INFORMATION BRIEF (RAPID REVIEW)

LEADLESS PACEMAKERS

Malaysian Health Technology Assessment Section (MaHTAS)
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TITLE: LEADLESS PACEMAKERS

PURPOSE

To provide brief information on the effectiveness, safety and economic implications of leadless pacemakers following request from the Director of Medical Practice Division, Malaysia as this procedure is currently not listed in the Fee Schedule.

BACKGROUND

Globally, cardiovascular diseases, including arrhythmias remain the leading cause of mortality, responsible for approximately 17.9 million fatalities annually.[1] Among these, arrhythmias, such as bradycardia, affect millions worldwide. In Malaysia, cardiovascular diseases were the leading cause of death, accounting for 15.7% of all deaths in 2020 attributed to heart-related conditions.[2] Cardiac pacemakers have long been central to managing arrhythmias, significantly improving both survival rate and patients' quality of life.[3] With advancements in diagnostic methods and an aging population, conditions requiring pacemaker implantations such as bradycardia and other conduction system abnormalities are becoming more prevalent and this has led to significant rise in pacemaker implantations.[4] According to European Society of Cardiology (ESC), the median number of pacemaker implantations is 607.3 per million inhabitants (IQR 251.7–874.0). Rates vary widely, ranging from less than 40 implants per million people in Uzbekistan to more than 1000 per million people in Italy, Sweden, France, Portugal, and Lithuania.[5]

Conventional pacemakers have limitations due to potential short- and long-term complications related to either the transvenous lead or the subcutaneous pulse generator. The introduction of leadless pacemakers (LP) in 2012 marked a significant advancement in the treatment of cardiac arrhythmias, offering a viable alternative to conventional transvenous pacemakers.[6] In 2020, Malaysia's National Heart Institute (IJN) made history as the first hospital outside of the United States to implant the [redacted] AV pacemaker, showcasing global milestone in the healthcare industry.[7] According to a Malaysian cardiologist, Malaysia has implanted more than 800 [redacted] leadless pacemaker since 2013, leading the leadless pacemaker implantation in Southeast Asia. These cutting-edge devices, which are self-contained and implanted directly into the heart through a minimally invasive transcatheter method, eliminates the need for leads. This minimizes complications related to conventional systems, including lead fractures, lead dislodgements, pneumothorax, infections, and venous thrombosis.[8,9] Despite these advantages, the adoption of this technology remains slower due to high costs of these devices, lack of reimbursements and limited availability.[10]

TECHNICAL FEATURES

Three primary leadless pacing systems have been introduced to date: the [redacted] launched in 2012; [redacted] introduced in 2013, and the [redacted] which debuted in 2022. Each of these systems has received the CE mark but only [redacted] have received approval from the United States by the Food and Drug

Administration (FDA).[11-14] The [redacted] system, however, was withdrawn from the market in 2016 due to reported incidents of battery malfunctions.[15]

A leadless pacemaker is composed of four components: pulse generator, pacing or sensing electrode, a long-lasting battery and a fixation mechanism. These components are fully contained within a single unit in the leadless pacemaker and is implanted directly into the right ventricular wall. The pacemaker is powered by a high-density lithium carbon monofluoride battery, which offers a projected lifespan of 14.7 years, a significant improvement over the 9.6 years expected from traditional transcatheter pacing systems (TCP). The fixation mechanism is comprised of an active screw-in helix and a secondary fixation to secure the placement within the myocardium. Both [redacted] and [redacted] leadless pacemakers are entirely intracardiac, with both the generator and the pacing and sensing electrodes integrated within a single capsule-shaped compartment[16] as shown in Figure 1 below.

Figure 1: The Micra pacemakers (left) and Aveir leadless pacemakers (right)

Figure 2 below illustrates the leadless pacemaker alongside conventional pacemakers for comparison while Table 1 below outlines the key differences between leadless cardiac pacemakers (LCP) and transcatheter pacing systems (TCP).

