25 cm and timing shock delivery to avoid PM inhibition are advisable. Mobile phones can inhibit pacing output and trigger inappropriate pacing; using analog phones, keeping them at least 15 cm away from the PM, and using the opposite ear can minimize interference. Understanding these EMI sources and implementing preventative measures can significantly reduce the risk of PM malfunction. Transcutaneous nerve stimulation can be sensed by pacemakers (PM), especially unipolar ones, but recent studies show it’s safe for PM patients. Hospital pager systems may disrupt telemetry due to overlapping frequencies with PM programmers. Dental instruments and certain cardiac monitoring systems can cause transient PM output inhibition or inappropriate rate changes. Antitheft devices, especially acoustomagnetic systems, can cause temporary PM interference, such as asynchronous pacing. Patients should avoid leaning or lingering near EMI sources. Electric arc welding typically causes interference, but specific PM models may remain unaffected under certain conditions. Understanding these EMI sources and precautions can reduce PM malfunction risks (O).

3.5 Engineering of the implants:

Pacemaker engineering has evolved significantly since the first implants, addressing early challenges to enhance reliability and patient outcomes. In the early pacemakers, stainless steel leads were used to transfer heart pulses but were prone to fractures and corrosion, leading to short lifespans. For example, a pacemaker implanted by Swedish physician Senning in 1958 failed after seven days due to a lead fracture. Recognizing the mechanical and chemical limitations of stainless steel, researchers experimented with alloys of cobalt, chromium, and nickel, though these materials also had high fracture rates, dislodgement issues, electromagnetic interference, high capture thresholds, and corrosion. The advent of silicone or polyurethane-insulated noble metal coils, such as those made from platinum, iridium, or titanium, resolved many of these issues, providing improved durability and performance. Another significant advancement was the development of lithium-iodine batteries by Greatbatch and Holmes in 1973, offering a long lifetime, low current drain, and stable voltage output, crucial for the smaller, lighter electronic
systems in pacemakers (Greatbatch W) (Larsson B) (H Burri).

Early pacemakers used epoxy resin for encapsulation to protect electronic circuits and batteries from body fluids, but these polymers swelled and dissolved in the body. Consequently, housing materials were upgraded to ceramics and titanium. Modern pacemakers use titanium encapsulation with laser welding, providing strong mechanical hardness, corrosion resistance, biocompatibility, and durability. To address electrical connection issues between the metal housing and lead wires, polymer- or ceramic-based electrical feedthroughs were developed to ensure perfect separation between the electronic system and the body environment. The first pacemaker implant involved a complex and invasive open thoracotomy. Today, the procedure is minimally invasive, taking around 1 to 2 hours, with 4- to 5-mm diameter electrodes fixed in the right ventricle and atrium. Patients are typically discharged the next day, returning to their regular activities, thanks to the compact and lightweight design of modern pacemakers and flexible platinum lead coils that simplify the procedure. These engineering advancements have made pacemakers more reliable and patient-friendly, significantly improving quality of life for individuals with cardiac conditions (Chirife R) (Davies JG) (Kramar T) (P.).

Engineers designing pacemakers and implantable cardioverter defibrillators (ICDs) must prioritize biocompatibility to ensure long-term integration without adverse reactions, selecting materials like titanium, platinum, and specific polymers that resist body fluids and immune responses. Effective sterilization methods such as EtO, gamma radiation, and E-beam are crucial to eliminate harmful microorganisms. Packaging and hermeticity are essential to protect electronic components from bodily fluids and ensure device longevity, utilizing materials like ceramics, metals, and polymers, and employing vacuum packaging and helium leak detection for airtight sealing. Structural design must consider the complex and varied anatomy of patients, necessitating extensive research, simulations, and testing. Power management is vital, with single-use and rechargeable batteries being the primary energy sources, supplemented by emerging energy harvesting techniques. Wireless communication is critical for device monitoring, with low-frequency bands (402-405 MHz) designated for medical implants to ensure efficient data transfer without wires. These considerations collectively aim to create reliable, durable, and safe implantable devices that improve patient outcomes and quality of life (YH.).

