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Leadless pacemakers: A review of communication methods, energy management, and clinical applications

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Highlights

- This review explores advancements in leadless pacemaker technology, focusing on optimized wireless communication, energy-efficient strategies, and artificial intelligence-enhanced clinical applications.
- As a minimally invasive innovation, these devices enhance patient outcomes through adaptive algorithms and secure data transmission. Key developments include load modulation to maintain signal integrity and intelligent remote monitoring for real-time diagnostics.
- The review also addresses cybersecurity challenges and underscores the transformative potential of integrated intelligent systems in revolutionizing cardiac therapeutics.

Abstract

Leadless pacemakers have emerged as a mainstream clinical solution, and their communication capabilities, crucial for reliable pacing and device monitoring, continue to evolve. This review systematically examines the fundamental principles of leadless pacemaker communication systems, current design requirements, existing challenges, and future development trends. We outline the bidirectional communication mechanism between leadless pacemakers and external programmers through wireless technologies, focusing on radio-frequency field communication coupled with load modulation techniques to optimize energy efficiency and transmission reliability. Additionally, we analyze the role of artificial intelligence in adaptive communication protocols and explore the clinical potential of remote monitoring and control systems. This comprehensive analysis aims to serve as a reference for the development of communication architectures for leadless pacemakers.

Keywords: Pacemaker, leadless, wireless communication, radio frequency field, programming, remote control

Introduction

Leadless pacemakers represent a transformative advancement in cardiac rhythm management, offering a minimally invasive alternative to traditional lead-based systems by eliminating the need for transvenous leads and subcutaneous pockets. These devices mitigate lead-related complications such as infection, lead fracture, and dislodgement, while also improving patient comfort and cosmetic outcomes.

As the technology evolves, leadless pacemakers have expanded from single-chamber ventricular pacing to dual-chamber and even multi-chamber systems, enabling more physiological pacing modes.

However, the absence of physical leads necessitates robust wireless communication systems to ensure reliable bidirectional data transmission between the implanted device and exter-

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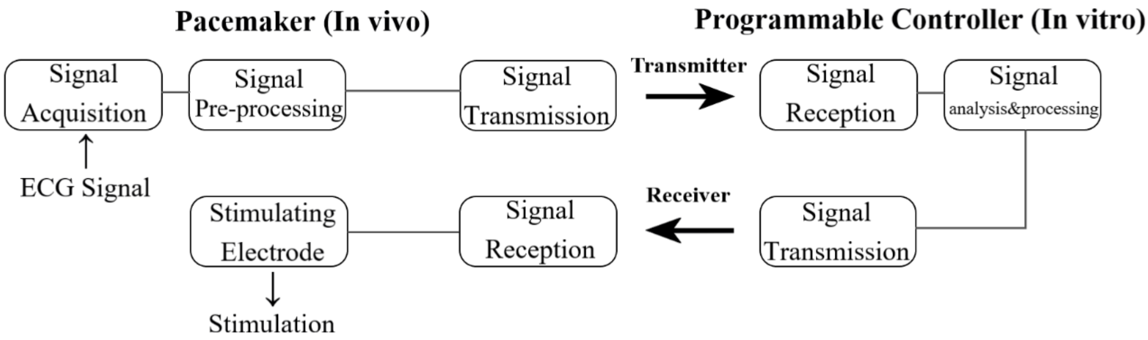

Figure 1. Schematic diagram of communication structure of the pacemaker in vivo and in vitro. ECG, electrocardiogram.

nal programmers, as well as among multiple devices within the heart.

The communication system is integral to the functionality of leadless pacemakers, enabling not only real-time telemetry and parameter adjustment but also advanced features such as adaptive pacing and remote monitoring. Despite significant progress, challenges remain in achieving energy-efficient, high-fidelity communication through biological tissues while minimizing power consumption and electromagnetic interference. This review provides a comprehensive overview of current state of leadless pacemaker communication technologies, including methods based on radio frequency (RF), load modulation, energy harvesting, and the emerging role of artificial intelligence in enhancing adaptive communication and cybersecurity. We also discuss clinical applications, ongoing challenges, and future directions aimed at optimizing the performance and safety of these innovative devices.