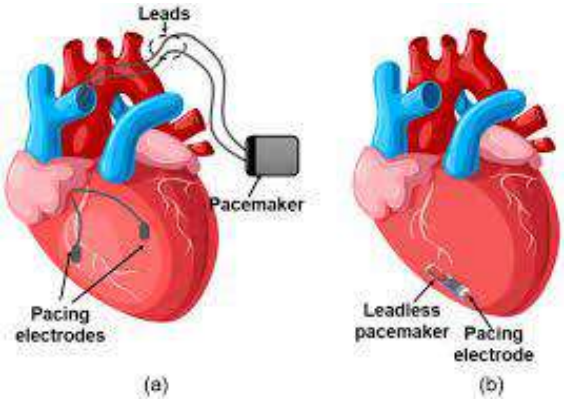

Figure 2: Illustration of conventional pacemaker (a) and leadless pacemaker (b) (Source: Sharma D et al. 2022)[17]

Table 1: Differences between leadless cardiac pacemakers (LCP) and transcatheter pacing system (TCP)

TABLE 1 Characteristics of the LCP and TCP

Parameter	LCP	TCP
Polarity	Bipolar	Bipolar
Pacing modes	VVI (R)	VVI (R)
Rate modulation mechanism	Blood temperature	3-axis accelerometer
Battery technology	Lithium carbon monofluoride	Lithium silver vanadium oxide / carbon monofluoride
Programmer	St. Jude Medical, model 3650	Medtronic, model 2090
Energy capacity (mAh)	248	120
Estimated longevity		
ISO standard, yrs*	9.8 yrs	4.7 yrs
Alternative setting, yrs†	14.7 yrs	9.6 yrs
Size (h × w), maximum thickness, mm	42 mm × 5.99 mm	25.9 mm × 6.7 mm
Volume (cc)	1.0	0.8
Fixation mechanism	Helix (screw-in)	Tines

LCP = leadless cardiac pacemaker; TCP = transcatheter pacing system.

Source: Miller MA et al (2015)[18]

The implantation of this device requires a catheter delivery system. The pacemaker is placed within a steerable catheter delivery system and inserted via the femoral vein using a 23-French introducer. The catheter is then guided into the right ventricle, where the device is secured to the myocardium with four electrically inactive nitinol tines at its distal end. Once the device fixation and electrical measurements are confirmed, the tether is severed, and the delivery system is withdrawn.[19]

Recently, a dual-chamber leadless pacemaker, featuring a self-contained design with a fixed helix, has been introduced for bradycardia pacing as illustrated in Figure 3 below. Unlike conventional pacing systems, the dual-chamber leadless pacemaker sends a series of short pulses through both the blood and myocardial tissue after each paced or sensed event which helps to maintain atrioventricular synchrony, ensuring that the heart's atria and ventricles work together effectively. A specialised retrieval catheter enables the removal and replacement of each leadless pacemaker when required. As with other leadless pacemaker procedures, fluoroscopy and contrast injection are required to visualise the pacemaker's placement and confirm proper positioning.[20]

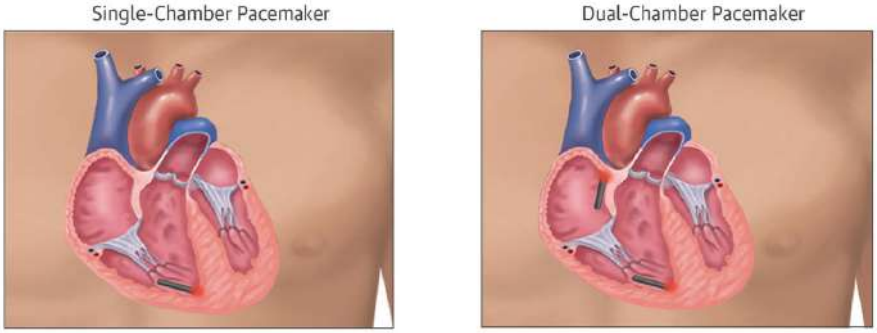

Figure 3: Illustration of single-chamber (left) and dual-chamber pacemakers (right)
Source: Miller MA et al (2015)[18]

EVIDENCE SUMMARY

A systematic review was conducted and search strategy was developed by the main author. The following electronic databases were searched through the Ovid interface: MEDLINE® All <1946 to 29th November 2024>. A systematic search was conducted through PubMed, Cochrane Library, EMBASE, US FDA, and INAHTA databases, along with cross-referencing. The search was limited to articles in human, with no language limitation. The last search was carried out on 2nd December 2024. There were five studies included in this review comprising of one systematic review with meta-analysis, two systematic reviews, one cohort study and one economic evaluation.

