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THE PAST, PRESENT, AND FUTURE OF LEADLESS PACEMAKERS: A NARRATIVE REVIEW OF TECHNOLOGICAL EVOLUTION AND CLINICAL EVIDENCE

Patrycja Sobantka *(Corresponding Author, Email: patsob84@gmail.com)*
Central Teaching Hospital of Medical University of Lodz, Pomorska 251, 92-213 Łódź, Poland
ORCID ID: 0009-0004-3128-5181

Aleksandra Woźniak
Norbert Barlicki University Clinical Hospital No. 1 in Łódź, Stefana Kopcińskiego 22, 90-153 Łódź, Poland
ORCID ID: 0009-0003-5382-1451

Aleksandra Straszewska
Central Teaching Hospital of Medical University of Lodz, Pomorska 251, 92-213 Łódź, Poland
ORCID ID: 0009-0003-6293-9689

Szymon Mokrzecki
Norbert Barlicki University Clinical Hospital No. 1 in Łódź, Stefana Kopcińskiego 22, 90-153 Łódź, Poland
ORCID ID: 0009-0005-8228-2711

Matylda Król
Copernicus Memorial Hospital, Pabianicka 62, 93-513 Łódź, Poland
ORCID ID: 0009-0000-7759-4933

Anna Mamach
Norbert Barlicki University Clinical Hospital No. 1 in Łódź, Stefana Kopcińskiego 22, 90-153 Łódź, Poland
ORCID ID: 0009-0004-5934-8674

Katarzyna Aleksandrowicz
Medical University of Lodz, Łódź, Poland
ORCID ID: 0009-0008-5935-8265

Zofia Grodzka
Independent Public Health Care Complex named after Marshal Józef Piłsudski in Płońsk, Sienkiewicza 7, 09-100 Płońsk, Poland
ORCID ID: 0009-0002-0904-810X

Mateusz Meszka
Central Teaching Hospital of Medical University of Lodz, Pomorska 251, 92-213 Łódź, Poland
ORCID ID: 0009-0001-6147-7000

Ewa Bełc
University Clinical Hospital No. 2, Żeromskiego 113, 90-549 Łódź, Poland
ORCID ID: 0009-0004-0224-8162

Karolina Brzezińska
Medical University of Lodz, Łódź, Poland
ORCID ID: 0009-0008-4403-6060

ABSTRACT

Background: Conventional transvenous pacemakers (TVPs) have been the gold standard for bradyarrhythmia management for over six decades. However, transvenous leads and the subcutaneous pocket remain the primary sources of acute and chronic morbidity. Recent large-scale meta-analyses confirm that leadless pacemakers (LPMs) systematically eliminate pocket infections and significantly reduce lead-induced valvular complications.
Aim: The primary objective of this review is to evaluate the clinical safety, efficacy, and technological progression of leadless pacing systems - from first-generation devices (e.g., Nanostim, Micra VR) to contemporary multi-component modular networks, resynchronization therapies, and novel physiologic sensors.
Methods: A comprehensive literature search was performed across major medical databases (PubMed, EMBASE, Cochrane Library) for studies published up to May 2026, focusing on randomized controlled trials, large prospective registries, and clinical updates.
Results: First-generation single-chamber ventricular LPMs demonstrated an excellent long-term safety profile in global registries, outperforming historical transvenous cohorts. The contemporary era is characterized by major structural breakthroughs: advanced accelerometer algorithms for mechanical atrial tracking (Micra AV) and dual-chamber leadless pacing systems (AVEIR DR) utilizing intrabody conductive communication for implant-to-implant (i2i) synchronization. Advanced features now include temperature-based rate response and median battery longevity exceeding 15 years.
Conclusions: Leadless pacemakers have evolved from a niche solution into a primary therapeutic standard. The future of this field relies on multi-component modular networks (pairing LPMs with subcutaneous ICDs), entirely leadless cardiac resynchronization therapy (CRT) utilizing ultrasound acoustics, and the pursuit of energy-harvesting technologies.

KEYWORDS
Leadless Pacemakers, Cardiac Pacing, Transcatheter Pacing, Atrioventricular Synchrony, WiSE-CRT

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1. Introduction: The Structural Flaws of Traditional Pacing

The field of permanent cardiac pacing has achieved major technological milestones since its inception in the mid-20th century. Although the integrated circuitry miniaturization and battery chemistry of traditional transvenous pacemakers (TVPs) have successively improved, the core architecture of the system - consisting of a surgically carved subcutaneous pocket in the pectoral region and transvenous leads guided through the venous system into the right cardiac chambers - has remained fundamentally unchanged.