Communication with a leadless pacemaker

Basic communication functions of leadless pacemakers

For patients with arrhythmia, heart block, or cardiac insufficiency, a permanent cardiac pacemaker is commonly implanted to deliver electrical stimulation pulses at the required frequency and intensity, restoring sinus rhythm [1]. Pacemakers can be classified into leaded and leadless types, based on the presence or absence of leads. Leadless pacemakers are smaller and differ from leaded pacemakers in terms of size and implantation site. Without leads traversing blood vessels or cardiac chambers, leadless pacemakers offer simpler implantation, reduced trauma, and a lower risk of associated complications. Additionally, the absence of subcutaneous implantation device, further reduces the risk of infection. Leadless pacemakers also offer advantages such as lighter weight, smaller size, and minimal interference with daily activities [2]. Currently, leadless pacemakers are the mainstream choice among implantable cardiac pacemakers in clinical practice.

The primary communication requirement of leadless pacemakers pertains to bidirectional signal transmission between the implantable device and the external programming unit. The implantable component of a leadless cardiac pacing system includes a stimulation circuit, electrode, communication system, battery, and protective housing. For pacemakers with adaptive functions, a sensing circuit may also be included to capture specific signals such as acceleration, pressure, and pH. The communication system includes signal acquisition, processing, and conversion modules, along with signal transmitter and receiver modules [3]. It functions by converting physiological signals, such as electrocardiogram (ECG), into digital signals via analog-to-digital conversion and transmitting them to the external programming device. The receiver module accepts command signals from the external programming system, decodes them through digital-to-analog conversion, and adjusts the pacing pulse amplitude and frequency accordingly. This facilitates real-time, bidirectional wireless transmission of both data and commands [4]. **Figure 1** illustrates the interaction between the intracavity and extracavity structures of the pacemaker communication system.

Wireless communication methods for leadless pacemakers

Since the leadless pacemaker is directly implanted in the heart chamber, 6-10 cm beneath the body surface, and its position changes with cardiac motion, wireless communication is the only viable method for achieving two-way communication between the pacemaker and the

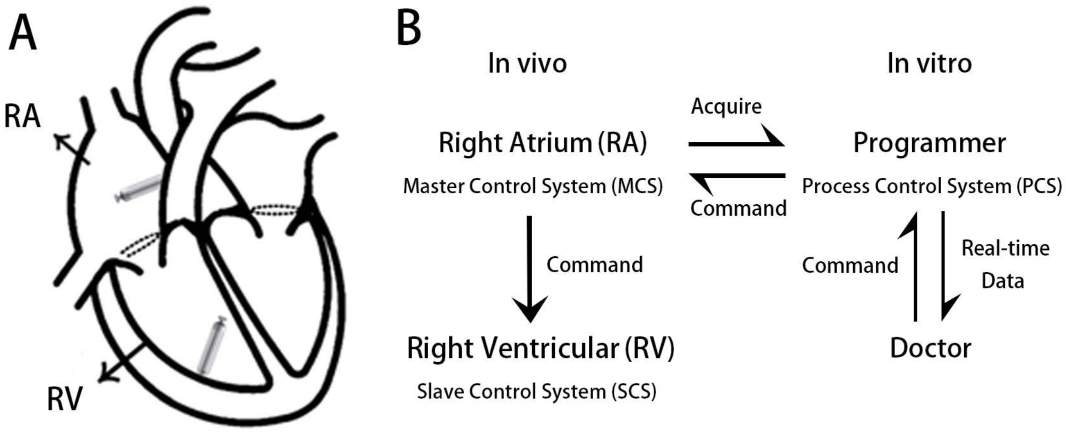

Figure 2. Configuration and intracardiac communication of a dual-chamber leadless pacemaker. (A) Schematic diagram of the implantation position of the dual-chamber leadless pacemaker in the heart. The two pacemakers are typically located in the right atrium and right ventricle respectively; (B) The intracavitary and extracavitary communication mode diagram of the dual-chamber pacemaker.

external programmer. Common wireless communication methods include Bluetooth, Wi-Fi, 5G, and RF field communication [5].