EFFECTIVENESS

Oliveira et al (2024) performed a systematic review with meta-analysis on the effectiveness and safety of leadless pacemakers through systematic search using PubMed, Scopus, Embase, Cochrane Library, and ClinicalTrials.gov databases from inception to September 2023. This systematic review with meta-analysis encompasses 21 studies with 47,229 patients with a mean age of 80 years old, of whom 12,199 (25.8%) received leadless pacemaker implantation. Of the 21 studies, 15 studies utilised [redacted], two [redacted], three included both devices and one study did not specify the device used. Leadless pacemakers demonstrated a notably lower pacing capture threshold when compared to transvenous pacemakers (MD -0.19 V; 95% CI -0.22 to -0.16 V; p<0.01). Nevertheless, no significant variations were found in impedance ((MD 32.63 ohms; 95% CI -22.50 to 87.76 ohms; p = 0.25). However, the studies included in the analysis only had a follow-up period of maximum up to two years.[21]

A systematic review conducted by Noor TA et al (2023) evaluated the outcomes of leadless pacemaker implantation including procedure duration, major complications, mortality and hospital stay. Systematic search across five databases: EMBASE, PubMed, CINAHL, Web of Science, and Cochrane until January 2023 identified four relevant studies, all of which were prospective cohort studies, encompassing a total of 1276 patients. Of these four studies, two studies compared with temporary permanent pacemakers and single chamber pacemakers while another study compared leadless pacemaker implantation between emergency and elective cases. The studies showed that the duration of the procedure shortens by almost half the duration needed for temporary-permanent pacemaker implantation. The hospital stay was also shorter between 2 to 4 days in leadless pacemaker as compared to 8 to 13 days with a temp-perm pacemaker. In Schiavone et al., emergency LP implantation resulted in longer hospital stay compared to elective procedures (7 days (3–16) vs. 3 days (2–5)). Meanwhile, pacing parameters were not significantly different across all the four studies. Overall, LP implantation showed minimal procedural duration, shorter hospital stays, and reduced fluoroscopy time; however, one study indicated longer procedure time in an urgent setting.[22]

A systematic review with meta-analysis on the safety and efficacy of leadless pacemakers was conducted by Ngo L et al. (2021). A comprehensive systematic search through PubMed and Embase databases until June 2020 identified 36 observational studies involving 4788 patients with 66.7% of them having atrial fibrillation. The majority of patients (61.0%) were male, with most patients falling within the 80 to 85 age range. The median follow up time was 6 months (range 0-24months). Out of the 4748 patients, 66.7% patients had atrial fibrillation while only 24.3% had heart failure at implantation. The findings highlighted that 98.96% of patients with Micra implants demonstrated excellent electrical device performance with pacing capture thresholds less than 2V at 1 year. There were four other studies which reported effectiveness outcomes. Two of the studies showed that there is improved quality of life and good patient satisfaction following LPM implantation. In contrast, another two studies assessed right ventricular and tricuspid valve (TV) function, with one indicating that 43% of patients had worsening TV regurgitation and in the other study, 1 out of 23 patients (4.35%) exhibited significantly reduced TV function. While observational data supports the safety and efficacy of this study, long-term outcomes beyond 2 years and randomised control trials are still needed to solidify the clinical utility and adoption of this technology.[23]

A long-term cohort study was conducted by El-Chami MF et al (2024) on [redacted] leadless pacemakers. The aim of this study was to evaluate major complications related to the system or procedure, system revisions for any reason, and all-cause mortality over a period of five years. A total of 1,809 patients were enrolled across 179 centers in 23 countries between July 2015 and March 2018 with a median follow-up duration of 51.1 months (IQR 21.6 to 64.2). The median age of the patients was 79 years (IQR: 71–84), 38.8% were female, and the majority had multiple co-morbidities. During the follow-up period, 676 deaths were reported from all causes, resulting in a 5-year mortality rate of 39.5%. Among these deaths, five (0.7%) were related to the procedure (including two due to cardiac perforation), 35 were classified as sudden cardiac death, 113 as non-sudden cardiac, 345 as non-cardiac (with 15 attributed to COVID-19), and 178 had an unknown classification.[24]

An Information Brief (Rapid Review) on leadless cardiac pacemakers was published in 2021 by Ministry of Health, Malaysia. This review included three health technology assessments (HTA), one rapid review and two systematic reviews up to year 2021. The review showed that there was inadequate comparative evidence to demonstrate whether leadless cardiac pacemakers were as effective or more effective than conventional cardiac pacemakers but maybe beneficial for patient whom are contraindicated to conventional pacemakers. According to the Norwegian Institute of Public Health (NIPH), it was concluded that [redacted] leadless pacemakers has a longer battery lifespan and is effective in providing consistent pacing as required.[25]

