

Interventional procedure overview of leadless cardiac pacemaker implantation for bradyarrhythmias

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Table 1 Abbreviations

Abbreviation	Definition
6MWT	6-Minute Walk Test
AF	Atrial Fibrillation
AV	Atrioventricular
AVF	Arteriovenous Fistula
CAD	Coronary Artery Disease
CHD	Congenital Heart Disease
CHF	Congestive Heart Failure
CIEDs	Cardiac Implantable Electronic Devices
COPD	Chronic Obstructive Pulmonary Disease
DC-TV	Dual-chamber Transvenous (DC-TV)
ESRD	End Stage Renal Disease
GLS	Global Longitudinal Strain
HR	Hazard Ratio
HRQoL	Health-Related Quality of Life
HTN	Hypertension
LPs	Leadless Pacemakers
LV	Left Ventricular
LVEF	Left Ventricular Ejection Fraction
MAPSE	Mitral Annular Plane Systolic Excursion
M-mode	Motion-mode
MINORS	Methodological Index for Non-Randomised Studies
NIH	National Institutes of Health
NOS	Newcastle-Ottawa Scale
NICE	National Institute for Health and Care Excellence
NT-pro-BNP	N-terminal pro B-type Natriuretic Peptide
OR	Odds Ratio
PAR	Post-Approval Registry
PACES	Pediatric and Congenital Electrophysiology Society
ROBINS-I	Risk of Bias Tool for Non-Randomised Studies
RV	Right Ventricular
TAPSE	Tricuspid Annular Plane Systolic Excursion
TLR	Transvenous lead removal
TPS	Transcatheter Pacing System
TTE	Transthoracic Echocardiography
TVPs	Transvenous Pacemakers
VP	Ventricular Pacing

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SD	Standard Deviation
sdHR	Sub-distribution Hazard Ratio

The condition, current treatments, unmet need and procedure

[Information about the procedure, condition, current practice and unmet need is available in NICE's interventional procedures guidance on leadless cardiac pacemaker implantation for bradyarrhythmias.](#)

Outcome measures

The efficacy outcomes included successful implantation rate, adequate pacing performance, 6-minute walk test (6MWT), cardiac function, length of hospital stay, health-related quality of life and device durability. Safety outcomes included cardiac perforation, cardiac tamponade, pericardial effusion, pulmonary oedema, AF, device failure (dislodgement, migration, embolisation, malfunction, battery issues), repeat surgery (for device retrieval and revisions), venous thromboembolism, vascular complications, bleeding, infections, mortality, pacemaker syndrome, cardiomyopathy, pericarditis, activity restrictions, overall complication rates and other device- or procedure-related adverse events. Some of the measures used, which are not self-explanatory, are detailed in the following paragraphs.

Adequate pacing performance

Adequate pacing performance is evaluated based on several key parameters. The pacing threshold, or capture threshold, should ideally be less than or equal to 1.5 V at 0.4 ms pulse width for ventricular pacing (VP) and less than or equal to 1.0 V at 0.4 ms pulse width for atrial pacing, with lower values preferred to reduce battery consumption and ensure effective capture. Sensing amplitude, which reflects intrinsic signal detection, should be 5 mV or more for ventricular sensing (R-wave amplitude) and 1.5 mV or more for atrial sensing (P-wave

amplitude) to ensure proper sensing and minimise the risk of under-sensing events. Pacing impedance, which helps assess lead integrity and connection, should be between 300 to 1,500 ohms. Values outside this range may indicate lead failure, insulation damage, or poor connection. The percentage of VP should ideally be less than 40% in people who are non-dependent to minimise unnecessary pacing. But it should be 100% in people who are pacemaker-dependent. AV synchrony of more than or equal to 90% is considered optimal for dual-chamber pacemakers, ensuring physiological pacing and reducing the risk of AF.

Global Longitudinal Strain (GLS)

GLS is an advanced echocardiographic parameter that measures myocardial deformation, reflecting left ventricular (LV) systolic function more sensitively than ejection fraction (EF). It quantifies the percentage of myocardial shortening during contraction, with more negative values indicating better function. The normal range for GLS is typically between -18% to -22%, with values closer to zero suggesting impaired LV function. A GLS less negative than -16% is often considered abnormal and may indicate early myocardial dysfunction.

Right Ventricular Free Wall Strain (RVFWS)

Right Ventricular Free Wall Strain (RVFWS) is an echocardiographic measure of the deformation of the RV free wall during contraction. The normal range for RV free wall strain is typically more negative than -20%, with values less negative than -17% suggesting impaired RV function.

Tricuspid Annular Plane Systolic Excursion (TAPSE)

TAPSE is a measure of right ventricular (RV) function that evaluates RV longitudinal systolic performance. TAPSE is measured using TTE and the systolic displacement of the annulus is recorded in millimetres. A lower TAPSE

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value, typically less than 17 mm, suggests impaired RV function and is often seen in conditions such as pulmonary hypertension (HTN) and heart failure.

Mitral Annular Plane Systolic Excursion (MAPSE)

MAPSE assesses the longitudinal contraction of the LV myocardium, to evaluate LV function. Like TAPSE, MAPSE is measured using TTE, recording the displacement of the mitral annulus during systole. Normal values usually exceed 10 mm. A reduced MAPSE value indicates impaired LV function, which is commonly seen in people with heart failure or cardiomyopathy.

N-terminal pro B-type Natriuretic Peptide (NT-pro-BNP)

NT-pro-BNP is a biomarker that reflects cardiac stress and heart failure. It is released by the heart in response to increased ventricular wall tension because of volume overload or myocardial dysfunction. Elevated NT-pro-BNP levels are associated with worsening heart failure, with values above 125 pg/ml in non-acute settings or 300 pg/ml in acute settings indicating a significant risk of heart dysfunction.

Health-related Quality of Life

The SF-36 is a widely used questionnaire that measures health-related quality of life (HRQoL) across 8 domains, including physical and mental health. Each domain is scored from 0 to 100, with higher scores indicating better health. Scores are summarised into physical and mental component scores, standardised to a mean of 50 (SD 10). Normal values in the general population typically range from 70 to 95, and a change of 5 to 10 points is considered clinically meaningful. It is commonly used to assess the impact of illness or treatment on peoples' overall well-being.

The 6-Minute Walk Test (6MWT)

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6MWT is a functional exercise test used to evaluate a person's cardiovascular endurance and overall functional capacity. During the test, the person is instructed to walk as far as possible within 6 minutes on a flat, measured surface. The total distance covered in metres is recorded and compared over time to assess disease progression or response to treatment. A normal 6MWT distance varies by age, sex, and comorbidities, but in healthy adults, it typically ranges from 400 to 700 m. Distances below 300 m often indicate significant impairment in cardiovascular or pulmonary function.

Evidence summary

Population and studies description

This overview of interventional procedures is based on data from 1,099,488 people across multiple studies, including a randomised controlled trial (RCT) (Garweg 2023), 4 systematic reviews with meta-analyses (Inoue 2024, Wu 2023, Mhasseb 2025, Oliveira 2024), 5 registry studies (El-Chami 2024, El-Chami 2024, Shah 2023, Panico 2024 and Ueyama 2024), 8 prospective studies (Tjong 2018, Amrani 2020, Molitor 2024, Knops 2023 and 2025, Reddy 2025, Nair 2025, and von Felten 2025) and 2 retrospective studies (Cabanas-Grandio 2020 and Strik 2023). Among these, 71,116 people had LP implantation. There was considerable overlap in studies between the systematic reviews. Most studies were conducted in the US and Europe. This is a rapid review of the literature, and a flow chart of the complete selection process is shown in [figure 1](#). This overview presents 20 studies as the key evidence in [table 2](#) and [table 3](#), and lists other relevant 150 studies in [appendix B, table 5](#).

Sixteen studies focused on ventricular leadless pacing.

The RCT (Garweg 2023) compared the outcomes of LP with conventional TVP using single-chamber VP. The study cohort included 51 people with a mean age of 82.5 years, and 61% were male. The study employed standardised

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echocardiographic assessments conducted at baseline, 6 months, and 12 months, along with NT-proBNP measurements at baseline and 12 months.

The systematic review and meta-analysis by Inoue (2025) synthesised evidence on the safety and optimal timing of LP implantation following the removal of cardiac implantable electronic devices (CIEDs) because of infection. Data from 16 observational studies (n=653) published between 2015 and 2024 were included. The mean age was 77 years, 69% were male, with a mean left ventricular ejection fraction (LVEF) of 56%. The average follow up was 14 months, ranging from 6 to 47 months across studies. Results were grouped based on LP implantation timing, either during CIED removal, or after a set interval.

The meta-analysis by Mhasseb (2025) compared the safety profile of TVPs and LPs. The study included data from 19 observational studies, comprising 12 retrospective cohort studies and 7 prospective cohort studies, conducted across various regions, including the US, Italy, France, Spain, and Japan. The total sample size was 972,479 people, with 57,974 having LPs. The mean age ranged from 70 to 90 years, and the proportion of males ranged from 52% to 70%. The prevalence of comorbidities varied, with AF (89%), HTN (90%), diabetes mellitus (46%), and coronary artery disease (CAD) (56%). Follow-up durations ranged from 30 days to over 5 years.

The systematic review and meta-analysis by Oliveira (2025) included 21 observational studies, with 47,229 people, of whom 12,199 had LP implantation. The study population had a mean age of 80 years and 56% were male. Among the included studies, 8 were prospective and 13 were retrospective, with no RCTs identified. The mean follow-up periods ranged from 6 to 24 months.