3.6 Future challenges:

Future advancements in ICDs focus on enhancing communication between patients with advanced heart failure and their clinicians. The WISDOM trial highlights the need for proactive conversations regarding ICD deactivation as patients approach the end of life. Future interventions aim to increase the frequency of these conversations, improve psychological outcomes for bereaved caregivers, and integrate advanced technologies such as AI to enhance device functionality and patient monitoring. However, several challenges persist. There is a significant gap in the discussions about deactivating ICDs, leading to many patients receiving painful and distressing shocks at the end of their lives. Institutional Review Board concerns, accurate identification of high-risk heart failure populations, and adapting to the evolving landscape of ventricular assist devices and cardiac transplants are notable hurdles. Addressing these challenges requires robust training for clinicians, automated reminders, and individualized feedback to ensure that conversations about ICD management are both timely and compassionate (Nathan E. Goldstein MD a c).
Modern pacemakers, integrated with cloud-connected devices, enhance patient care but also introduce cybersecurity risks. Ethical hackers have shown that pacemakers can be vulnerable to attacks, potentially compromising patient safety by extracting personal information or altering device functions. Security breaches in pacemakers could lead to fatal outcomes through denial-of-service attacks or unauthorized reconfiguration. Healthcare organizations must invest in robust cybersecurity measures, including device-specific security protocols, regular software updates, and constant network monitoring. Managed Detection and Response (MDR) services are essential for identifying and addressing threats in real-time. Despite the technological advancements, the priority remains on safeguarding patient data and device functionality to prevent malicious cyber-attacks (Rahman).

Pacemakers and ICDs face a range of challenges that impact their integration and functionality within healthcare systems. The primary issues can be categorized into technical, security, interoperability, and data management challenges. Pacemakers and ICDs generate vast amounts of data, requiring robust data management solutions to handle, store, and analyze this information. The increasing number of connected devices also raises scalability concerns, necessitating infrastructure capable of supporting a large and growing number of devices without performance degradation. These devices transmit sensitive patient data over open communication channels, exposing them to potential cyber-attacks. Security vulnerabilities include unauthorized access, data breaches, and advanced threats like replay attacks and denial of service (DoS) attacks. Ensuring robust authentication, data integrity, confidentiality, user privacy, and availability are critical to protecting patient information and maintaining system integrity. Integrating diverse medical devices and systems within hospital networks leads to significant interoperability issues. Different devices often use various protocols and standards, complicating seamless data exchange and integration. This lack of standardization hinders effective communication between devices, causing problems with data fragmentation and system crashes, which can adversely affect patient care. The enormous volume of data produced by pacemakers and ICDs can overwhelm healthcare professionals, making data analytics and interpretation difficult. Ensuring data quality, accuracy, and completeness is essential for reliable healthcare delivery. Additionally, managing and securing this data while maintaining patient privacy poses a considerable challenge (Singh).

Discussion:

The figure 3 highlights key advancements in pacemaker technology from 1928 to the modern era. It starts with early innovations by Mark Lidwell and Albert Hyman, progresses through significant developments like the first battery-operated wearable pacemaker by Earl Bakken in 1957, and concludes with recent advancements in telemetry, leadless pacemakers, and non-invasive programmability. The figure 4 outlines the evolution of ICDs, beginning with foundational research on defibrillation in the 1940s. It includes milestones such as Claude Beck's successful human defibrillation in 1947, Michel Mirowski's development of the first ICD in 1980, and the advancement to smaller, more sophisticated devices by the 1990s.

