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Editorial

Leadless Pacemakers: Clinical Advances, Outcomes, and Comparison With Conventional Systems

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1. Introduction

Leadless cardiac pacemakers (L-PMs) represent a significant innovation in bradycardia management, offering an alternative to conventional transvenous pacemaker systems within a rapidly evolving, increasingly digital pacing landscape [1]. Unlike traditional pacemakers, which require a subcutaneous pulse generator and transvenous leads, L-PMs are self-contained, single-unit devices that are implanted entirely within the heart [2]. This editorial examines the clinical utility of L-PMs, recent advances in their design and delivery, their safety profile and complication rates, and their comparison with conventional pacemakers. A global perspective on their clinical adoption and regulatory approvals is also discussed.

2. Clinical Utility and Indications for L-PMs

L-PMs offer an attractive option for patients requiring long-term pacing, particularly when eliminating leads and surgical pockets is beneficial. In conventional transvenous pacemakers, the generator pocket and leads are often the "Achilles heel" of the system, associated with complications such as infections, hematomas, lead fractures, and venous occlusions. By design, L-PMs eliminate pocket-related issues and lead complications. Clinical studies have shown that about 8–12% of patients with transvenous pacemakers experience complications over time, the vast majority related to the leads or the pocket [3]. L-PMs address this by embedding a miniaturised pacemaker directly in the right ventricle and/or right atrium, eliminating the need for a chest incision or transvenous lead. Leadless pacing was initially limited to single-chamber ventricular support. Modern systems now enable atrial sensing and true atrial pacing. Medtronic's Micra atrioventricular (AV) offers AV synchrony using an accelerometer for patients with AV block and intact sinus rhythm. Abbott's Aveir dual chamber system, Food and Drug Administration-approved in 2023, combines atrial and ventricular leadless devices for wireless dual-chamber pacing. While AV-synchronised pacing is now possible, Cardiac Resynchronization Therapy (CRT) and defibrillation remain beyond the current capabilities of leadless devices. For example, those with occluded upper veins or on hemodialysis with ipsilateral access issues. Because no leads are placed in the venous system, the risk of causing or exacerbating venous obstruction or tricuspid regurgitation is minimised. In elderly or frail patients, the less invasive percutaneous implantation offers a gentler alternative to surgical pocket creation.

3. Complication Rates and Safety Profile

L-PMs have a superior safety profile because they eliminate leads and pockets, thereby reducing the risk of infection. Large Micra trials reported no device infections requiring removal, unlike conventional pacemakers, which carry a small risk of pocket infection and endocarditis [4]. Similarly, lead dislodgement and lead fracture do not apply to leadless devices, thereby eliminating those failure modes. A rare risk is device dislodgement (0.1–0.3%), which has declined with better operator training [2,5]. L-PMs avoid lead-related issues but carry unique risks. Implantation via a large femoral sheath can cause access-site complications (approximately 1%), and cardiac perforation occurs in approximately 1–1.5% of cases [6]. Another safety consideration is that the extraction of leadless devices is challenging, even if required. Unlike a pacemaker lead, which can sometimes be removed years later via laser sheath extraction, a tiny L-PM becomes endothelialized in the heart wall. Retrieval is feasible (and is built into devices such as Aveir) in the acute phase or early months, particularly if the device malfunctions or the patient develops an infection. However, it can become difficult later, once tissue growth occurs around the device [7].

4. Comparison With Conventional Transvenous Pacemaker Systems

Leadless devices were initially limited to single-chamber pacing but now offer AV synchrony (Micra AV) and dual-chamber options (Aveir), although CRT and defibrillation remain unavailable. Leadless devices are implanted percutaneously via the femoral or jugular vein, thereby avoiding chest wounds and enabling faster recovery; however, femoral access necessitates brief bed rest. From a cosmetic perspective, L-PMs are completely in-