Currently, most pacemakers used in clinical practice rely on RF electromagnetic waves for communication between pacemakers and program controllers [6]. Research and development by universities and companies primarily focus on improving RF-based communication between pacemakers and external devices.

This method requires both the pacemaker and the program controller to have coil structures for signal transmission and reception. When the pacemaker sends a signal to the program controller, effective coupling between the coils of the pacemaker and the program controller is necessary to ensure efficient and accurate signal transmission.

The microprocessor first converts the signal through analog-to-digital coding, then modulates it using a modulation circuit. The signal is then transmitted as a high-frequency electromagnetic wave capable of penetrating the pacemaker housing and human tissues. The modulated signal is amplified by the power amplification circuit and transmitted via the transmitting coil. The receiver circuit in the program controller receives the signal, separates the high-frequency carrier signal using a demodulation circuit, and decodes it to obtain the original ECG signal and other data collected by the pacemaker. The process by which the program controller sends control signals to the pacemaker follows a similar mechanism.

For dual-chamber or multi-chamber pacing systems, communication is required not only between the internal pacemaker and the external programming device but also between pacemakers in different cardiac chambers to ensure synchronized pacing between the atrium and the ventricle [7]. In a dual-chamber pacemaker system, for example, the pacemaker implanted in the atrium initiates the pacing pulse, and the pacemaker implanted in the ventricle follows suit. Thus, only one-way communication from the atrium to the ventricle is needed [8]. While the distance between the two pacemakers is minimal, strict requirements for pacing time intervals, communication transmission rates, and the safety and accuracy of communication still make RF field communication the preferred method.

In this system, the atrial pacemaker serves as the master pacemaker, communicating bidirectionally with the external programming device while simultaneously sending control signals to the ventricular pacemaker. The ventricular pacemaker, as a slave pacemaker, receives control signals from the atrial pacemaker, enters a period of atrioventricular delay, and then delivers pacing pulses to control ventricular pacing. **Figure 2** depicts the communication relationship between the components of the dual-chamber pacing system. A similar communication mode applies to multi-chamber pacemakers.

Design requirements for communication systems in leadless pacemakers

The communication system of a leadless pacemaker includes modules for signal acquisition, processing, and conversion, as well as signal transmitter and receiver modules. These components convert ECG signals into digital data, which is transmitted to the external device. This communication is bidirectional: the pacemaker transmits information about its working state, parameters, and collected electrophysiological signals to the external programming device for analysis and storage for future research [9]. In turn, the external device can send control commands to adjust pacing parameters, such as pacing frequency, threshold, maximum pulse stimulation amplitude, and refractory period to optimize the pacemaker's performance [10-12].

For a leadless pacemaker to function effectively, its communication system must fulfill several hardware and software requirements:

- Accurate and Secure Two-Way Communication: The pacemaker must reliably receive and interpret signals from the external programming device to avoid incorrect responses that could harm the user's health.

- Basic Communication Functions: These include collecting the intracavity ECG, heart rate, and real-time supply voltage of the pacemaker.

- Minimized Resource Consumption: The pacemaker's communication system should be designed to minimize energy use while ensuring normal operation, aiming to keep the average operating current at microampere levels or lower. Alternatively, external devices should provide power for the pacemaker's communication system.

- Adaptability to Multi-Parameter Adjustment: The communication system should facilitate easy and fast adjustment of pacing parameters across multiple levels to avoid complications caused by mismatches between pacemaker settings and the user's physiological needs.

- Support for Optimization and Additional Functions: The system should support functions such as achieving a transmission rate of 20 kb/s or higher and maintaining normal operation under MRI conditions.

Challenges in leadless pacemaker communication

Ideally, the communication function of a pacemaker should be instant, controllable, and resource-efficient. However, due to the current technological limitations, achieving these requirements simultaneously remains difficult. Based on a comprehensive analysis of leadless pacemaker products, such as Medtronic Micra and St. Yoda Nanostim, approved by the US Food and Drug Administration or undergoing clinical trials, several communication challenges need to be ddressed [13-16].