Data from national registries indicate that this architecture carries inherent biomechanical and infectious vulnerabilities. Transvenous leads are subjected to continuous mechanical stress from cardiac contractions (up to 100,000 times a day) and upper extremity movements. This constant friction can lead to "subclavian crush syndrome," insulation degradation, and conductor fractures. Furthermore, leads crossing the tricuspid valve often cause mechanical interference. Recent systematic reviews highlight the severe long-term consequences of this interaction. As demonstrated by Yuyun et al. (2024), mechanical interference by standard leads frequently exacerbates tricuspid regurgitation.

By contrast, a meta-analysis by Haeberlin et al. (2022) confirmed that the implantation of leadless pacemakers, which sit entirely within the right ventricle and do not traverse the valve apparatus, is associated with a significantly reduced progression of tricuspid valve regurgitation. Furthermore, LPMs eliminate pocket-related infections, hematomas, and lead fractures. National-level data meta-analyses (Ngo et al., 2021; Sarsenbayeva et al., 2025) demonstrate a low risk of major complications and a good safety profile.

LPMs were engineered to address the structural limitations by integrating the generator, battery, and pacing/sensing electrodes into a single, highly miniaturized self-contained capsule (typically <10% the size of a conventional pacemaker).

2. Literature Search Strategy

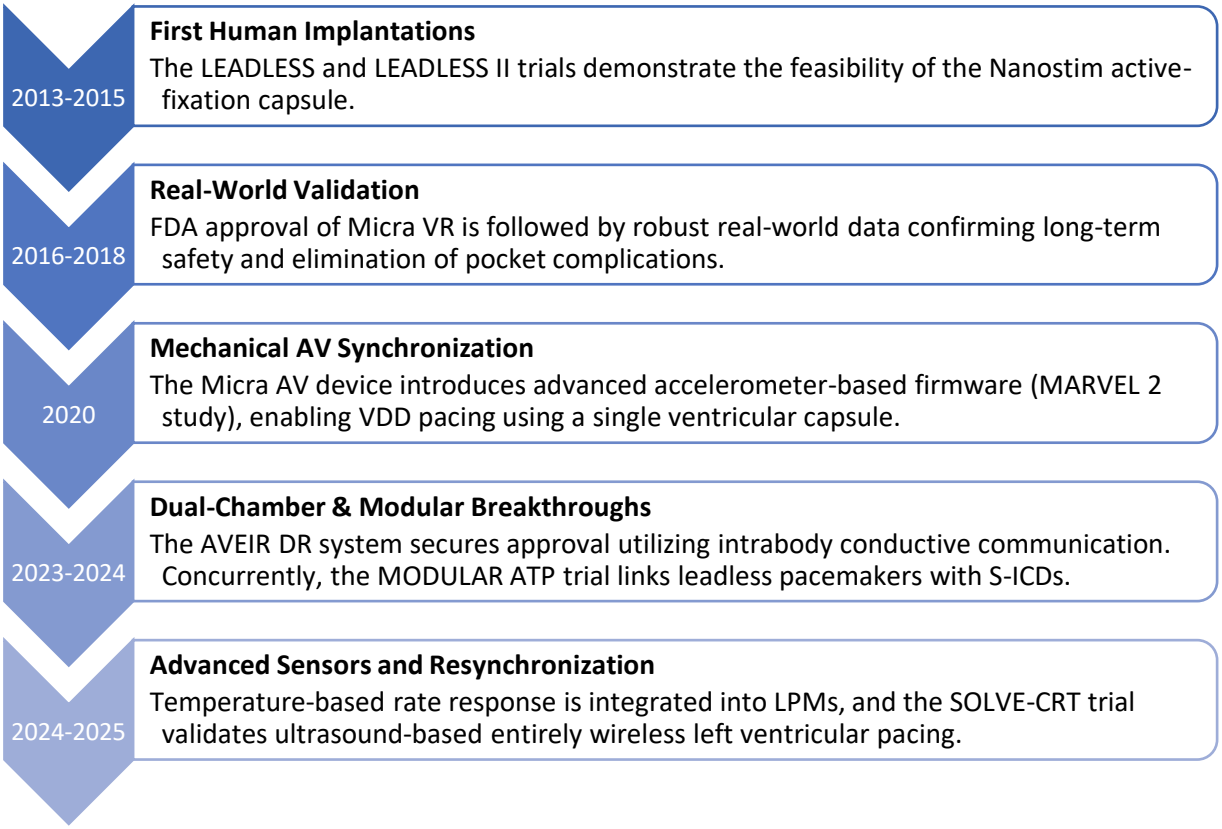
To provide a comprehensive, state-of-the-art overview of the technological evolution and clinical performance of leadless pacing systems, a narrative literature synthesis was conducted. A descriptive search of major medical databases, including PubMed, EMBASE, and the Cochrane Library, was carried out for relevant peer-reviewed articles published between December 2013 and May 2026.