The evolution of pacemakers and implantable cardioverter-defibrillators (ICDs) highlights the remarkable progress in cardiac care technology. From the rudimentary alternating current devices of the 1920s to the sophisticated microprocessor-driven systems of today, the development of pacemakers has significantly enhanced the management of heart rhythm disorders. Early devices, such as those developed by Lidwell and Hyman, were bulky and unreliable, but innovations...
in the 1950s, including the first battery-operated wearable pacemaker by Earl Bakken, marked pivotal advancements. Modern pacemakers now offer features like rate-responsive pacing and leadless designs, drastically improving patient outcomes by minimizing complications associated with traditional transvenous leads. Pacemaker implantation is primarily indicated for patients with symptomatic bradycardia, notably from atrioventricular (AV) block or sick sinus syndrome (SSS). Symptoms like syncope, dizziness, fatigue, and reduced exercise tolerance drive the decision, particularly when documented bradycardia is present. Clinical guidelines classify indications into three classes: Class I for conditions with strong evidence supporting pacemaker use, Class II for conditions with less consensus, and Class III where pacemakers are not recommended. Emerging indications include cardiac resynchronization therapy (CRT) for advanced heart failure with specific criteria. Correcting conduction abnormalities with pacing improves symptoms and prognosis, although it doesn't fully replicate normal cardiac electrophysiology (Toogood) (J A Mariani 1) (Michael Semelka 1).

Pace Maker:

*Mark Lidwell used an alternating current device to revive a child in cardiac arrest.*

*Albert Hyman developed a hand-crafted “artificial pacemaker”*

*Early 1950s*

*Development of mains-powered portable pacemakers by researchers like Wilfred Bigelow, John Callaghan, and John Hopps.*

*1952*

*Paul Zoll created an external tabletop pacemaker*

*Mid 1950s*

*Aubrey Leatham and Geoffrey Davies developed the first demand circuit device*

*1957*

*Earl Bakken developed the first battery-operated wearable pacemaker.*

*1958*

*Wilson Greatbatch and Dr. William Chardack created the first implantable pacemaker*

*1960*

*Transition to transvenous leads and introduction of demand pacemakers*

*1970*

*Introduction of lithium-iodine batteries and programmable pacemakers*

*1980*

*Development of steroid-eluting leads and rate-responsive pacemakers*

*1990*

*Introduction of microprocessor-driven pacemakers and bi-ventricular pacing.*

*Modern era*

*Advancements in telemetry, leadless pacemakers, and non-invasive programmability.*

**Figure 3: evolution of pacemaker**

ICDs
Similarly, the evolution of ICDs has transformed the prevention and management of sudden cardiac death. Initial ICDs in the 1980s were large and invasive, requiring open-chest surgery. Over time, advancements in battery technology, lead design, and microprocessor capabilities have led to smaller, more efficient devices. The integration of anti-tachycardia pacing (ATP) and sophisticated detection algorithms has significantly improved the efficacy and patient comfort. Modern ICDs, including subcutaneous (S-ICDs) and extravascular (EV-ICDs), offer enhanced shock efficacy and reduced inappropriate shocks, thanks to advanced programming and detection strategies.

Both pacemakers and ICDs have seen reductions in device-related complications through innovative designs and materials. For instance, leadless pacemakers (LPs) like the Micra device eliminate the risks associated with transvenous leads, though long-term efficacy data are still needed. Similarly, advancements in ICD technology have addressed issues such as inappropriate shocks and lead malfunctions, improving overall patient safety and device performance.

Initially, stainless steel leads were prone to fractures and corrosion, leading to short lifespans. Researchers replaced these with noble metal coils insulated with silicone or polyurethane, improving durability and performance. The development of lithium-iodine batteries in 1973 provided long lifetimes and stable voltage output. Modern pacemakers use titanium encapsulation with laser welding for mechanical hardness and corrosion resistance. Electromagnetic interference (EMI) remains a concern, necessitating the use of bandpass filters and bipolar leads to mitigate risks. Effective sterilization methods and biocompatible materials like titanium and specific polymers are essential for long-term integration. Packaging techniques ensure hermetic sealing to protect components from bodily fluids. Structural design requires extensive research to accommodate varied patient anatomies. Power management includes single-use and rechargeable batteries, with emerging energy harvesting techniques offering future potential. Wireless communication is vital for device monitoring, using low-frequency bands to ensure efficient data transfer.