SAFETY

There have been three primary leadless pacemakers introduced to date: the [redacted] launched in 2012; [redacted] introduced in 2013, and the [redacted]. Each of these systems has received the CE mark but only [redacted] have received approval from the United States by the Food and Drug Administration (FDA).[11-14] [redacted], however, was withdrawn from the market in 2016 due to reported battery malfunctions incident.[15]

A systematic review with meta-analysis conducted by Ngo L et al. (2021) regarding the safety and efficacy of leadless pacemakers included 12 studies (n=2376 patients) assessing the safety of pacemakers up to 90 days post-implant. Of these, three studies reported a high 90-day complication rate up to 23.5% with the use of [redacted] pacemaker which subsequently showed lower complication rate of 6.67% beyond 90 days post-implantation and 1.8% at 24 months post-implantation. Meanwhile, the [redacted] (n=1608 patients) showed a pooled incidence of complications of 0.46% at 90 days (95% CI, 0.08% to 1.05%; I^2=0.00%) and 1.7% at one year. The rate of device-related complications including dislodgement, tamponade/cardiac perforation, infection and vascular injury at 90 days were exceedingly rare with reported incidences close to 0% at 90 days. In studies comparing [redacted] to TVPs, the odds of complications were reduced by 51% for [redacted] (3.30% for [redacted] vs 7.43% for Transvenous pacemakers (TVP) at one year). However, there is insufficient safety data on leadless pacemakers beyond 2 years, underscoring the need for further studies on long-term outcomes.[23]

Oliveira et al (2024) conducted a meta-analysis on the efficacy and safety of leadless pacemakers, which indicated that there was no statistically significant difference in the risk of all-cause mortality between groups (OR 1.43; 95% CI 0.65 to 3.14; p=0.37). Leadless pacemakers were notably associated with lower risk of overall complications including dislodgement and post-procedure pneumothorax in comparison to transvenous pacemakers (OR 0.59; 95% CI 0.42 to 0.82; p<0.01). Nevertheless, leadless pacemaker was associated with an increased risk of pericardial effusion (OR 2.47; 95% CI 1.39 to 4.38; p<0.01) and cardiac tamponade (OR 3.75; 95% CI 2.41 to 5.83; p< 0.01). The other safety outcomes such as haematoma, myocardial perforation, or tricuspid regurgitation demonstrated no significant differences between the two groups.[21]

In the systematic review by Noor TA et al (2023), their findings stated that the mortality and major complications rates are lower despite the effect of the learning curve of operators involved. However, the overall complication rate was higher with emergency leadless pacemaker implantation in comparison to elective implantation (6.9% vs 4.2%). Furthermore, leadless pacemaker presents a reduced risk of device infection while preventing pocket formation and venous access. This study also indicated that leadless pacemakers are well-tolerated by all age groups including the elderly and the very elderly. The authors of this study concluded that leadless pacemakers may be a better option than temporary pacemakers even as an urgent treatment.[22]

In a cohort study by El-Chami et al. (2024), the five year complication rate was reported to be 4.5% (95% CI: 3.6% to 5.5%) and at 36 months, it was 4.1%, which was significantly lower than the 8.5% rate observed for transvenous systems (95% CI: 0.36 to 0.61; P < 0.001). There were 85 major complications reported among 79 patients during the follow-up period, with most (58.8%) occurring within 30 days post-implant, mainly related to procedure issues such as thrombosis, groin puncture complications, pericardial effusions/perforations, and pacing capture or elevated threshold events. Longer-term complications included pacing capture and elevated threshold issues, pacemaker syndrome, and pacing-induced cardiomyopathy. Nine all-cause infection events were reported, five of which were classified as major complications, including sepsis, abdominal wall infection, haematoma infection, catheter site groin infection, and a potential device-related infection. Importantly, none of these infections led to device removal. All in all, long-term results with the Micra leadless pacemaker show low rates of complications such as thrombosis, groin puncture events, and pericardial effusions/perforations with 0.7% procedure-related mortality rate and an exceptionally low incidence of infections.[24]