The search strategy utilized a combination of key terms and indexing descriptors related to leadless technology, such as "leadless pacemaker", "transcatheter pacing", "Micra VR/AV2", "AVEIR VR/DR", "Nanostim", and "WiSE-CRT". These terms were systematically combined with descriptors of clinical and technical outcomes, including "atrioventricular synchrony", "battery longevity", "device retrieval", and "complication rates".

Literature selection focused on high-impact randomized controlled trials, large prospective registries, and major meta-analyses. Rather than applying rigid statistical exclusion protocols, papers were gathered based on their capacity to inform the narrative synthesis of the past, present, and future paradigms of leadless cardiac rhythm management.

3. The Past: Proving the Concept with Single-Chamber Devices

The initial era of leadless pacing focused exclusively on replicating single-chamber right ventricular (VVI) pacing. While effective for patients with permanent atrial fibrillation, VVI pacing in patients with sinus rhythm can lead to pacemaker syndrome due to AV dyssynchrony, as reinforced by insights from the MOST trial (Loring et al., 2020). Therefore, the primary goal of this first generation was to establish foundational hardware safety and procedural viability.



3.1. The Nanostim System

The Nanostim (St. Jude Medical) was the pioneer of the field. It was an active-fixation device featuring a distal helix.

- **Implantation Technique:** Delivered via an 18-French steerable transvenous catheter introduced through the femoral vein. Upon reaching the right ventricular apex, the entire delivery catheter was rotated to screw the distal helix into the myocardium.
- **Outcomes:** The pivotal **LEADLESS II** IDE trial and earlier phases (Knops et al., 2015; Reddy et al., 2015) documented a 95.8% successful implantation rate. However, long-term observation revealed critical vulnerabilities. A high rate of premature battery depletion - caused by resistive layer formation on the lithium anodes - and structural docking button detachments led to a voluntary global commercial withdrawal. Despite its commercial failure, Nanostim proved that the leadless form factor was viable.

3.2. The Micra VR Platform

Commercially introduced by Medtronic, the Micra Transcatheter Pacing System (TPS) became the first globally successful LPM.

- **Implantation Technique:** Delivered using a 23-French transvenous sheath system, it utilizes a passive fixation mechanism consisting of four electrically inactive, highly flexible nitinol tines. Once positioned, the capsule is deployed from a protective cup. The operator performs a "pull-and-hold" test - applying tension to a tether attached to the device to visually confirm via fluoroscopy that at least two tines are securely engaged in the trabeculae before permanently releasing the tether.
- **Outcomes:** Following the pivotal IDE trial (Reynolds et al., 2016), the Micra system underwent rigorous post-market scrutiny. The 12-month follow-up data (Duray et al., 2017) and subsequent real-world global registries (El-Chami et al., 2018) confirmed highly stable electrical performance and a nearly 50% reduction in major complications compared to historical TVP cohorts. Even in patients from diverse geographical demographics, such as the Japanese cohort analyzed by Soejima et al. (2017), the device demonstrated consistent pacing thresholds. Furthermore, Piccini et al. (2017) demonstrated that even in rare cases where implantation resulted in acutely elevated pacing thresholds, long-term outcomes remained stable without premature battery depletion. Boveda et al. (2023) later confirmed these sustained two-year outcomes even in high-risk subgroups.

4. The Present: Achieving Atrioventricular Synchrony and Longevity

The most significant recent leap in LPM technology is the restoration of atrioventricular (AV) synchrony, expanding device indication to the vast majority of patients with sinus node dysfunction or AV block. This was achieved through two entirely different engineering approaches.

4.1. Mechanical Atrial Tracking (Micra AV / AV2)

Medtronic approached AV synchrony without implanting a second device in the atrium. Instead, they upgraded the internal software and sensors of their ventricular capsule to detect atrial contractions mechanically.