- Excessive Resource Consumption by the Communication Module: While leadless pacemakers are designed to be small to fit within the heart chamber, the size of the communication module often exceeds that of the pacemaker itself, reducing available space for the battery and pacing circuits. This reduces the pacemaker's battery life. Additionally, the communication function contributes significantly to the internal power consumption of the pacemaker, as it requires signal amplification, processing, and bidirectional transmission. If not carefully managed, this can lower battery life.

- Limited Communication Range and Interference: The communication signal must penetrate both the pacemaker's metal housing and the human chest during transmission. This results in significant signal attenuation, meaning the external programming device must be positioned close to the chest to maintain normal signal transmission. Otherwise, the pacemaker may fail to transmit signals, or severe signal distortion may occur.

- Communication Efficiency Challenges: The pacemaker must perform signal acquisition, processing, transmission, analysis, and reception within a short time frame—typically less than one second—since the R-R interval between heartbeats is around 1 second, and can shorten to about 0.6 seconds during intense exercise or with certain medications. If the pacemaker's communication system fails to meet this speed requirement, pacing may be delayed or even induce arrhythmias. Achieving such high communication speeds poses significant challenges for both the hardware and algorithms. The need for interchamber communication, which has higher efficiency demands, further complicates this issue. Currently, leadless pacemakers struggle to meet these requirements due to algorithm limitations, hardware constraints, and space limitations, particularly for interchamber communication, where effective solutions are lacking.

Leadless pacemaker communication technology

Factors influencing communication efficiency and accuracy

Like other medical devices with communication functions, evaluating the communication performance of leadless pacemakers requires a comprehensive analysis of both internal system factors and external influences on communication efficiency and accuracy.

In wireless communication systems, the signal transmission rate is a key factor affecting communication efficiency. The transmission rate between the sending and receiving devices is determined by Shannon's formula (Equation (1)), where C represents the maximum transmission rate (in bits per second), W represents the channel bandwidth (in Hertz), S is the signal power, and N is the noise power (both in watts). As shown in Equation (1), the transmission rate is mainly determined by the Channel Bandwidth and the Signal-to-Noise Ratio (SNR). Channel bandwidth is typically determined by network equipment (e.g., switches, routers, hubs), topology, data type, the number of devices, and other factors.

For leadless pacemakers, increasing the bandwidth requires advanced network hardware, which would place additional strain on the pacemaker's power supply [17]. Therefore, increasing the transmission rate by expanding channel bandwidth is generally not considered feasible in leadless pacemakers. Instead, enhancing the signal transmission rate by improving the SNR is a more feasible strategy in pacemaker design [18]. To improve the SNR, two approaches can be employed:

Designing appropriate filters based on the frequency of the effective signal to exclude interference at the acquisition end.

Amplifying the effective signal to facilitate transmission without significantly increasing the resource consumption of the transmission circuit [19].

$$C = W * log_2(1 + S/N) \tag{1}$$

Communication accuracy refers to the reliability of the communication system, commonly measured by the Bit Error Rate and Mean Time Between Failures. The bit error rate is influenced by factors such as channel noise, transmission distance, data rate, and the transmission power and receiving sensitivity. Since reducing the communication distance between the internal communication module of the pacemaker and the external programming device is challenging, and the data rate is constrained by the hardware at the time of implantation, efforts to minimize Bit Error Rate focus on two areas:

- Limiting the interference from external noise, particularly electromagnetic radiation and signal interference from other electronic devices.

- Increasing the transmission power and improving the receiving sensitivity of the communication module, while ensuring user safety and maintaining efficient resource consumption.