The meta-analysis by Wu (2023) included data from 8 observational studies with a total of 464 people with complete or high-grade AV block and sinus node dysfunction with or without AF. There were 3 multicentre prospective studies, IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

3 single-centre prospective studies, and 2 single-centre retrospective studies. The study population had a mean age of 76.3 years and 44% were female. The follow-up duration across studies ranged from immediate post-procedure outcomes to a maximum of 12 months, with most studies reporting follow-up durations of less than 3 months.

El-Chami (2024) conducted a multinational, non-randomised, prospective registry study (the Micra VR Post-Approval Registry, PAR) to evaluate the long-term performance of the LP in real-world clinical settings. The study enrolled 1,809 people across 179 centres in 23 countries between July 2015 and March 2018, with a median follow-up duration of 51.1 months and a leading-edge follow up of 86.7 months. The mean age of the study population was 75.6 years, with a median age of 79 years (IQR 71.0 to 84.0), and 39% were female (701 out of 1,808). There was a high prevalence of comorbidities, including atrial tachyarrhythmias (76%), congestive heart failure (CHF) (15%), chronic obstructive pulmonary disease (COPD) (10%), CAD (22%), HTN (65%), diabetes (27%), renal dysfunction (22%), and dialysis dependency (8%).

A comparative effectiveness analysis conducted by El-Chami (2024) evaluated the long-term outcomes (over a follow-up period of 2 years) of a LP in comparison to a traditional dual-chamber TVP in a large cohort of US Medicare population. A total of 118,110 people were included, of whom 7,552 had a LP and 110,558 had a TVP. The mean age was 79.0 years (range 21 to 105) in the LP group and 78.7 years (range 23 to 106) in the TVP group. The proportion of females was 48% in the LP group and 47% in the TVP group. People in the LP group had a higher burden of comorbidities compared to those in the TVP group.

A multicentre retrospective registry study by Shah (2023) was conducted across 13 centres in the US, 1 in the UK, and 1 in Italy, using data from the Pediatric and Congenital Electrophysiology Society (PACES) registry. A total of 63 people were enrolled, with a mean age of 15 years; standard deviation (SD) 4.1 years and

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59% were male. Of the 63 children and young people, 32% had congenital heart disease (CHD), 29% had previous cardiac surgery and 22% had a prior pacemaker implantation. The mean follow-up was 9.5 months, ranging from 2 to 32 months.

The multicentre, retrospective, observational study by Strik (2023) was based in France and included 35 young adult people aged between 18 and 40 years, with 21 males (60%). The cohort had a mean LVEF of 57%. Indications for LP implantation included congenital AV block (n=3), postoperative AV block (n=7), post-heart transplantation (n=2), muscular dystrophy syndrome (n=5), symptomatic paroxysmal AV block (n=8) and symptomatic sinus node dysfunction (n=10). The mean follow-up period was 26 months; SD 15 months.

Amrani (2020) conducted a prospective observational study in Spain on 129 people over 70 years old who had LPs for single-chamber pacing. The outcomes were stratified into 2 groups based on age: 41 people aged 90 years or over and 88 people under 90 years. Sex distribution differed between the groups, with 18 males (44%) and 23 females (56%) in the 90 years and over cohort, compared to 32 males (36%) and 56 females (64%) in the younger cohort. Both groups had a high prevalence of comorbidities, and AV block was the main pacing indication. Follow ups were done at 7 days, and at 1, 3, 6, and 12 months post-implant, then annually.

A retrospective cohort study (Panico 2024) in France compared outcomes of LPs versus single-chamber TVPs implantation in 384 people on haemodialysis. After 1:1 propensity score matching, 178 people were included (89 in each group), with a mean age of 77.9 years and 30% female. Comorbidities were common: chronic heart failure (63%), AF or flutter (67%), ischaemic heart disease (55%), and diabetes (74%). Median follow-up was 24 months (range 7 to 37).

Molitor (2024) conducted a prospective study in Switzerland and the Netherlands comparing internal jugular versus femoral vein approaches for LP implantation in IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

200 people (mean age 81.2 years, 60% male). In the jugular group, primary indications included AV block (39 people), AF-related conditions (32), and sick sinus syndrome or pauses (29). AF was more common in the femoral group, though detailed indications were not provided. Comorbidities were prevalent, with 73% having AF, 36% CAD, 43% valvular disease, 37% chronic kidney disease, and others including COPD, diabetes, cancer, and prior stroke. Follow ups were on days 1 and 14 with clinical reviews and device checks.

The prospective multi-centre clinical trial study (Tjong 2018) involved 726 people undergoing Micra transcatheter pacing system (TPS) implantation across 56 centres in 19 countries between December 2013 and May 2015. The cohort had a mean age of 76 years, with 59% being male. The primary outcomes measured included health-related quality of life, patient satisfaction, and activity restrictions post-implantation.

The comparative retrospective study (Cabanas-Grandío 2020) examined 106 people (64 with TVPs and 42 with LPs) undergoing single-chamber pacemaker implantation from December 2016 to March 2018 across 4 tertiary hospitals in Spain. The participants had an average age of 79.8 years, with significant differences in age and diabetes prevalence between the groups. Quality of life was assessed using the SF-36 questionnaire at baseline and 6 months post-implantation.

The retrospective cohort study by Ueyama (2024) analysed data from 10,338 Medicare fee-for-service beneficiaries aged 65 or above who had transcatheter aortic valve replacement (TAVR) followed by permanent pacemaker implantation between January 2017 and December 2020 in the USA. Among them, 730 people (7%) had LPs and 9,608 (93%) had TVPs. People were identified using procedure codes from national Medicare claims databases. The study aimed to compare short- and midterm outcomes between the 2 pacemaker types using propensity score overlap weighting to adjust for confounding. The

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primary outcome measures included in-hospital complications, and midterm outcomes up to 2 years, including all-cause mortality, heart failure hospitalisation, infective endocarditis, and device-related complications.

Two studies focused on atrial pacing either as a standalone therapy or as part of a dual chamber leadless pacemaker system (Nair 2025, von Felten 2025) and 3 studies focused on a dual chamber leadless pacemaker system (Knops 2023, 2025, Reddy 2025).

The single-centre prospective study by von Felten (2025) evaluated the first European real-world experience with dual-chamber leadless pacemakers in patients requiring dual-chamber pacing. The study included 45 people with a mean age of 75.5 years, and 49% were male. The primary indications were atrioventricular block (58%) and sinus node disease (33%). The study reported device testing during implantation, day 1 post-implantation, and follow-up examination after 5 weeks mainly measuring electrical parameters.

The multicentre prospective study by Nair (2025) analysed and reported the safety and efficacy from a single-chamber atrial leadless pacemaker in people with isolated sinus node dysfunction. The study cohort included 75 people with a mean age of 72.1 years, and 52% were male. The primary indication was sinus node dysfunction, and 92% of people had de novo implants while 8% had existing dual-chamber transvenous devices that were replaced. The study reported electrical measurements during pre-fixation mapping, post-fixation tether mode, after device release, and before discharge, and with a 30-day safety follow up. The authors also reported total procedure duration and fluoroscopy time.

Knops et al conducted a prospective multicentre study across 55 sites in the US, Canada, and Europe to assess the long-term safety and performance of a dual-chamber LP systems in 300 people (mean age 69.2 years, 62% male). Main pacing indications were sinus node dysfunction (63%) and AV block (33%). The primary safety outcome was freedom from serious device- or procedure-related IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

events within 90 days. Performance was evaluated at 3 months by atrial capture and sensing, and by AV synchrony while seated, targeting at least 70%. Follow-up visits were done at 1-, 3-, 6- and 12-monthly intervals to evaluate performance success, AV synchrony and monitor procedure related complications and adverse events (Knops 2023, 2025).

The prospective study Reddy (2025) assessed the battery longevity of dual-chamber leadless pacemaker systems as part of the AVEIR DR i2i clinical trial. The study included 302 people with a mean age of 70.3 years, and 65% were male. The primary indications were sinus node dysfunction (58%) and atrioventricular block (27%). The study reported safety and efficacy outcomes at 12 months post-implant measuring programmed parameters, device diagnostics, pacing percentages, event rates, and projected battery longevities.

[Table 2](#) presents study details.