- **Operating Principle:** The Micra AV relies on a highly sensitive 3-axis integrated accelerometer. The cardiac cycle generates distinct acoustic signatures: A1 (mitral/tricuspid valve closure), A2 (aortic/pulmonary valve closure), A3 (passive ventricular filling), and A4 (active atrial contraction). The device's complex algorithm isolates the A4 signal. When it detects the physical vibration of the atria contracting, it triggers a synchronized ventricular pacing pulse (VDD pacing mode).
- **Outcomes:** The MARVEL 2 study (Steinwender et al., 2019) demonstrated that this algorithm successfully provides AV synchronous pacing in the majority of resting patients. However, Garweg et al. (2020) identified specific predictors of mechanical sensing success, noting that patients with lower atrial signal amplitudes or those undergoing strenuous physical activity may experience temporary drops in AV synchrony due to overlapping cardiac motion artifacts (blurring the distinction between A3 and A4 signals).

4.2. True Dual-Chamber Pacing via i2i Conductive Communication (AVEIR DR)

Abbott resolved the dual-chamber barrier by developing the AVEIR DR system, which physically places two separate, active-fixation leadless capsules: one in the right atrium (RA) and one in the right ventricle (RV).

- **Implantation Technique:** The procedure is sequentially staged. A unique advantage of the AVEIR delivery system is its mapping capability - the device can measure electrical parameters (R-wave amplitude, pacing thresholds) while still attached to the catheter, before the active helix is screwed into the tissue, minimizing the need for device repositioning.
- **The Physics of i2i Communication:** To coordinate pacing, the two independent devices must communicate. Radiofrequency (Bluetooth) transmission requires too much battery power and is heavily attenuated by dense cardiac muscle. Instead, the AVEIR system utilizes intrabody conductive communication. The devices send sub-threshold, high-frequency electrical pulses directly through the blood pool and myocardial tissue. Blood, being highly conductive, acts as an excellent, low-energy transmission medium.
- **Outcomes:** Recent rigorous data published by Ip et al. (2024) and Defaye et al. (2026) confirmed that the AVEIR DR system maintains robust, continuous AV synchrony (exceeding 90%) in real-world ambulatory conditions, closely mimicking the performance of dual-chamber transvenous pacemakers.

4.3. Novel Physiologic Sensors and Hardware Longevity

Beyond conductive communication, Rashtian et al. (2025) recently described the integration of a temperature-based rate response system within the LPM. Because the device sits directly within the intracardiac blood pool, it can detect minute fluctuations in central blood temperature during exertion, providing a highly physiologic modulation of heart rate without relying solely on standard accelerometers.

Simultaneously, the field faces a critical paradigm shift regarding hardware longevity when theoretical manufacturer modeling is compared against true clinical battery depletion. While initial bench testing predicted multi-decade lifespans, real-world data from the AVEIR DR i2i cohort (Reddy et al., 2025) exposed a severe energy trade-off inherent in continuous intrabody conductive communication. At 12 months post-implantation, the median remaining battery longevities for the Atrial Leadless Pacemaker (ALP) and Ventricular Leadless Pacemaker (VLP) were 4.3 years and 9.1 years, respectively. This results in a median total longevity of just 5.3 years for the ALP and 9.9 years for the VLP.

Because dual-chamber (DDD) pacing demands active, synchronized communication between both components, the true operational lifespan of the entire system is strictly limited by the rapid battery depletion of the atrial component (median 5.3 years). This stands in stark contrast to Medtronic's single-capsule Micra AV2, which leverages a passive, non-communicative accelerometer algorithm for mechanical atrial tracking to achieve a substantially higher projected longevity of approximately 15.6 years.

5. Current Device Specifications Comparison

Device Model	Fixation Mechanism	Pacing Mode	Communication Method	Projected Longevity
Medtronic Micra VR	Passive (4 nitinol tines)	VVI(R)	None (Single-component)	10.0–12.1 years
Medtronic Micra AV2	Passive (4 nitinol tines)	VDD(R)	Accelerometer (Mechanical)	15.6 years
Abbott AVEIR VR	Active (screw-in helix)	VVI(R)	None (Single-component)	10.3 years
Abbott AVEIR DR	Active (screw-in helix)	DDD(R)	i2i conductive pulses	5.3 years (True dual-chamber lifespan; limited by ALP: 5.3y vs. VLP: 9.9y)

6. Device Retrieval and End-of-Life Management

As leadless pacemakers inevitably reach their battery end-of-life (EOL), electrophysiologists face a critical clinical dilemma. Grubman et al. (2017) explored the "retrieve or not to retrieve" paradigm.