In addition to the communication system itself, the environment in which the system operates also affects communication efficiency. Wireless signals inevitably experience loss as they penetrate obstacles, and the material of the obstacles significantly influences signal attenuation [20]. Additionally, nearby equipment such as switching power supplies, high-voltage grids, welding machines, or other high-frequency devices can negatively impact the pacemaker's communication function [21]. For example, patients with traditional pacemakers cannot undergo MRI scans unless their pacemaker is specifically designed for MRI compatibility. Even with MRI-compatible pacemakers, the device must be adjusted to the "ventricle paced, none sensed, none response" mode or another pacing-only mode during MRI operation [22]. Failure to do so may result in severe electromagnetic interference that disrupts the pacemaker's sensing and communication functions, posing significant risks to the patient's health and safety.

Energy-efficient solutions for communication

Several solutions have been proposed to address energy consumption issues in leadless pacemakers, including advanced battery technologies and wireless power transfer (WPT) techniques.

The core issue limiting the lifetime and communication functionality of leadless pacemakers is their small size, which limits battery capacity. Once implanted in the heart chamber, the pacemaker is difficult to retrieve for recharging or replacement, and attempting to do so could cause significant harm to the patient. As a result, the communication power and transmission efficiency of the pacemaker are often constrained, which can lead to complications or misdiagnosis during follow-up due to communication issues [23].

A direct solution to this issue is to use batteries with higher energy storage capacities. Biofuel cells and micro-nuclear batteries are promising alternatives. However, biofuel cells have limited energy storage and lifespan, while nuclear power batteries, although efficient and clean, pose uncontrollable risks, such as potential radiation leakage and disposal issues after patient death. Moreover, both types of batteries are still too bulky for compact, implantable medical devices like leadless pacemakers.

WPT technology, which allows wireless energy transfer from an external source to the pacemaker, offers a more sustainable solution by reducing dependence on the pacemaker's internal power supply [24]. Near-field WPT technology enables non-invasive, contact-free energy delivery from an external source to the pacemaker, extending its battery life and reducing the need for additional surgeries.

Two main types of near-field WPT exist: inductive coupling and magnetic resonance coupling. Inductive coupling uses magnetic field induction, where two resonating coils transfer energy. Magnetic resonance coupling, on the other hand, employs oscillating electromagnetic fields to transmit energy between the coils, offering higher efficiency, larger coupling distances, and greater resistance to interference. When applying WPT to leadless pacemakers, it is necessary to consider the limited space and geometry of the coils within the pacemaker, as well as the uncertainty of pacemaker positioning after implantation [25]. This requires careful selection of operating frequencies and optimization of the inductor's quality factor in the design of the transmission system.

The combination of WPT and RF technology has become one of the most effective methods for overcoming the limited battery capacity in communication systems [26]. Load modulation enables both signal transmission and energy delivery by sending carrier signals from the transmitting unit to the receiving unit. In leadless pacemakers, load modulation works by sending a carrier signal from the external programming device to the implanted device. The load change in the receiving unit is reflected as a voltage deviation at the transmitting unit, and the timing of this deviation serves as a time reference.

The advantage of this approach is that the receiver unit can communicate with the external device without additional power consumption, while also establishing synchronization between leadless pacemakers. In dual-chamber leadless pacemakers, load modulation facilitates communication between the atrial and ventricular modules. If the atrium generates a depolarized ECG due to contraction, a voltage deviation signal is sent after a delay of T_o, and after T_α, it is received and recognized by the envelope detection circuit in the ventricle. The ventricular module then depolarizes accordingly. The time interval between atrial and ventricular depolarization meets the interval T_v shown in Equation (2), where τ represents the error time due to signal recognition.

$$T_v = T_o + T_a + \tau \tag{2}$$

Another way to reduce the communication power consumption is through the use of mixed-signal Application-Specific Integrated Circuits, which enable low-power signal transmission. These Application-Specific Integrated Circuits can implement pulse width modulation to facilitate signal transmission. Besides the channel for collecting intracardiac ECG, the pacemaker includes channels for extracting the phase and amplitude of intracardiac impedance, a pulse generator for myocardial stimulation, and a transmitter for signal transmission.

Additionally, digital/analog converters and low-voltage module bias generators are used for acquiring bioelectric signals, while high-voltagebias generators are used for stimulation [27]. Application-Specific Integrated Circuits convert biological signals into pulse width modulation signals, which are transmitted to the transmitter through the switching circuit without requiring additional analog-to-digital conversion or digital modulation [28]. This approach reduces the power consumption of the pacemaker, with the bulk of signal processing occurring in the external device, while the implanted pacemaker provides minimal conversion power.