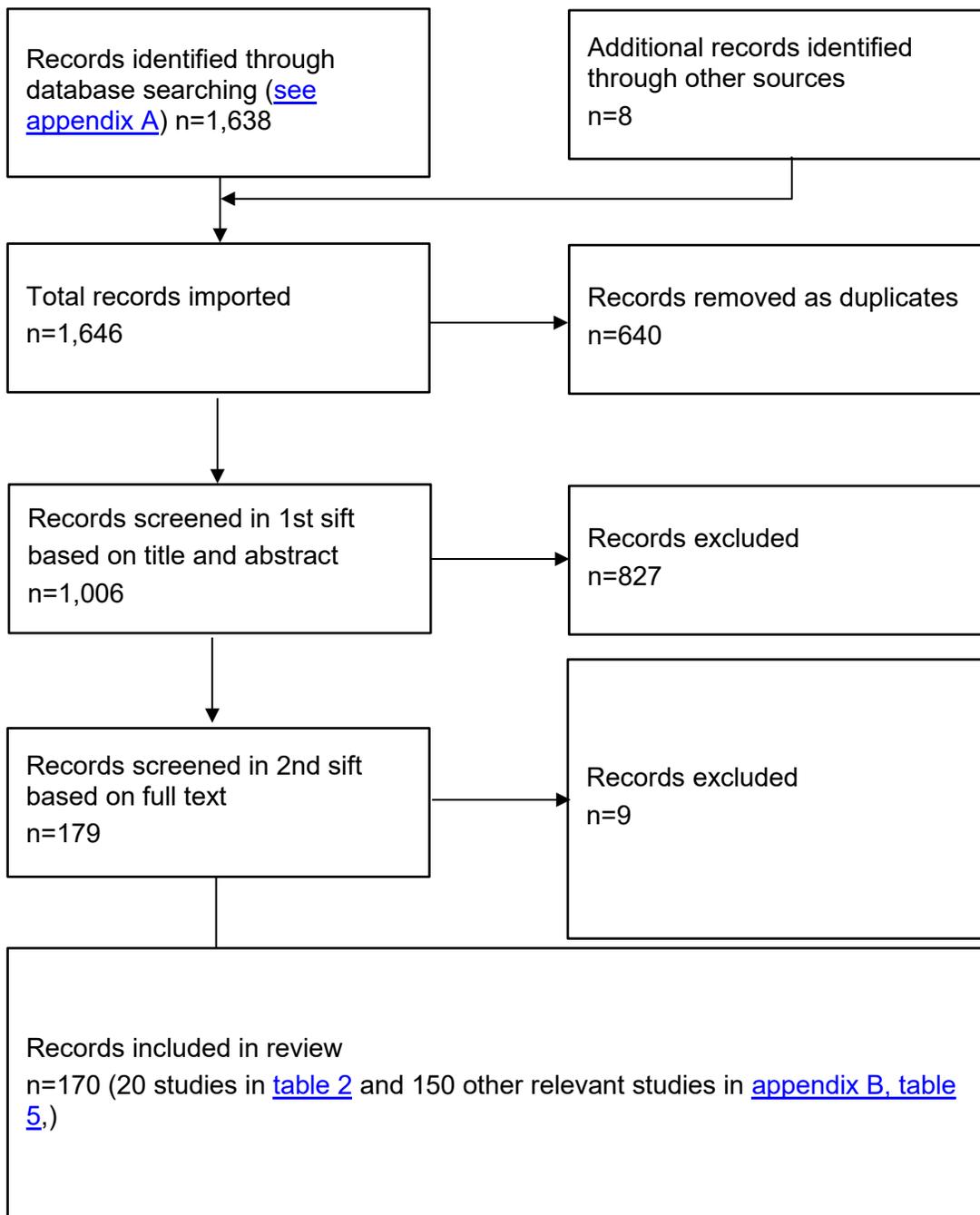
Figure 1 Flow chart of study selection

Table 2 Study details

Study no.	System	First author, date, country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
1	Right ventricular leadless pacing	Garweg C, 2023, Belgium	<p>n=51 Mean age: 82.5 years (SD 4.6) Male: 61% Indications:</p> <ul style="list-style-type: none"> • severe bradycardia • sinus node dysfunction • high-degree AV block <p>Comorbidities:</p> <ul style="list-style-type: none"> • arterial HTN (78%) • diabetes mellitus (21%) • previous AF (61%) • CAD (27%) • COPD (8%) 	Prospective, randomised, non-inferiority, single-centre study.	18 years or over; Class I or II indication for single-chamber VVI pacemaker; LVEF greater than 40%; adequate baseline echocardiographic image quality; no previously implanted cardiac devices or mechanical valves; no pre-existing conditions challenging or precluding conventional pacemaker implantation; capable and willing to provide informed consent.	Intervention group (n=27): LPs (Micra LP) implanted via femoral approach targeting RV mid-septum or basal outflow tract; Control group (n=24): TVP (single-chamber VVI pacemaker, Medtronic Advisa ADSR03) implanted transvenous with RV pacing lead, also targeting mid-septum or basal RV outflow tract	12 months; echocardiography at baseline, 6 and 12 months; NT-pro-BNP measured at baseline and 12 months; clinical assessments at day 10, 1, 6, and 12 months.

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			renal impairment (mean eGFR ~60 mL/min) Median CHA2DS2-VASc score around 4.			initially, apical positioning considered secondary if necessary.	
2	Right ventricular leadless pacing	Inoue N, 2024, Japan	n=653 Mean age: 76.9 years Male: 69%; Mean LVEF: 56% (95% CI: 52% to 59%). Common comorbidities: <ul style="list-style-type: none"> • HTN (62%) • diabetes mellitus (32%) • chronic kidney disease (26%) • COPD (14%) • sinus node dysfunction (17%) • AV block (40%) 	Systematic review and meta-analysis of 16 studies: 1 prospective 7 retrospective 4 case series 4 unclear designs	Included clinical studies and case series reporting 2 or more cases of CIED removal because of infection followed by LP implantation. Outcomes assessed: all-cause mortality or reinfection after LP implantation. Excluded were reviews, single-case reports, abstracts, indications other than infection, unclear follow-up durations, additional cardiac	LP implantation done either simultaneously (immediate strategy: median interval of 0 days) or staged after extraction of infected CIEDs (delayed strategy: median interval of 8 days).	Mean=14 months (SD 9.3); outcomes monitored included mortality rates (all-cause mortality) and occurrences of reinfection.

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<ul style="list-style-type: none"> AF with bradycardia (30%) 		devices other than LPs, animal studies, and non-English literature.		
3	Right ventricular leadless pacing	Mhasseb C, 2025, Lebanon	<p>n=972,479 People with cardiovascular diseases needing permanent pacemaker implantation. Sample size: ranged from 62 to 580,925, mean age ranged from 70 to 90 years. Common comorbidities included:</p> <ul style="list-style-type: none"> AF (43 to 96%) HTN (59 to 90%) CAD (17 to 56%) diabetes mellitus (18 to 45%) hyperlipidemia peripheral vascular disease 	<p>Meta-analysis including 19 observational studies (no RCTs): 7 prospective observational cohort 12 retrospective observational cohort studies or database analyses. High methodological heterogeneity (I^2 varied from 3% to 99%).</p>	<p>Studies comparing TVP and LP, published between 2018 and 2023, in English, with safety-related outcomes: major complications, reintervention, mortality, device malfunction, thromboembolic events, infections, pneumothorax, and haemothorax.</p>	<p>LP, specifically Micra (Medtronic, Minnesota – 17 studies), versus conventional TVP.</p>	<p>Varied widely among studies: from immediate post-procedure (in-hospital outcomes) up to long-term follow-ups ranging from 6 months to approximately 3.5 years (median follow-up durations ranged from 180 days to 39 months across studies).</p>

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
4	Right ventricular leadless pacing	Oliveira VMR, 2025, Brazil	n=47,229 (12,199 LP) Mean age: 80 years (SD 10); 26,646 (56%) males.	Meta-analysis of 21 observational studies: 8 prospective 13 retrospectives No RCTs included.	Studies published up to September 2023 comparing LP with TVP, reporting on effectiveness or safety endpoints; adults needing VP.	LP: primarily Micra (Medtronic, Minnesota) – 15 studies; Nanostim – 2 studies; both Micra and Nanostim – 3 studies; unspecified – 1 study. LP compared to conventional TVP.	Varied widely among studies: from immediate post-procedure (in-hospital outcomes) up to 24 months. Mean follow-up ranged between 6 months to 24 months across studies.
5	Right ventricular leadless pacing	Wu S, 2023, China	n=464 Mean age: 76.3 years (SD 4.2); Females: 44%. Indications for pacing included: <ul style="list-style-type: none"> complete or high-grade AV block sinus node dysfunction (with or without AF) 	Systematic review and meta-analysis, including 8 observational studies: 3 prospective multicentre 3 prospective single centres 2 retrospective single centre	Studies evaluating LP with AV-synchrony algorithm. Reported AV synchrony outcomes post-implantation. Excluded case reports, reviews, non-human studies, duplicated cohorts, studies with combined	LP, specifically Micra AV (Medtronic, Minneapolis, Minnesota, USA) in 100% of included studies. Acceleromete r-based AV synchrony algorithm in	Immediate post-procedure (in-hospital outcomes) up to a maximum of 12 months follow-up (most studies reported follow-up durations less than 3 months).

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			VP burden varied (from about 10% in sinus node dysfunction to about 100% in complete AV block).	All studies published between 2018 and 2022.	interventions (ablation or defibrillation) and studies not reporting AV synchrony.	VDD pacing mode versus conventional VVI pacing mode.	
6	Right ventricular leadless pacing	El-Chami MF, 2024, Multinational (23 countries)	<p>n=1,809 LP (2,667 historical controls) Mean age: 75.6 years (SD 13.4) Median age: 79 years (IQR: 71 to 84) Female: 39% (701/1808)</p> <p>Comorbidities:</p> <ul style="list-style-type: none"> Atrial tachyarrhythmias : 76% (1,373/1,808) CHF: 15% (279/1808) COPD: 10% (177/1808) CAD: 22% (398/1808) 	<p>Micra VR PAR, non-randomised, prospective registry study Multinational: 179 centres, 23 countries Data collection: Implant to 9 years post-implant Comparator group: Historical control (2,667 people with TVPs, studies 2000 to 2012) Outcomes adjudicated by</p>	<p>People having Micra VR LP implantation Class I or II indications for pacing No comorbidity restrictions Enrolment July 2015 to March 2018 Exclusion: previous enrolment in pre-market trials</p>	<p>Micra VR LP Implantation Device model: MC1VR01, Medtronic, Inc., Minnesota, USA</p>	<p>Median follow-up: 51.1 months (IQR: 21.6 to 64.2)</p>

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<ul style="list-style-type: none"> • HTN: 65% (1173/1808) • Diabetes: 27% (479/1808) • Renal dysfunction: 22% (389/1808) • Dialysis: 8% (143/1808) Pacing Indication: <ul style="list-style-type: none"> • Bradyarrhythmia with AF: 63% • AV block: 12% • Sinus node dysfunction: 10% • Syncope: 14% 	Clinical Events Committee Statistical analysis: Fine-Gray competing risk models, propensity score overlaps weights			
7	Right ventricular leadless pacing	EI-Chami MF, 2024, USA	n=118,110 (n=7,552 LP, n=110,558 TVP) Mean age: LP AV: 79.0 years (SD 10.2); (range: 21 to 105) TVP: 78.7 years (SD 8); (range: 23 to 106)	Comparative effectiveness analysis using Medicare administrative claims linked to device registry data. People identified via	US Medicare Fee-for-Service (FFS) population undergoing first-time pacemaker implantation (LP AV or TVP) between February 2020 and December 2021.	LP (Micra AV, Medtronic) versus TVP	2 years post-implantation.