Though several challenges remain in the field, one major issue is the risk of inappropriate shocks, which can cause significant discomfort and anxiety for patients. Efforts are ongoing to enhance the specificity of arrhythmia detection algorithms to minimize false positives. Another challenge is the risk of infection, particularly with traditional transvenous leads. Leadless devices and subcutaneous ICDs (S-ICDs) offer potential solutions, but their long-term efficacy and safety require further validation. The psychological impact of living with an ICD, including anxiety and depression, also needs to be...
addressed through comprehensive patient education and support systems. Ensuring device affordability and accessibility, especially in low-resource settings, remains a critical challenge to achieving widespread benefit from these advanced technologies.

The integration of ICDs and pacemakers into hospital networks presents numerous challenges, primarily centered around security, interoperability, scalability, and data management. The risk of cyber-attacks on these devices is significant, potentially compromising patient data and safety. Interoperability issues arise due to the diversity of devices and systems, making seamless data exchange difficult. The increasing number of connected devices also exacerbates scalability problems, while the vast amount of data generated creates storage and management challenges, complicating timely and accurate data analysis for healthcare professionals. To overcome these challenges, robust security measures such as firewalls, intrusion detection systems, and secure token services are essential to protect patient data from cyber threats. Enhancing interoperability through standards like HL7 and FHIR ensures smoother data exchange between different systems. Scalability issues can be addressed by leveraging cloud-based solutions and predictive maintenance powered by AI and machine learning. Advanced data analytics tools facilitate real-time monitoring and insights, improving decision-making processes. Moreover, regulatory compliance and clear guidelines for device connectivity and data management foster trust and ensure that patient data is handled securely and efficiently. Implementing these measures can significantly enhance the safety, efficiency, and effectiveness of using ICDs and pacemakers in healthcare settings.

Future advancements in pacemaker and ICD technology will likely focus on enhancing miniaturization, extending battery life, and improving biocompatibility. The development of fully leadless pacemakers and ICDs will reduce complications associated with transvenous leads and device pockets. Innovations in wireless power transfer and energy harvesting could further extend device longevity, minimizing the need for replacements. Enhanced algorithms and machine learning integration will improve arrhythmia detection and therapy personalization, reducing inappropriate shocks and optimizing patient outcomes. Additionally, advancements in remote monitoring and telemetry will enable more precise, real-time management of cardiac conditions, allowing for proactive adjustments and improved patient care. The integration of biodegradable materials and more sophisticated biocompatible coatings may also reduce the risk of infection and inflammation, further improving patient safety. These technological strides will continue to revolutionize cardiac care, offering more effective, durable, and patient-friendly solutions for managing heart rhythm disorders. Looking ahead, innovations like energy-harvesting mechanisms and artificial intelligence promise further enhancements. Energy-harvesting aims to extend battery life, while AI can improve device performance and predictive capabilities, paving the way for more personalized and effective cardiac care.

**Conclusion**

The evolution of pacemakers and ICDs underscores a transformative journey in cardiac care, marked by significant technological advancements. From the bulky, rudimentary devices of the early 20th century to today's sophisticated, miniaturized systems, these innovations have dramatically improved patient outcomes and quality of life. Modern pacemakers, with features like leadless designs and rate-responsive pacing, have minimized complications and enhanced functionality. Similarly, advancements in ICD technology, including anti-tachycardia...
pacing and improved detection algorithms, have optimized efficacy and patient comfort. Future developments promise further enhancements through miniaturization, extended battery life, and biocompatibility improvements. Innovations in wireless power transfer, energy harvesting, and artificial intelligence will likely revolutionize device longevity and personalization of care. These strides highlight the potential for more effective, durable, and patient-friendly solutions in managing heart rhythm disorders, paving the way for continued progress and better patient outcomes in cardiac care.

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