Enhancing signal transmission efficiency

As previously mentioned, improving the SNR is the most effective strategy to enhance signal transmission efficiency in leadless pacemakers. This requires the pacemakers to have better filtering and amplification capabilities. A feasible solution involves using an antenna implanted within the pacemaker to collect RF energy from outside the body, which is then used for pacemaker pulse delivery and communication. Deeply implantable conformal antennas based on this design have shown good impedance matching characteristics in High Frequency Structure Simulator and Tissue Simulation Liquid experiments. These antennas exhibit radiation patterns similar to planar microstrip antennas in free space and can be integrated with commercial pacemakers.

Compared to previous compact rectifier antennas, the size of the antenna increases by only about 4 mm when integrated with the pacemaker, and it can still be implanted via cathe-

Table 1. Comparison of characteristics of different types of adaptive sensors

Sensor Types	Sensing speed	Perceive proportionality	Perceived specificity	Perceptual sensitivity
Body movement	High	Low	Low	Low
Q-T interval	Low	Medium	High	Medium
Arterial diastolic pressure	Lower	Higher	Medium	Low
Ventilation per minute	Medium	High	Medium	Low
Combination sensor	Higher	High	High	Medium

ter. Additionally, using the emerging Wide Band Numerical Model has further improved the antenna's design, offering more flexible resonant frequencies, lower return loss in the same frequency band, and a further reduction in the antenna's size [29]. The integrated antenna diameter is only about 7 mm.

Tissue Simulation Liquid experiments reveal that blood is a highly attenuating medium, and the pacemaker's communication effectiveness decreases as the blood content in the cardiac chamber increases. The Human Genome Organisation (HUGO) simulation experiments also showed a 3.1 dB difference in received power during systole and diastole, and a 1.3 dB difference in external communication received power. By continuously monitoring and analyzing the received power, it is possible to determine whether the heart is in systole or diastole without additional energy expenditure for heart state detection. This analysis helps the signal transmitting module select the optimal communication time, minimizing mismatch effects, enhancing coupling between the transmitting (T_x) and receiving (R_x) antennas, and improving communication efficiency while reducing communication frequency. The received power normalization formula at the R_x end is as follows.

$$|S_{21}|_{norm} = |S_{21}|/\sqrt{1-|S_T|^2}\sqrt{1-|S_R|^2} \qquad (3)$$

In Equations (3), $|S_{21}|_{\text{norm}}$ represents the normalized standard received power. $|S_{21}|$ represents the received power before normalization, and S_T and S_R represent the return loss of T_x and R_x, respectively.

Adaptive communication systems in pacemakers

Adaptive pacemakers, which have been in development since the 1980s, can adjust pacing parameters based on physiological signals, unlike traditional pacemakers that require manual adjustment after implantation. These pacemakers use sensors or algorithms to create a closed-loop system, calculating the difference between the desired pacing rate and the actual pacing rate, and automatically adjusting the pacing rate and amplitude. Adaptive functionality has become a core trend in leadless pacemaker development, aiming to address the mismatch between pacemaker performance and user needs.

Currently, most adaptive pacemakers are frequency adaptive, using body movement or physiological parameters such as ventricular blood impedance, arterial diastolic pressure, or minute ventilation for adjustment [30]. **Table 1** lists the characteristics of adaptive pacemakers based on different sensor types.

The basic principle and communication mode of adaptive pacemakers are similar to those of other pacemakers. However, adaptive pacemakers require enhanced anti-interference capabilities for their algorithms and automatic programming due to frequent pacing parameter adjustments. Multi-sensing pacemakers, which combine multiple sensors, offer stronger resistance to interference from the chest and external sources. By stacking, fusing, or cross-checking sensor data with appropriate algorithms, the pacemaker can determine the optimal pacing mode for the user, making the pacing more suitable for the user's physiological needs.