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			Female: <ul style="list-style-type: none"> • LP AV: 48% • TVP: 47% Key Comorbidities (LP AV versus TVP): <ul style="list-style-type: none"> • End stage renal disease (ESRD): 15% versus 2% • Renal dysfunction: 48% versus 34% • Diabetes: 46% versus 38% • CHF: 41% versus 31% • COPD: 25% versus 21% • AF: 40% versus 45% • AV block indication: 74% versus 48% Charlson Comorbidity Index: <ul style="list-style-type: none"> • LP AV: 5; SD 3.4 	device implantation registry and Medicare claims. Adjusted using propensity score overlap-weighted analysis to control for population characteristics.			

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<ul style="list-style-type: none"> TVP: 3.9; SD 3.0 				
8	Right ventricular leadless pacing	Shah MJ, 2023, USA, UK, and Italy	<p>n=63 Mean Age: 15 years (SD 4.1) Weight: 55 kg (SD 19) Sex: 58% male CHD: 32% Prior cardiac surgery: 28% Indications for LP:</p> <ul style="list-style-type: none"> Sinus bradycardia or sinus pauses=33% (21/63) Atrial standstill=1/63 AV node dysfunction or AV block=63% (40/63) Other conduction abnormalities=1/63 	Retrospective registry study, multicentre Study Setting: 15 centres, including the US, UK, and Italy.	<p>Inclusion criteria: People aged 21 years or younger LP implantation (Medtronic) Complete LP procedure documentation Clinical follow-up of 1 week or more Exclusion criteria: People over 21 years Incomplete procedural data Follow-up less than 1 week</p>	Micra Transcatheter LP (Medtronic), implanted via femoral (87%) or internal jugular (13%) venous access. Micra VR was used in 97% of people, and Micra AV in 4.8%.	Mean follow-up duration of 9.5 months (SD 5.3); range: 2 to 32 months, median: 10 months. Follow-up data categorised in 4-month intervals: 1 to 4 months, 5 to 8 months, and 9 to 12 months.

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			24 (38%) had symptomatic bradycardia. Prior pacemaker: 14 (22%) had a prior pacemaker (transvenous: 5, epicardial: 9).				
9	Right ventricular leadless pacing	Strik M, 2023, France	n=35 young adult people, with 21 males (60%) and average age of 34 years (SD 8). People had the following characteristics: height: 165 cm (SD 29) weight: 66 kg (SD 19) LVEF of 57% (SD 14%) Indications: <ul style="list-style-type: none"> congenital AV block (3 people, 9%) 	Multicentre (4), retrospective, observational study conducted between 2015 and 2021.	People aged between 18 and 40 years who had implantation of a LP for any indication. The protocol was approved by the ethics committee at each of the 4 participating centres, and all the people provided written and informed consent.	Implantation of the Micra VR LP (Medtronic)	The mean follow-up was 26 months (SD 15); range: 6 to 60 months.

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<ul style="list-style-type: none"> • postoperative AV block (7 people, 20%) • post-heart transplantation (2 people, 6%) • muscular dystrophy syndrome (5 people, 14%) • symptomatic paroxysmal AV block (8 people, 23%) • symptomatic sinus node dysfunction (10 people, 29%) 				
10	Right ventricular leadless pacing	Amrani AE, 2020, Spain	<p>n=129</p> <p>Age:</p> <p>41 people aged 90 years or above (mean age 92.9 years; SD 2.4)</p> <p>88 people aged less than 90 years (mean</p>	Prospective observational study: People were divided into 2 groups based on age: 90 and above and younger than 90 years.	People over 70 years with indications for single-chamber pacing. Specific indications for LP implantation included previous TVP infection,	Micra LPs implanted via transcatheter approach. The procedure was performed under	At 7 days, and 1, 3, 6, and 12 months after implantation, with subsequent annual follow-ups. Electrical parameters and clinical outcomes

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<p>age 83.9 years; SD 4.1).</p> <p>Gender Distribution:</p> <p>≥90 Years: 18 males (44%) and 23 females (56%)</p> <p><90 Years: 32 males (36%), 56 females (64%)</p> <p>Comorbidities:</p> <p>HTN: 36 (86%) in ≥90 years, 73 (83%) in <90 years.</p> <p>Diabetes mellitus: 9 (22%) in ≥90 years, 23 (33%) in <90 years.</p> <p>Chronic kidney disease: 24 (59%) in ≥90 years, 31 (35%) in <90 years</p> <p>Structural heart disease: 14 (34%) in ≥90 years, 49 (56%) in <90 years</p>		absence of upper vascular access, and clinical need assessed by the treating physician.	conscious sedation and local anaesthesia.	were monitored throughout the follow-up period.

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<p>AF: 9 (22%) in ≥90 years, 10 (11%) in <90 years</p> <p>CHF: 4 (10%) in ≥90 years, 36 (41%) in <90 years.</p> <p>Indications for Pacing:</p> <p>AV block: 29 (71%) in ≥90 years, 61 (69%) in <90 years</p> <p>AF with slow ventricular response: 8 (20%) in ≥90 years, 11 (13%) in <90 years</p> <p>Sinus node dysfunction: 4 (10%) in ≥90 years, 36 (41%) in <90 years.</p>				
11	Right ventricular leadless pacing	Panico A, 2024, France	n=384 adult people with ongoing haemodialysis implanted with a first-time single-chamber pacemaker	Retrospective cohort study using propensity score matching (1:1) to balance	Inclusion Criteria: Adult (≥18 years) haemodialysis population First-time implantation of a single-chamber	LP group (n=89): Majority implanted with Medtronic Micra LP.	Median 24 months (range 7 to 37 months).

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<p>between 2017 to 2020. Indications: cardiac conduction disorders</p> <p>Demographics: Age: Mean 77.9 years (SD 8.6), Median: 80 years (IQR 74 to 84). Female: 30% (n=27).</p> <p>Comorbidities:</p> <ul style="list-style-type: none"> • chronic heart failure: 63% (n=56) • AF or flutter: 67% (n=60) • ischemic heart disease: 55% (n=49) • Diabetes: 74% (n=66). <p>Vascular Access for Dialysis:</p> <ul style="list-style-type: none"> • Arteriovenous fistula: 75% (n=67) 	<p>baseline characteristics. Data was sourced from the French REIN registry and linked to the SNDS national health database.</p>	<p>TVP or LP between January 2017 - December 2020</p> <p>Matched from the REIN registry and SNDS database</p> <p>Exclusion Criteria: History of any previous pacemaker or defibrillator implantation</p>	<p>TVP group (n=89): Conventional single-chamber TVPs.</p>	

IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<ul style="list-style-type: none"> Catheter: 21% (n=19) Baseline Health Conditions: <ul style="list-style-type: none"> high risk for pacemaker-related infections venous stenosis because of frequent vascular access use. 				
12	Right ventricular leadless pacing	Molitor N, 2024, Switzerland and Netherlands	n=200. 100 jugular approaches (University Hospital Zurich: n=50, Haga Teaching Hospital: n=50) + 100 femoral approach (comparison group, Zurich only) Mean Age: 81.2 years (SD 8.29) Gender: 60% male Primary Indications (for the jugular	Prospective study comparing jugular vein approach versus femoral vein approach for LP implantation in 2 tertiary centres.	People with indication for LP implantation No contraindications for standard femoral implantation No severe valvular disease preventing pacemaker implantation No history of superior vena cava obstruction	Micra LP implantation via the internal jugular vein. Right internal jugular vein punctured under ultrasound guidance. Standard 9Fr sheath followed by 27Fr introducer. Pacemaker	At day 1 and day 14 post-implantation Monitoring through clinical records, hospital visits, and pacemaker interrogation

IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<p>approach group only, n=100):</p> <ul style="list-style-type: none"> • AV block: 39 (39%) • Tachy-brady syndrome or planned AV node ablation in AF: 32 (32%) • Sick sinus syndrome or pre-automatic pauses: 29 (29%) <p>Comorbidities:</p> <ul style="list-style-type: none"> • AF (73%) • CAD (36%) • valvular disease (43%) • chronic kidney disease (37%) • COPD (13%) • peripheral artery disease (18%) 		No active infection at the time of implantation	delivered via guidewire-assisted catheter technique. Device positioned at inferior (25%), mid (50%), or high (25%) ventricular septum. Compared to standard femoral implantation group	

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<ul style="list-style-type: none"> diabetes mellitus (24%) cancer (14%) previous stroke (20%) 				
13	Right ventricular leadless pacing	Tjong FVY, 2018, Multiple countries (56 centres across 19 countries), with notable involvement from the Netherlands (Amsterdam UMC, University of Amsterdam).	<p>n=720 implanted with a LP.</p> <p>Mean age: 76; SD 11 years.</p> <p>Gender: 59% male.</p> <p>Clinical indications aligned with class I or II guidelines for VVIR pacing.</p>	Prospective multicentre clinical trial	People suitable for VVIR pacing as per clinical guidelines.	Implantation of a Micra LPs.	At baseline, and then at 3 and 12 months post-implantation.
14	Right ventricular	Cabanas-Grandío,	n=106 (64 TVPs and 42 LPs); average	Comparative retrospective	Age 18 or more, indication for	Single-chamber	6 months post-implantation,

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
	leadless pacing	2020, Spain	age 79.8 years; baseline characteristics included demographic factors such as sex distribution and prevalence of diabetes.	study between LPs and TVPs with follow-up assessments.	single-chamber pacemaker implantation, absence of cognitive impairment, ability to complete the SF-36 questionnaire, and ability to provide informed consent.	pacemaker implantation (the research did not specify the brand names of the LPs or TVPs)	with additional assessments at 1 month for some people.
15	Right ventricular leadless pacing	Ueyama HA, 2024, USA	n=10,338 (LP=730, TVP=9,608), median age 82 years, male: 434 (60%) in LP group and 5,398 (56%) in TVP group. Conditions (LP versus TVP): <ul style="list-style-type: none"> • AF (55% versus 33%) • end-stage renal disease (14% versus 4%) 	Retrospective cohort study using Medicare claims data	People aged 65 or above who had TAVR between January 2017 to December 2020 with permanent pacemaker (LP or TVP) implanted during same admission.	Micra VR and Micra AV LPs (Medtronic USA), compared to TVPs.	Median duration of 17.3 months (IQR: 7.4 to 29.5), until the occurrence of an outcome event, death, disenrollment from Medicare Part A and B, or up to 2 years post-procedure, whichever came first.