The previous information brief on leadless cardiac pacemakers issued by the Ministry of Health, Malaysia concluded that while leadless pacemakers present a lower risk of major complications, however there is a higher risk of cardiac perforation or pericardial effusion in comparison to conventional cardiac pacemakers. Therefore, the implantation of leadless cardiac pacemakers should be recommended solely for patients for whom conventional cardiac pacemaker implantation is not viable, following a comprehensive risk assessment, and should be performed by skilled clinicians with specialised training in adequately equipped centres that provide cardiac and vascular support for the emergency management of complications.[25]

ECONOMIC IMPLICATION

Makino K et al (2024) conducted an economic evaluation to evaluate the cost-effectiveness of the [redacted] VR leadless cardiac pacemaker compared to conventional transvenous pacemaker (TVP) for managing bradycardia among Australian patients. This study involved a large sample size comprising 16 431 patients ([redacted] n= 6219; TVP: n= 10 212). The study found that the [redacted] reduce risks of complications like infection and improve recovery and quality of life (QoL). The cost of implantation of [redacted] is AUD$ 12 158 (RM 33 952.43) while the cost of the conventional transvenous pacemaker is AUD$ 6503 (RM18 160.28). Utilizing a 17-year Markov model, the study found that while [redacted] incurs higher upfront costs, it offsets some cost through reduced complications. It provides an estimated incremental cost of AUD$ 4277 (RM 11 943.95) and an incremental quality-adjusted life years (QALYs) of 0.09 in comparison to TVP, resulting in an incremental cost-effectiveness ratio of AUD$ 47 379 (RM 132 310.60) per QALY gained. The study found this technology a cost-effective alternative to the conventional TVP in managing patients with bradycardia and atrial fibrillation, particularly benefiting patients at high infection risk or requiring improved QoL.[26] In the United States, it is estimated that the [redacted] costs about $10,000 (RM44,995.00) per unit.[27] According to a consultant cardiologist in Malaysia, the treatment with [redacted] AV leadless cardiac pacemaker is estimated to cost about RM50,000 per patient.[28]

ORGANISATIONAL/ SOCIAL/ ETHICAL ISSUES

A study by El-Chami et al (2017) concluded that the success rate of implantation was high, irrespective of the level of experience among a large group of operators. However, the duration of the procedure and fluoroscopy time decreased as the number of implants increased, nearing the typical times seen with traditional pacemakers after just 10 procedures. The study additionally indicated that the complications remained low and were not linked to the number of cases performed. Outcomes related to the procedure and safety were comparable across different training methods.[29]

Expert who are local cardiologists told that leadless pacemaker implanters must learn how to handle device redeployment, acute or chronic device dislodgement, pericardial effusion/tamponade, pulmonary/air embolism and vascular access related complications. Such risks may be mitigated as learning curve improves with certified cardiologists gaining experience through training and supervision.

A study by Nava S et al. (2013) demonstrated that pacemakers obtained through cadaveric donation were successfully reused, providing a feasible and safe option for patients with bradyarrhythmias. These reused pacemakers were found to be comparable to new devices, except for the expected shorter battery life.[30] However, leadless pacemakers are currently approved for single-use only by the U.S. Food and Drug Administration (FDA).[31] Reusing pacemakers presents several social and ethical challenges. One major concern is the potential risk of complications, such as device malfunction or infection, for patients receiving a reused pacemaker.[32] Additionally, cultural and religious factors may affect the acceptance of reused medical devices. In Malaysia, some individuals, particularly within Muslim communities where bodily integrity is highly valued, the reuse of pacemakers may be viewed as unethical or disrespectful, potentially leading to resistance. In certain religious beliefs, taking a device from a deceased individual is considered taboo.[33]

CONCLUSION

There is fair amount of evidences retrieved on effectiveness, safety and cost-effectiveness of leadless pacemakers. Evidences demonstrated that leadless pacemakers, particularly the [redacted] device offers advantages in terms of device performance, procedural outcomes (shorter procedural duration, shorter hospital stays) and lower complication rates (dislodgement, infection, vascular injury) compared to conventional transvenous pacemakers. However, despite these benefits, leadless pacemakers carry a heightened risk of cardiac tamponade and pericardial effusion, higher upfront costs and limited long-term data beyond five years. Leadless pacemaker implantation is an alternative to conventional transvenous pacemaker system especially for patients where transvenous system is prohibitive or problematic. These procedures should be performed by trained specialists in well-equipped centres. From an economic perspective, leadless pacemaker is a cost-effective alternative to the conventional transvenous pacemakers in Australia.

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