Compared to traditional pacemakers that require manual programming, adaptive pacemakers can self-learn, eliminating the need to set pacing rate slopes, upper/lower limits, and sensor thresholds [31]. This reduces the pacemaker's resource usage and minimizes communication-related issues, especially in children and the elderly with complex physiological conditions [32].

New trends in pacemaker communication

Role of artificial intelligence in pacemaker communication

Currently, pacemaker parameter adjustments are primarily based on manual analysis of user data, which is time-consuming, labor-intensive, and not real-time. Even pacemakers with adaptive functions rely on pre-set algorithms, adjusting pacing parameters within a limited range based on the user's physiological state. However, as patients with permanent pacemakers age or develop acute or chronic conditions, their physiological parameters often change in ways that are not autonomously detected and adjusted by the pacemaker [33, 34]. In special conditions such as intense exercise or large amplitude movements after prolonged rest, pacemaker algorithms may fail to make necessary adjustments, leaving the pacemaker unable to meet the user's heart requirements.

AI can address this issue by enabling pacemakers to autonomously update their algorithms in response to changes in the user's physiological state, optimizing the structure and algorithm of the pacemaker. For example, a deep learning-based method using multi-dimensional features can detect ECG signals under compressed sampling conditions. A multi-channel convolutional neural network can identify pacing and non-pacing heart rates, avoiding missed detection of pacemaker spikes, even at low sampling rates. AI also reduces errors in manual pacemaker control and improves pacemaker algorithm performance. Using tools like Matlab and Simulink, deep reinforcement learning can be applied to pacemaker algorithms to achieve high-precision continuous control [35].

One significant challenge in pacemaker communication is low SNR, especially when the pacemaker battery voltage is low, making it difficult to detect pacing spikes. T_o address this, an improved ECG signal processing algorithm based on convolutional networks was proposed, with its performance evaluated using Leave-One-Out Cross-Validation to test robustness [36]. The robustness of the pacemaker can be improved using the Mitchell and Schaeffer model, commonly used in cardiac electrophysiology. This model helps derive the recovery curve of Action Potential Duration under single or multiple stimuli. Equations (4) and (5) show the improved Mitchell and Schaeffer model, where J_s is the externally applied voltage, v_m is the transmembrane potential, h is the gate variable of the incoming current, and T_i, T_p, T_o, T_c are the four time constants affecting the four phases of the transmembrane potential.

Considering the possible malfunction of the pacemaker in the communication process, it has been proposed that software agents can continuously verify the behavior of implantable pacemakers based on Colored Pett-net and Hierarchical Fuzzy Colored Pett-net [37].

The autonomy and intelligence of AI software can be used to help pacemakers avoid behavior delay or decision-making errors caused by faults, especially in checking the operation rules of the pacemaker and enhancing the communication decision-making with more than 90% efficiency improvement.

$$\partial v_m/\partial t = h v_m(v_m - v_g)(1 - v_m)/T_{in} - (1 - h)v_m/T_o + J_s \tag{4}$$

$$\partial h/\partial t = \begin{cases} (1 - h)/T_p & v_m \leq v_g \\ -h/T_c & v_m > v_g \end{cases} \tag{5}$$

Remote monitoring (RM) and control technologies for pacemakers

Postoperative follow-up for implantable pacemakers is crucial to prevent malfunctions or complications that could harm the patient's health. However, data shows that approximately a quarter of pacemaker users fail to follow up as scheduled [38]. RM functions allow pacemakers to send real-time data to medical professionals, overcoming the limitation of face-to-face follow-ups and improving patient prognosis [39]. RM enables continuous monitoring of changes in pacing threshold, pacemaker duration, and remaining battery life. This allows for early detection of when pacemaker replacement is needed and assists in diagnosing changes in the user's physiological state, identifying complications or maladaptive symptoms.