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<ul style="list-style-type: none"> • congestive heart failure (85% versus 81%) • anaemia (70% versus 63%) • prior stroke or TIA (14% versus 10%) • complete heart block (59% versus 78%) • unknown indications (27% versus 7%) 				
16	Right atrial leadless pacing alone (either as single chamber pacing or as part of	Nair, 2025 USA	<p>n=75 Mean age=72.1 years Male: 52.0% (39/75) Indications: Sinus node dysfunction: 100% (75/75)</p>	Prospective, multicentre, single-arm study.	Age 18 and over with sick sinus syndrome or sinus node dysfunction meeting standard criteria for permanent pacemaker implantation (per	AVEIR AR atrial leadless pacemaker: De novo implants: 92.0% (69/75) Replacing dual-chamber	30 days

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
	a dual chamber leadless pacing)		Comorbidities: Hypertension: 73.3% (55/75), coronary artery disease: 42.7% (32/75), diabetes mellitus: 40.0% (30/75), atrial fibrillation: 38.7% (29/75), chronic kidney disease: 37.3% (28/75), and congestive heart failure: 14.7% (11/75).		AHA guidelines), without clinical evidence of high-grade AV block, scheduled for Aveir AR pacemaker implantation.	transvenous device: 8.0% (6/75). Dual-helix fixation mechanism.	
17	Right atrial leadless pacing alone (either as single chamber pacing or as part of a dual chamber leadless pacing)	von Felten, 2025, Switzerland	n=45 Mean age=75.5 years Male: 48.9% Indications: AV-block: 57.8% (26/45) Sick sinus syndrome: 33.3% (15/45) Binodal disease: 6.7% (3/45)	Prospective, single-centre study	Adults having implantation of active fixation single chamber atrial LP (AR) or dual chamber LP system (DR) from July 2024 to January 2025 who consented to study inclusion.	AVEIR leadless pacemaker system: dual chamber: 48.9% (22/45). Upgrade from ventricular device (VR) single chamber to dual chamber	Median follow-up: 21 days

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<p>Pace-and-ablate: 2.2% (1/45)</p> <p>Comorbidities % (n):</p> <p>Hypertension: 66.7 (30/45), dyslipidaemia: 46.7 (21/45), chronic kidney disease: 35.6 (16/45), atrial fibrillation: 33.3 (15/45), diabetes: 20.0 (9/45), heart failure: 13.3 (6/45), coronary artery disease: 13.3 (6/45), cerebrovascular disease: 13.3 (6/45), malignancy: 13.3 (6/45), valvular heart disease: 8.9 (4/45), COPD: 4.4 (2/45), sleep apnoea: 4.4 (2/45).</p>			<p>system (DR): 20% (9/45)</p> <p>Atrial single chamber (AR) only: 31.1% (14/45)</p> <p>Active fixation with external helix, wireless communication via i2i technology.</p>	
18	Dual chamber leadless pacing	Knops RE, 2023, USA, Canada, Europe	n=300 Male: 62%, Female: 38%	Prospective, multicentre, single-arm study,	Inclusion: Adults 18 years and over with at least 1 standard indication for dual	Dual-chamber LP (Aveir DR i2i, Abbott Medical)	Primary follow-up period was 90 days

IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
		(55 centers)	Age: 69.2 years (SD 13.5) BMI: 28.1 (SD 5.6) <ul style="list-style-type: none"> • Sinus-node dysfunction: 63% • AV block: 33% • Previous ablation: 20% • Tricuspid valve disease: 24% • Arrhythmia history: 45% (nonventricular), 4% (ventricular) Previous lead extraction: 8%	(Aveir DR i2i Study, NCT05252702).	chamber pacing according to US or EU guidelines. <u>Exclusion:</u> mechanical tricuspid valve prosthesis, inferior vena cava filter, pre-existing pacing or defibrillation leads, other electrically active implantable devices.	implanted percutaneously via the femoral vein, with 2 separate LPs (1 in the right atrium and 1 in the right ventricle), using an active fixation helix for endocardial attachment and beat-to-beat wireless communication to maintain AV synchrony.	
19	Dual chamber leadless pacing	Knops, 2025 (USA, Canada, Europe)	n=300 Mean age=69.2 years Male: 62%; female 38% Indications:	Prospective, multicentre, single arm study. (Aveir DR i2i Study,	Adults 18 years and over with at least 1 standard indication for dual chamber pacing according to US or EU guidelines.	Dual-chamber LP (Aveir DR i2i, Abbott Medical) implanted percutaneously via the	Mean 12 months

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<p>Sinus node dysfunction: 63.3% (190/300)</p> <p>Atrioventricular block: 33.3% (100/300)</p> <p>Other: 3.4% (10/300)</p> <p>Comorbidities: Not reported.</p>	NCT05252702).	<p><u>Exclusion:</u> mechanical tricuspid valve prosthesis, inferior vena cava filter, pre-existing leads, other electrically active implantable devices.</p>	femoral vein, with 2 separate LPs (1 in the right atrium and 1 in the right ventricle), using an active fixation helix for endocardial attachment and beat-to-beat wireless communication to maintain AV synchrony.	
20	Dual chamber leadless pacing	Reddy, 2025 Multi-centre (USA, Canada, Europe, Asia-Pacific)	<p>n=302</p> <p>Mean age=70.3 years</p> <p>Male: 65% (197/302)</p> <p>Indications: Sinus node dysfunction: 57.9% (175/302)</p>	Prospective, multicentre, international clinical trial (post hoc analysis). (Aveir DR i2i Study, NCT05252702).	Standard indications for dual-chamber pacing, de novo dual-chamber LP implants, no subsequent device revision, dual-chamber pacing programmed (DDD(R) or	AVEIR DR dual-chamber leadless pacemaker system Both use Li-CFx battery technology and implant to implant	12 months

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Study no.	System	First author, date country	Characteristics of people in the study (as reported by the study)	Study design	Inclusion criteria	Intervention	Follow up
			<p>AV block, 3rd degree: 15.6% (47/302) Other: 15.6% (47/302) AV block, 2nd degree: 6.3% (19/302) AV block, 1st degree: 4.6% (14/302).</p> <p>Comorbidities (values are shown as percent or mean): History of atrial fibrillation: 33.4% (101/302), body surface area: 1.9 m², weight: 80.0 kg, height: 170.4 cm, ejection fraction: 59.8%, intrinsic heart rate: 55.4 beats per minute.</p>		<p>DDI(R)), complete longevity measurements at 12 months.</p> <p>Exclusion criteria: mechanical tricuspid valve prosthesis, inferior vena cava filter, pre-existing pacing/defibrillation leads, or electrically active implantable devices.</p>	communication for AV synchrony.	

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Table 3 Study outcomes

First author, date	System	Efficacy outcomes	Safety outcomes
Garweg, 2023	Right ventricular leadless pacing	<p>LV Ejection Fraction (LVEF)</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=58% (SD 6%), ○ TVP=59% (SD 6%), p=0.637 • 6 months: <ul style="list-style-type: none"> ○ LP=50% (SD 8%), ○ TVP=52% (SD 8), p=0.370 • 12 months: <ul style="list-style-type: none"> ○ LP=48% (SD 7%), ○ TVP=46% (SD 9%), p=0.328 <p>Global Longitudinal Strain (GLS)</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=-18% (SD 4%), ○ TVP=-19% (SD 3%), p=0.537 • 6 months: <ul style="list-style-type: none"> ○ LP=-14% (SD 4%), ○ TVP=-14% (SD 3%), p=0.994 • 12 months: <ul style="list-style-type: none"> ○ LP=-13% (SD 2%) ○ TVP=-13% (SD 6%), p=0.878 <p>RV Free Wall Strain</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=-21% (SD 5%), ○ TVP=-22% (SD 5%), p=0.812 • 6 months: <ul style="list-style-type: none"> ○ LP=-19% (SD 5%), ○ Conventional=-19% (SD 5%), p=0.887 	<p>NT-pro-BNP (pg/dL)</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=1,176, ○ TVP=907, p=0.355 • 12 months: <ul style="list-style-type: none"> ○ LP=970, ○ TVP=1,394, p=0.041 <p>Tricuspid Valve Regurgitation</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP (Grade I=59%, Grade II=22%, Grade III=15%, Grade IV=4%), ○ TVP (Grade I=58%, Grade II=38%, Grade III=4%, Grade IV=0%) • 12 months: Statistically significant; less worsening in LP versus TVP p=0.009 <p>Mitral Valve Regurgitation</p> <ul style="list-style-type: none"> • Baseline:

IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

First author, date	System	Efficacy outcomes	Safety outcomes
		<ul style="list-style-type: none"> • 12 months: <ul style="list-style-type: none"> ○ LP=-19% (SD 5%), ○ Conventional=-18% (SD 5%), p=0.794 <p>TAPSE (cm)</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=2.2 (SD 0.7), ○ Conventional=2.1 (SD 0.5), p=0.460 • 6 months: <ul style="list-style-type: none"> ○ LP=1.9 (SD 0.6), ○ Conventional=1.7 (SD 0.5), p=0.439 • 12 months: <ul style="list-style-type: none"> ○ LP=1.7 (SD 0.4), ○ Conventional=1.7 (SD 0.3), p=0.729 <p>MAPSE (cm)</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=1.5 (SD 0.4), ○ Conventional=1.5 (SD 0.4), p=0.723 • 6 months: <ul style="list-style-type: none"> ○ LP=1.3 (SD 0.3), ○ Conventional=1.2 (SD 0.3), p=0.336 • 12 months: <ul style="list-style-type: none"> ○ LP=1.3 (SD 0.3), ○ Conventional=1 (SD 0.6), p=0.053 <p>LV End-Diastolic Volume (mL)</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=78.4 (SD 24.5), ○ Conventional=68.7 (SD 21.9), p=0.143 	<ul style="list-style-type: none"> ○ LP (Grade I=67%, Grade II=30%, Grade III=4%), ○ TVP (Grade I=75.0%, Grade II=21%, Grade III=4%) <ul style="list-style-type: none"> • 12 months: <ul style="list-style-type: none"> ○ Stable in LP; worsened in TVP, p=0.304 <p>Procedural Complications</p> <ul style="list-style-type: none"> • LP group: None • Conventional group: 1 minor complication (pocket haematoma) – resolved with further interventions (details not mentioned). <p>NOTE: The study provided baseline, and 12-month follow-up results only for these specific safety outcomes.</p>

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First author, date	System	Efficacy outcomes	Safety outcomes
		<ul style="list-style-type: none"> • 6 months: <ul style="list-style-type: none"> ○ LP=76.9 (SD 20.4), ○ Conventional=70.1 (SD 16.8), <p>p=0.221</p> • 12 months: <ul style="list-style-type: none"> ○ LP=74.5 (SD 19.2), ○ Conventional=65.2 (SD 21.5), <p>p=0.122</p> <p>LV End-Systolic Volume (mL)</p> <ul style="list-style-type: none"> • Baseline: <ul style="list-style-type: none"> ○ LP=33.5 (SD 12.8), ○ Conventional=27.2 (SD 8.5), <p>p=0.043</p> • 6 months: <ul style="list-style-type: none"> ○ LP=38.9 (SD 13.0), ○ Conventional=34.3 (SD 13.4), <p>p=0.224</p> • 12 months: <ul style="list-style-type: none"> ○ LP=39.0 (SD 12.0), ○ Conventional=34.4 (SD 14.2), <p>p=0.226</p> <p>6-Minute Walk Distance (m)</p> <ul style="list-style-type: none"> • Day 10: <ul style="list-style-type: none"> ○ LP=390, ○ Conventional=318, p=0.215 • 12 months: <ul style="list-style-type: none"> ○ LP=392.5, ○ Conventional=322, p=0.088 	

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First author, date	System	Efficacy outcomes	Safety outcomes
Inoue, 2024	Right ventricular leadless pacing		<p>Primary Safety Outcome: Incidence of combined all-cause mortality and reinfection following LP implantation:</p> <ul style="list-style-type: none"> • Simultaneous implantation and extraction: 19% (95% CI: 13 to 28%; I²=0%) • Post-extraction implantation: 8% (95% CI: 4 to 14%; I²=4%) • Comparison: Statistically significant increase in adverse outcomes with simultaneous approach (p=0.009). <p>Reinfection outcomes:</p> <ul style="list-style-type: none"> • Reinfection specifically defined as recurrence of initial pathogen post-discharge after LP implantation. • Findings: No reinfections reported in any included study.
Mhasseb, 2025	Right ventricular leadless pacing		<p>All-cause Mortality:</p> <ul style="list-style-type: none"> • TVP slightly higher risk than LP (Cohen's d: -0.1; 95% CI: -0.2 to 0.01; I²=99%).

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First author, date	System	Efficacy outcomes	Safety outcomes
			<ul style="list-style-type: none"> • Comparison: Difference not statistically significant ($p=0.07$). • Subgroup Analysis: Varied by follow-up (1-month, 6-month, 1-year, ≥ 3 years). Mortality trend slightly favoured LP, not statistically significant across subgroups ($p=0.27$ between subgroups). <p>Reintervention (device revision or extraction)</p> <ul style="list-style-type: none"> • TVP increased the risk of reintervention compared to LP (LogOR=-0.7, 95% CI -1.2 to -0.3, $I^2=77\%$; $p=0.01$; 7 studies) <p>Major Complications:</p> <ul style="list-style-type: none"> • Composite outcomes including perforation, generator malfunction, haematoma, infection, dislodgement, pneumothorax or haemothorax, erosion, thromboembolic events.

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First author, date	System	Efficacy outcomes	Safety outcomes
			<ul style="list-style-type: none"> • TVP higher risk (LogOR: -0.3; 95% CI: -0.6 to 0.1; I²=79%). • Comparison: Difference not statistically significant (p=0.14) <p>Cardiac Perforation and Tamponade:</p> <ul style="list-style-type: none"> • LP: statistically significant higher risk than TVP (LogOR: 1; 95% CI: 0.6 to 1.5; p<0.001, I²=81%; 10 papers). <p>Thromboembolic Events:</p> <ul style="list-style-type: none"> • LP higher risk, not statistically significant (LogOR: 0.5; 95% CI: -0.3 to 1.2; p=0.19; I²=97%, 6 papers). <p>Infection Rates:</p> <ul style="list-style-type: none"> • TVP higher risk, not statistically significant (LogOR: -0.6; 95% CI: -1.7 to 0.6; I²=98%). • Comparison: Difference not statistically significant (p=0.27) <p>Pneumothorax and Hemothorax:</p>

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First author, date	System	Efficacy outcomes	Safety outcomes
			<ul style="list-style-type: none"> • TVP: higher risk (LogOR: - 1.1; 95% CI: -2.2 to -0.1; I²=93%) • Comparison: TVP higher risk (p=0.04), statistically significant. <p>Generator Malfunction:</p> <ul style="list-style-type: none"> • The overall effect estimate showed that TVP increased the risk of generator malfunction compared to LP, but this was not statistically significant (LogOR = - 0.5, 95% CI -1.1 to 0.2, p=0.1, I²=97%; 11 papers) <p>Device or Lead Dislodgement:</p> <ul style="list-style-type: none"> • TVP has a higher dislodgement risk (LogOR: - 1.1; 95% CI: -1.6 to -0.6; I²=3%), while LP shows a lower risk. LP reduces dislodgements compared to TVP (p<0.001), which was statistically significant.
Oliveira, 2025	Right ventricular leadless pacing	Pacing Capture Threshold: lower in LP compared to TVP: statistically significant	Primary Safety Outcome (All-cause mortality):

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First author, date	System	Efficacy outcomes	Safety outcomes
		<ul style="list-style-type: none"> • Mean difference: -0.2 V • 95% CI: -0.2 to -0.2 V • p<0.01 <p>Impedance: No statistically significant difference LP versus TVP:</p> <ul style="list-style-type: none"> • Mean difference: 32.6 ohms • 95% CI: -22.5 to 87.8 ohms • p=0.25 (<i>No I² or SD explicitly reported.</i>) 	<ul style="list-style-type: none"> • No statistically significant difference for LP compared to TVPOR: 1.4 • 95% CI: 0.7 to 3.2 • p=0.35 <p>Overall complications: Statistically significant and lower with LP:</p> <ul style="list-style-type: none"> • OR: 0.6 • 95% CI: 0.5 to 0.8 • p<0.01 <p>Lead dislodgement: Statistically significant lower with LP:</p> <ul style="list-style-type: none"> • OR: 0.3 • 95% CI: 0.2 to 0.6 • p<0.01 <p>Post-procedure pneumothorax: Statistically significant lower with LP:</p> <ul style="list-style-type: none"> • OR: 0.3 • 95% CI: 0.2 to 0.5 • p<0.01 <p>Pericardial effusion: Statistically significant higher with LP:</p>

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			<ul style="list-style-type: none"> • OR: 2.5 • 95% CI: 1.4 to 4.4 • p<0.01 <p>Cardiac tamponade: Statistically significant higher with LP:</p> <ul style="list-style-type: none"> • OR: 3.8 • 95% CI: 2.4 to 5.8 • p<0.01 <p>Infection: No significant difference LP versus TVP:</p> <ul style="list-style-type: none"> • OR: 0.5 • 95% CI: 0.2 to 1.4 • p=0.18 <p>Myocardial perforation: No significant difference LP versus TVP:</p> <ul style="list-style-type: none"> • OR: 1.8 • 95% CI: 0.5 to 6.5 • p=0.39 <p>Hematoma:</p> <ul style="list-style-type: none"> • No significant difference LP versus TVP: • OR: 1.02