Acute extractions (within 12 months) are technically straightforward. However, over several years, advanced myocardial encapsulation (endothelialization) covers the device in a thick layer of fibrotic tissue. Forceful extraction of an encapsulated device risks catastrophic right ventricular perforation or tricuspid valve avulsion. In many cases, especially with the highly miniaturized Micra platform, the safest strategy is to abandon the depleted device and implant a new capsule in an adjacent location, as the right ventricle can safely accommodate up to three miniaturized capsules without hemodynamic compromise.

To facilitate future retrieval, modern extraction protocols utilize highly specialized tools. For AVEIR devices, a dedicated retrieval catheter locks onto a docking button on the capsule's proximal end. The catheter features a protective sleeve that provides direct *counter-traction* against the myocardium while the helix is unscrewed, safely freeing the device from the fibrotic capsule without tearing the heart wall.

7. The Future: Modular Networks, CRT, and Physiologic Pacing

7.1. A Modular Communicative Pacing-Defibrillator System

Subcutaneous Implantable Cardioverter-Defibrillators (S-ICDs) prevent sudden cardiac death without transvenous leads but lack the ability to deliver Anti-Tachycardia Pacing (ATP) - a painless sequence of rapid pacing pulses that can terminate ventricular tachycardia.

The landmark MODULAR ATP trial (Knops et al., 2024; Lloyd et al., 2026) successfully established a wireless network between an S-ICD and a specialized leadless right ventricular pacemaker. When the S-ICD detects a dangerous arrhythmia, it wirelessly commands the LPM to deliver ATP. This unidirectional communication bridges the gap between purely extrathoracic shock therapy and intracardiac pacing.

7.2. Leadless Cardiac Resynchronization Therapy (WiSE-CRT)

Heart failure patients often require biventricular pacing to resynchronize the heart's contraction. Traditionally, this requires a highly challenging transvenous lead placed through the coronary sinus to pace the left ventricle (LV) epicardially.

The **WiSE-CRT System** achieves *endocardial* LV pacing completely wirelessly. The system consists of a subcutaneous battery/transmitter, a traditional RV pacemaker (or LPM), and a tiny receiver electrode anchored inside the left ventricle. When the RV pacemaker fires, the subcutaneous transmitter detects the pulse and instantly emits a targeted beam of **ultrasound waves**. The LV receiver absorbs this acoustic energy, converts it into an electrical pulse via a piezoelectric core, and paces the LV in perfect synchrony.

- **Evidence:** Following the initial proof-of-concept SELECT-LV study (Reddy et al., 2017) and early phase I SOLVE-CRT results (Okabe et al., 2022), a comprehensive meta-analysis by Wijesuriya et al. (2022) confirmed the high procedural success and clinical efficacy of ultrasound-based endocardial pacing. The technology has now been robustly corroborated by the full SOLVE-CRT trial (Singh et al., 2024), providing a crucial therapeutic option for patients who have failed conventional lead placement.

7.3. Conduction System Pacing (CSP) and Energy Harvesting

The electrophysiology field is rapidly moving toward Conduction System Pacing - targeting the His-bundle or the Left Bundle Branch Area (LBBAP). Experimental designs for next-generation LPMs are modifying the shape and fixation mechanisms of capsules to allow them to be driven deep into the interventricular septum to capture the conduction system directly.

Furthermore, the ultimate frontier in leadless pacing is eliminating the battery limitation entirely. Experimental prototypes are exploring piezoelectric energy harvesting materials that convert the continuous kinetic energy (mechanical deformation) of the beating heart directly into electrical power, theoretically creating a "lifetime" pacemaker.

8. Discussion

The clinical evidence and technical milestones analyzed up to May 2026 demonstrate that leadless pacemakers (LPMs) have successfully moved beyond an experimental niche to become a frontline therapeutic option in modern cardiac electrophysiology. By re-engineering permanent pacing into a miniaturized, self-contained intracardiac capsule, LPMs effectively resolve the structural and infectious vulnerabilities inherent to conventional transvenous pacemakers. National registry data and large-scale meta-analyses, such as those by Sarsenbayeva et al. (2025) and Ngo et al. (2021), confirm that eliminating the subcutaneous pectoral pocket prevents many serious complications. Furthermore, traditional pacing leads crossing the tricuspid valve frequently cause mechanical interference and exacerbate tricuspid regurgitation, as shown by Yuyun et al. (2024). In contrast, the data compiled by Haeberlin et al. (2022) validate that because leadless capsules reside entirely within the right ventricle without traversing the valve apparatus, they significantly reduce the progression of tricuspid valve regurgitation. This structural improvement provides substantial long-term hemodynamic benefits for the right ventricle.