For hospitals, RM facilitates the collection and aggregation of patient data via online channels such as the Internet, significantly reducing the difficulty and time required for postoperative follow-up [40]. Additionally, big data analysis models can be introduced to provide personalized diagnosis and treatment recommendations for patients. RM also helps reduce care disparities across patients, facilitating cross-referencing of pacing statuses to better address individual differences. For patients, RM serves as a real-time monitoring and alert system, with studies showing that the survival rate is positively correlated with RM usage. It can also reduce unnecessary pacing shocks and improve the overall comfort of the pacemaker experience [41].

RM has shown significant value in pacemaker fault detection. By constructing a Petri net model of the leadless pacemaker, targeted checkpoints can be integrated to create a fault diagnosis network. This allows pacemaker data to be sent as check codes, enabling medical staff to assess the pacemaker's operational status and the patient's health remotely. RM-based follow-up has demonstrated a better ability to identify rare pacemaker failures, particularly overwork situations where the pacemaker operates beyond its normal capacity. These abnormalities, such as atrial/ventricular episodes exceeding daily limits, excessive pacemaker mode switching, or high heart rates during switching periods, can be observed and recorded over extended time frames, providing crucial data for diagnosis.

For frail populations, such as the elderly, RM offers a valuable solution. Since these patients often have difficulty attending regular follow-ups due to mobility issues, RM enables healthcare providers to remotely monitor patients, significantly reducing the cost and burden of postoperative care and making it more convenient and accessible for both patients and their families.

However, there are ongoing concerns about the validity and reliability of RM. The primary issue is the potential risk of information leakage through remote communication and vulnerabilities in the communication network, which could be exploited by hackers [42]. Such attacks could render the pacemaker inoperative or cause disruptions in communication, such as sensing failures or oversensing, leading to serious clinical complications. Additionally, hackers may access sensitive personal data, resulting in privacy breaches. To mitigate these risks, medical device manufacturers must regularly assess the security of pacemaker communication systems, identifying and addressing software vulnerabilities promptly. Moreover, cooperation between manufacturers, hospitals, and governments is essential to strengthen medical network systems and enhance penalties for unauthorized access to medical device communications.

A potential solution to protect pacemaker communications involves using specialized communication firmware to establish a secure, direct link between the pacemaker and the manufacturer's server. However, this firmware must be regularly updated, which could temporarily disrupt communication with the pacemaker. Although the likelihood of update failures and parameter loss is minimal, these risks should not be overlooked. Furthermore, adding additional hardware to improve security can increase the device's resource consumption and failure risk.

Conclusion and future directions

Leadless pacemakers are one of the most widely adopted and promising technologies in active implantable medical devices. As a critical component for ensuring proper pacing, the communication system of leadless pacemakers has seen substantial advancements in both hardware design and algorithm development, with significant clinical applications. As clinical usage grows, the design requirements for pacemaker communication systems have become more defined, highlighting both achievements and challenges.

Current research and development efforts focus primarily focus on optimizing energy utilization and improving signal transmission efficiency. WPT technology supports low-power signal transmission, while load modulation enables the replacement of internal batteries by utilizing externally transmitted energy, addressing the limitations of traditional batteries' low energy storage efficiency and short lifespan. These advances reduce the physiological risks and surgical burden associated with frequent pacemaker replacements. To further enhance communication efficiency, software optimization strategies, such as improved signal filtering and amplification algorithms, are widely adopted, alongside hardware enhancements in antenna design to improve signal transmission reliability.

Adaptive pacing technologies, which incorporate automatic programming and anti-interference communication mechanisms, enhance the pacemaker's sensing speed, compatibility, specificity, and sensitivity. These innovations minimize the need for manual programming and reduce the dependency on regular follow-ups.

AI-driven cardiac pacing algorithms are emerging as a key research direction, enabling pacemakers to autonomously adjust pacing modes and parameters according to patients' physiological condition. This improves the precision of medical assistance and enhances the overall user experience. With the growing integration of telemedicine, pacemaker programming and follow-up are shifting toward remote management, and RM technology is playing a crucial role in this evolution. As AI and RM technologies become increasingly embedded in leadless pacemakers, addressing their reliability and cybersecurity remains vital. This includes ensuring the protection of patients' personal data in the digital era and safeguarding against unauthorized access or potential malicious hardware attacks.

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