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			<ul style="list-style-type: none"> • 95% CI: 0.6 to 1.9 • p=0.96 <p>Tricuspid regurgitation:</p> <ul style="list-style-type: none"> • No significant difference LP versus TVP: • OR: 1.2 • 95% CI: 0.6 to 2.3 • p=0.69 <p>Pericarditis: Listed as prespecified but no explicit statistical results reported.</p> <p>Subgroup analysis (All-cause mortality):</p> <ul style="list-style-type: none"> • Overall Risk of Bias (ROBINS-I) <ul style="list-style-type: none"> ○ Statistically significant subgroup interaction (p=0.02) • LP device used (Micra versus Nanostim): <ul style="list-style-type: none"> ○ No significant subgroup interaction (p=0.81) <p>Meta-regression analysis (All-cause mortality):</p>

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			<ul style="list-style-type: none"> • Overall Risk of Bias: <ul style="list-style-type: none"> ◦ Statistically significant correlation (p=0.01) • Mean age: No significant correlation (p=0.52) • Proportion of females: No significant correlation (p=0.17) • Follow-up duration: No significant correlation (p=0.42) <p><i>Note: I² statistics were not reported.</i></p>
Wu, 2023	Right ventricular leadless pacing	<p>Primary Efficacy Outcome (AV Synchrony):</p> <ul style="list-style-type: none"> • Pooled mean AV synchrony: 79% (95% CI: 72% to 86%) • High heterogeneity across studies (I²=90%, p<0.01) • No significant predictors identified in meta-regression (age: p=0.23, gender: p=0.86, pacing indication: p=0.59, study quality: p=0.27, post-TAVI population: p=0.51) <p>Subgroup Analysis (Programmed Optimisation):</p> <ul style="list-style-type: none"> • Statistically significant increase in AV synchrony post-optimisation: Mean difference 11% (95% CI: 7% to 16%, p<0.01) 	<p>Overall Safety Outcomes (all studies):</p> <ul style="list-style-type: none"> • Overall complication incidence: 6.3% (22/351) <p>Complications Related to AV Algorithm:</p> <ul style="list-style-type: none"> • Extremely low (0.6%), 2 cases of atrial undersensing (post-TAVI subgroup) <p>Device/Procedure-related complications:</p> <ul style="list-style-type: none"> • Pericardial effusion: 1.1% (n=4)

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		<ul style="list-style-type: none"> • Low heterogeneity ($I^2=13\%$, $p=0.33$) <p>Secondary Efficacy Outcome (Cardiac Output, LVOT-VTI):</p> <ul style="list-style-type: none"> • Mean LVOT-VTI increased in VDD mode versus VVI mode: Mean difference: 1.9 cm (95% CI: 1.2 to 2.6, $p<0.01$) • No heterogeneity ($I^2=0\%$, $p=0.85$) 	<ul style="list-style-type: none"> • Cardiac rhythm disorders: 2.3% (n=8) • Device dislodgement: n=1 • Elevated pacing threshold: n=1 • Death (unrelated to device/algorithm): n=1 • Other minor complications: 1.4% (n=5) <p>Follow-up duration: Immediate post-procedure (in-hospital) up to maximum 12 months</p> <ul style="list-style-type: none"> • No significant heterogeneity or statistical comparisons reported explicitly for safety outcomes.
El-Chami, 2024	Right ventricular leadless pacing	<p>Primary Efficacy Outcomes:</p> <ul style="list-style-type: none"> • Successful Implantation: 1792/1809 (99%) <p>Electrical Performance (at 60 months):</p> <ul style="list-style-type: none"> • Pacing threshold: 0.7; SD 0.4 V • Pacing impedance: 533 ohms; SD 101 ohms • R-wave amplitude: 13.1 mV; SD 5.7 mV • Battery longevity: Median 6.8 years remaining after 5 years; ≥ 5-year longevity remaining: 83.8% 	<p>System/procedure-related major complications:</p> <ul style="list-style-type: none"> • At 30 days: 45 (2%) • At 12 months: 61 (3%) • At 36 months: 72 (4%) • At 60 months: 77 (5%, 95% CI: 4% to 6%) <p>System Revision Rate (60 months):</p>

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First author, date	System	Efficacy outcomes	Safety outcomes
			<ul style="list-style-type: none"> • 5% (95% CI: 4% to 6%), n=82 • Device upgrades: 41% of revisions • Elevated thresholds: 31% • Normal battery depletion: 14% (n=12) • Explantations: 11 total (9 percutaneous, 1 surgical, 1 transplant) • CRT upgrade rate: 2% at 5 years (95% CI: 1% to 3%) <p>All-cause Mortality (60 months):</p> <ul style="list-style-type: none"> • Total deaths: 676 (40%) • Procedure-related: 5 • Sudden cardiac: 35 • Non-sudden cardiac: 113 • Non-cardiac: 345 (including 15 COVID-19) • Unknown cause: 178 <p>Major Complication Types (at 60 months):</p> <ul style="list-style-type: none"> • Thrombosis: 2 (less than 1%) • Groin puncture events: 12 (less than 1%)

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			<ul style="list-style-type: none"> • Cardiac effusion/perforation: 8 (less than 1%) • Pacing-related issues: 28 (2%) • Infection-related: 5 (less than 1%). • No infection-related device removals needed <p>Comparative Safety Outcomes (LP versus TVP at 36 months):</p> <ul style="list-style-type: none"> • Major complications: HR 0.5 (95% CI: 0.5 to 0.6, p<0.001) • System revisions: HR 0.5 (95% CI: 0.3 to 0.7, p<0.001)
El-Chami, 2024	Right ventricular leadless pacing	No efficacy outcomes measured	<p>Chronic complications (2-year):</p> <ul style="list-style-type: none"> • LP: 5% (95% CI: 5% to 6%) • TVP: 10% (95% CI: 9% to 10%) • HR: 0.5 (95% CI: 0.5 to 0.6; p<0.0001) <p>Device-related re-interventions (2-year):</p> <ul style="list-style-type: none"> • LP: 4% (95% CI: 3% to 4%) • TVP: 6% (95% CI: 5% to 6%)

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			<ul style="list-style-type: none"> • HR: 0.62 (95% CI: 0.54 to 0.72; p<0.0001) <p>Specific Complications:</p> <ul style="list-style-type: none"> • Device-related complications: LP 3% versus TVP 7%; HR: 0.4; 95% CI: 0.4 to 0.5; p<0.0001 • Dislodgement: LP 1% versus TVP 3%; RR reduction 83%; p<0.0001 • Device revisions: LP 2%; RR reduction 94%; p<0.0001 • Device removals: LP 1%; RR reduction 83%; p<0.0001 • CRT upgrades: LP 2%, TVP 2%; p=0.3955 • LP upgrade to TVP: 1% (95% CI: 1% to 2%) <p>Additional Device-Related Outcomes:</p> <ul style="list-style-type: none"> • Embolism/thrombosis: LP 0.2%, TVP 0.2%; HR: 1 (95% CI: 0.4 to 2.6); p=0.9015

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			<ul style="list-style-type: none"> • Pericarditis: LP 2%, TVP 2%; HR: 1 (95% CI: 0.7 to 1.3); p=0.6876 • Hemothorax: LP 1%, TVP 1%; HR: 1 (95% CI: 1 to 1.3); p=0.7931 • Mechanical failure: LP 1%, TVP 2%; RR reduction: 48%; p<0.0001 • Device stenosis: LP 1%, TVP 1%; RR reduction: 14%; p=0.4152 • Pocket complications: LP N/A, TVP 2% <p>All-cause Mortality (2-year):</p> <ul style="list-style-type: none"> • LP: 34% (95% CI: 33 to 35%) • TVP: 24% (95% CI: 23 to 24%) • Statistical Comparison: higher mortality in LP group (HR: 1.5; 95% CI: 1.4 to 1.6; p<0.0001). <p>Sensitivity Analyses:</p> <ul style="list-style-type: none"> • Mortality conditional on survival at 6-months: Higher mortality remained in

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			<p>LP (HR: 1.39; 95% CI: 1.3 to 1.5; p<0.0001).</p> <ul style="list-style-type: none"> • Subgroup analysis (people with AV block): Mortality higher in LP (HR: 1.51; 95% CI: 1.4 to 1.6; p<0.0001). • Falsification test (hip fracture outcome): LP had higher hip fracture rate (HR: 1.3; 95% CI: 1 to 1.6; suggesting residual confounding). <p>Subgroup Analyses (by comorbidities):</p> <ul style="list-style-type: none"> • End-stage renal disease: LP statistically significantly higher (14.9%) than TVP (2.0%); p<0.0001. • CHF: LP higher (41.4%) versus TVP (30.6%); p<0.0001. • Higher mortality consistently observed in LP group, attributed to baseline higher comorbidity burden.