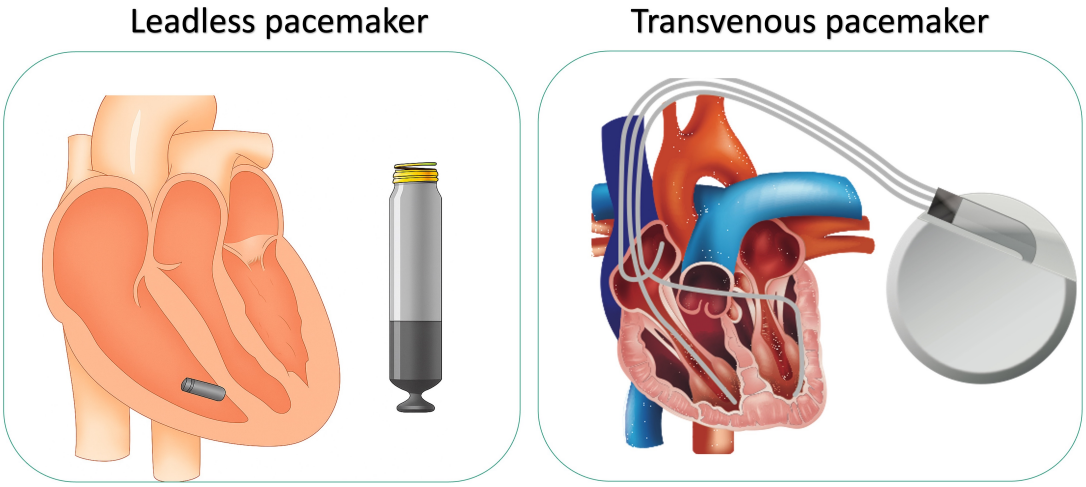

Fig. 1. A comparison of a leadless pacemaker and a transvenous pacemaker. Fig. 1 was drawn by the author using Adobe Illustrator (Adobe Inc. 2024. Adobe Illustrator version 28.0. San Jose, CA, USA).

visible externally, eliminating scars and pocket discomfort, unlike conventional systems that often leave a visible bulge and scar. Functionally, conventional pacemakers support single-, dual-, and biventricular (CRT) pacing. Leadless devices were initially limited to single-chamber pacing but now offer AV synchrony (Micra AV) and dual-chamber options (Aveir), although CRT and defibrillation remain unavailable. Cost is another consideration: leadless devices have higher upfront costs but may offset these through reduced complications and shorter hospital stay. We acknowledge that long-term management remains a limitation of leadless pacing, particularly in younger patients, in whom multiple device implantations over a lifetime may be required as batteries deplete, raising concerns about the cumulative intracardiac hardware burden and the future retrieval of devices once endothelialisation occurs. In the UK, L-PMs have a higher upfront device cost than conventional transvenous systems, but this may be partially offset by lower rates of device-related complications, reinterventions, and hospital readmissions; a formal cost-effectiveness evaluation will be critical to determining their broader adoption within the National Health Service (NHS). A comparison between transvenous and L-PMs is shown in Fig. 1.

5. Conclusion

L-PMs provide a safe and effective alternative to transvenous systems in selected patients. By eliminating leads and device pockets, they reduce infection and lead-related complications while maintaining comparable pacing efficacy and survival. Recent advances, including atrioventricular synchrony and dual chamber L-PMs, have expanded their clinical applicability. Careful patient selection remains essential, particularly for those who may require defibrillation or resynchronisation therapy or long-term pacing over several decades. Current evidence largely extends to one or two device lifecycles, and long-term outcomes with multiple retained leadless devices remain uncertain. As technology and longer-term data continue to evolve, leadless pacing is likely to play an increasing role in routine clinical practice.

Key Points

• Leadless pacemakers improve patient comfort and cosmesis while maintaining pacing efficacy and survival comparable to transvenous systems.

• Recent technological advances have expanded leadless pacing beyond single-chamber support to include atrioventricular synchrony and dual-chamber pacing.

•Procedural safety is high when implantation is performed by experienced operators, with low rates of vascular complications and cardiac perforation.

Availability of Data and Materials

Not applicable.

Author Contributions

IA, AA and RS designed the work. IA and AA wrote the first draft. RS revised the manuscript critically for important intellectual content. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

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Conflict of Interest

The authors declare no conflict of interest.

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