8.1. The Engineering Divergence: AV Synchrony vs. Longevity

A central focus of contemporary LPM development is achieving physiological atrioventricular (AV) synchrony, which has introduced a clear clinical trade-off between tracking efficacy and battery longevity. The two primary systems available today offer fundamentally different solutions to the same physiological problem:

- **The Single-Component Mechanical Approach (Micra AV/AV2)**: Medtronic's strategy avoids the complexity of a second intracardiac device by utilizing a 3-axis accelerometer to sense the physical vibrations of atrial contraction, specifically isolating the A4 acoustic signal. While the MARVEL 2 trial proved its resting efficacy, real-world data from Garweg et al. (2020) indicate that mechanical tracking can be suboptimal during strenuous activity or in patients with weak atrial mechanical signatures due to kinetic motion artifacts. However, because this passive software-based algorithm demands minimal power, the Micra AV2 achieves an outstanding projected battery longevity of approximately 15.6 years.
- **The Multi-Component Conductive Approach (AVEIR DR):** Abbott's dual-chamber system places physical capsules in both the right atrium and right ventricle, achieving robust, continuous AV synchrony exceeding 90% under ambulatory conditions, as demonstrated by Ip et al. (2024) and Defaye et al. (2026). Yet, the physics of their communication channel introduces a severe clinical bottleneck. The use of intrabody conductive pulses transmitted through the blood pool requires continuous electrical energy. Real-world data from the AVEIR DR i2i Study (Reddy et al., 2025) exposed the cost of this active communication: the median longevity of the atrial component drops to just 5.3 years, effectively capping the functional lifespan of the entire system.

This divergence forces clinicians to make a tailored choice: selecting the superior physiological tracking of a true dual-chamber system (at the cost of earlier replacement) versus the passive, single-capsule longevity of mechanical tracking.

8.2. Clinical Management at End-of-Life

As the clinical experience with leadless pacing matures, the management of device end-of-life (EOL) represents an ongoing area of expert consensus development. The early historical experience with the Nanostim system - marked by premature battery depletion and mechanical detachments in the LEADLESS II trial - underscored the absolute necessity of predictable long-term hardware performance.

For modern devices, the choice between device retrieval and abandonment remains a delicate clinical balance. While acute extractions are safe, chronic encapsulation under a thick fibrotic layer makes forceful extraction highly hazardous, risking ventricular perforation. The landmark study by Grubman et al. (2017) provided immense reassurance by showing that abandoning a depleted Micra capsule and placing a new one adjacently is hemodynamically benign, with the right ventricle capable of safely housing up to three miniaturized capsules. For active-fixation devices like the AVEIR, specialized extraction sleeves can provide direct counter-traction to unscrew the helix, but the long-term data on chronic extractions over multiple decades remain an active area of real-world surveillance.

8.3. Future Horizons: The Wireless Ecosystem

The future of leadless technology lies in its integration into a fully wireless, multi-component cardiac ecosystem. The success of the MODULAR ATP trial (Knops et al., 2024; Lloyd et al., 2026) in pairing an S-ICD with a leadless pacemaker via wireless communication proves that anti-tachycardia pacing can be achieved without transvenous components.

Furthermore, the expansion into entirely wireless left ventricular endocardial pacing via ultrasound acoustic energy (the WiSE-CRT System), validated by the SOLVE-CRT trial (Singh et al., 2024), offers a revolutionary alternative for heart failure patients who have failed conventional coronary sinus lead placement. As the field explores deep septal implantation for conduction system pacing (CSP) and experimental kinetic energy-harvesting technologies to eliminate battery depletion entirely, the virtualization of cardiac rhythm management is poised to eliminate traditional leads from clinical practice permanently.

9. Conclusions

Leadless pacemakers have successfully transitioned from a specialized alternative into a primary therapeutic standard in modern electrophysiology. By completely eliminating transvenous leads and subcutaneous pockets, they resolve significant long-term pacing morbidities, particularly pocket infections and tricuspid valve degradation. Contemporary mechanical tracking and dual-chamber conductive communication solutions have successfully overcome atrioventricular dyssynchrony, though they introduce a distinct clinical trade-off between physiological tracking performance and battery longevity. Supported by emerging modular communicative networks and wireless ultrasound-based resynchronization therapies, the transition toward an entirely wireless, multi-component cardiac device ecosystem represents the definitive future of cardiac pacing.

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