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First author, date	System	Efficacy outcomes	Safety outcomes
Shah, 2023	Right ventricular leadless pacing	<p>Primary Efficacy Outcomes:</p> <ul style="list-style-type: none"> • Implant success rate: 98% (62/63) • Capture threshold: <2 V in 96% • Mean R-wave amplitude: 10 SD 5.3 mV • Stable pacing impedances. <p>Capture Threshold:</p> <ul style="list-style-type: none"> • At Implant: 0.8 V (SD 0.5) (95% CI: 0.3 to 2.8 V) • 1 to 4 months: 0.7 V (SD 0.5) • 5 to 8 months: 0.7 V (SD 0.6) • 9 to 12 months: 0.7 V (SD 0.5) <p>Measured R-Wave Amplitude:</p> <ul style="list-style-type: none"> • At Implant: 10 mV (SD 5.3) (95% CI: 2.5 to 21.5 mV) • 1 to 4 months: 11 mV (SD 4.3) • 5 to 8 months: 11 mV (SD 4.2) 9 to 12 months: 10.8 mV (SD 4.9) <p>Pacing Impedance:</p> <ul style="list-style-type: none"> • At Implant: 710 ohms (SD 232) (95% CI: 480 to 1580 ohms) • 1 to 4 months: 641 ohms (SD 129) • 5 to 8 months: 603 ohms (SD 85) • 9 to 12 months: 601 ohms (SD 93) • <p>Device Longevity:</p>	<p>Complications:</p> <ul style="list-style-type: none"> • 16% (10/63) • Major complications (pericardial effusion, femoral venous thrombus, LP replacement for high pacing thresholds) • No deaths, LP infections, or device embolisations • Stable electrical parameters over follow-up <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • Follow-up of 9.5 (SD 5.3) months. • No device-related infections or embolisations. <p>Vascular Access Complications:</p> <ul style="list-style-type: none"> • Bleeding from femoral venous site resolved with manual compression • Nonocclusive right common femoral venous thrombus (treated with anticoagulation) <p>Long-Term Outcomes:</p> <ul style="list-style-type: none"> • Electrical performance remained stable in 3% (1 needing steroid treatment)

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		<ul style="list-style-type: none"> Estimated more than 8 years in 90% of people at 5 to 8 months follow-up (using Monte-Carlo Methods) 	<p>and 1 needing device replacement)</p> <p>Procedural Complications (≤ 24 hours after Implant): 11% (7/63)</p> <p>Pericardial effusion with tamponade: 1, successfully treated with pericardiocentesis.</p> <p>Unsuccessful LP implantation: 1, device retrieval performed.</p> <p>Femoral venous bleeding: 3 (5%), resolved with manual compression.</p> <p>Hematoma at femoral venous access site: 1, resolved without intervention.</p> <p>Right bundle branch block: 1, resolved spontaneously after 1 week.</p> <p>Arrhythmia/ECG changes: 1.</p>
Strik, 2023	Right ventricular leadless pacing	<p>Implantation Success: 100% (35/35)</p> <p>Primary Efficacy Endpoint (Low $\leq 2V$ & Stable Pacing Threshold at 6 Months): 97% (34/35)</p> <p>Baseline Pacing Threshold at Implantation: Mean 2.75V</p> <p>R-wave amplitude increases at 6 months: +1.4 mV ($p < 0.01$)</p>	<p>Freedom from Major Complications at 6 Months: 100% (35/35)</p> <p>Freedom from Major Complications Over Follow-up (26 SD 15 months, range 6 to 60 months): 100%</p> <p>Deaths (non-device related, because of pre-existing</p>

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		<p>Decreased impedance at 6 months: -89 ohms (p<0.01)</p> <p>Pacing threshold unchanged at 6 months: -0.11V (p=0.3)</p> <p>Pacing Threshold <1V at different time points:</p> <ul style="list-style-type: none"> • Hospital Discharge: 77% • 6 Months: 86% • 1 Year: 83% • 2 Years: 91% <p>People with >40% VP burden at 1 year: 37% (13/35)</p> <p>Follow-Up Syncope Cases: 1 presyncope despite pacemaker implantation</p> <p>Device interrogations and assessments conducted at multiple timepoints: Baseline, Discharge, 1 Month, 6 Months, 1 Year, and Yearly Thereafter</p> <p>Fluoroscopy Time for Implantation: Mean 6 (SD 5) min (range: 1 to 29 min)</p>	<p>conditions): 3</p> <p>Device-related infections: 0</p> <p>Device dislodgement: 0</p> <p>LP Retrieval Needed: 0</p> <p>1 case of pacemaker syndrome (resolved with reprogramming)</p> <p>No perforations, telemetry failure</p> <p>No major complications during follow-up</p> <p>No radiographically visible device dislodgements or telemetry failures</p>

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		<p>Final LP Position: 89% in the septum, 6% in RV apex, 6% in RV infundibulum</p> <p>Proportion of People Needing Multiple Deployments: 74% first attempt, 11% second, 11% third, 1 needed 6 deployments</p>	
Amrani, 2020	Right ventricular leadless pacing	<p>Primary Efficacy Outcome:</p> <ul style="list-style-type: none"> • Successful Implantation: 40/41 (98%) in ≥90 years group; 87/88 (99%) in <90 years group (p=0.58). • Less than 2 Repositions: 39 (98%) in ≥90 years group; 80 (92%) in <90 years group (p=0.32). • Procedure Time: 26.1 (SD 11.6) minutes in ≥90 years group; 30.3 (SD 14.2) minutes in <90 years group (p=0.11). • Fluoroscopy Time: 6.4 (SD 4.7) minutes in ≥90 years group; 7.2 (SD 4.9) minutes in <90 years group (p=0.41). • Pacing Threshold less than 1.0 V (0.24 ms): 39 (98%) in ≥90 years group; 83 (95%) in <90 years group (p=0.55). • R-wave Amplitude more than 5 mV: 93% in ≥90 years group; 92% in <90 years group (p=0.97). • Impedance (400 to 1500 OHMS): 100% in both groups. <p>Follow-up Pacing Outcomes:</p>	<p>Procedure-Related Complications:</p> <ul style="list-style-type: none"> • Major Complications: 0% (no events) in ≥90 years group; 2% (2 events) in <90 years group. • Incision Site Haematoma: 0% in ≥90 years group; 2 (2%) in <90 years group. • Pseudoaneurysm: 0% in ≥90 years group; 1 (1%) in <90 years group. <p>Mortality Rates:</p> <ul style="list-style-type: none"> • Total Deaths: 13 (32%) in ≥90 years group; 16 (18%) in <90 years group. • Non-cardiovascular Causes: 93% of deaths in both groups. • High Pacing Threshold more than 1.5 V (0.24 ms): 1 (1.5 V) in ≥90 years

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		<ul style="list-style-type: none"> • 1 month: Continued stability in thresholds; 100% <1.5 V in both groups. • 3 to 12 months: 100% of ≥90 years group-maintained threshold <1.5 V. • 24 months: Stability observed in pacing thresholds, but specific data for ≥90 years group not provided. <p>Length of Hospital Stay:</p> <ul style="list-style-type: none"> • Median stay: 3.0 days (IQR: 2.0 to 5.5) in ≥90 years group; 3.0 days (IQR: 1.0 to 9.0) in <90 years group (p=0.95). 	<p>group; 2 (1.5 V, 4.0 V) in <90 years group.</p>
Panico, 2024	Right ventricular leadless pacing	<p>Primary Efficacy Outcome: Survival Probability at 2 Years:</p> <ul style="list-style-type: none"> • LP was associated with lower all-cause mortality compared to TVP (HR=0.7, 95% CI: 0.5 to 1.0, p=0.045) <p>Complications at Follow-up: Device-related infections:</p> <ul style="list-style-type: none"> • LP: 0% (n=0), TVP: 9% (n=8) (HR=0.4, 95% CI: 0.2 to 0.8, p=0.0093). <p>Interventions on haemodialysis vascular access:</p> <ul style="list-style-type: none"> • LP: 19% (n=17), TVP: 33% (n=30) (HR=0.6, 95% CI: 0.4 to 1.1, p=0.09). <p>Annual rate of vascular interventions:</p> <ul style="list-style-type: none"> • LP: 4/10 py, TVP: 8.2/10 py (RR=0.49, 95% CI: 0.31 to 0.75, p=0.0014). 	<p>All-Cause Mortality Rates:</p> <ul style="list-style-type: none"> • In-Hospital Mortality: LP: 1.1% (n=1), TVP: 7.9% (n=7) (OR=0.13, 95% CI: 0.003 to 1.1, p=0.064). <p>Acute (<90 Days) Complications:</p> <ul style="list-style-type: none"> • Cardiac arrest: LP: 3.4% (n=3), TVP: 7.9% (n=7) (HR=0.4, 95% CI: 0.1 to 1.7, p=0.22). • Hemopericardium: LP: 1.1% (n=1), TVP: 0% (n=0). • Endocarditis or device-related infections: LP: 0%, TVP: 5% (n=4) (HR=0.4, 95% CI: 0.1 to 1, p=0.045)

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		<p>Thrombectomy/angioplasty on AVF:</p> <ul style="list-style-type: none"> LP: 3/10 py, TVP: 6.3/10 py (RR=0.5, 95% CI: 0.3 to 0.8, p=0.0034). <p>First AVF creation: LP: 0.30/10 py, TVP: 0.8/10 py (RR=0.4, 95% CI: 0.1 to 1.6, p=0.23).</p> <p>Ulterior AVF creation:</p> <ul style="list-style-type: none"> LP: 0.4/10 py, TVP: 0.8/10 py (RR=0.6, 95% CI: 0.1 to 2.1, p=0.43). <p>AVF closure/aneurysm resection:</p> <ul style="list-style-type: none"> LP: 0.3/10 py, TVP: 0.3/10 py (RR=0.9, 95% CI: 0.1 to 5.5, p=0.91). 	<p>Long-Term Complications (>90 Days):</p> <ul style="list-style-type: none"> Device-related infections: LP: 0%, TVP: 9% (n=8) (HR=0.4, 95% CI: 0.2 to 0.9, p=0.0093). DVT/PE: LP: 7.9% (n=9), TVP: 13% (n=11) (HR=1, 95% CI: 0.4 to 2.2, p=0.92). <p>Hospital Stay: LP: 6.8 days (mean), TVP: 11.2 days (mean) (mean difference=-4.4 days, 95% CI: -8.2 to 0.6 days).</p> <p>Surgical Interventions on Vascular Access: Total interventions: LP: 27, TVP: 75 (RR=0.5, 95% CI: 0.3 to 0.8, p=0.0014).</p> <p>Time before first intervention: HR=0.6, 95% CI: 0.4 to 1.1, p=0.09).</p>
Molitor, 2024	Right ventricular leadless pacing	<p>Baseline Pacing Threshold: Not reported Final Pacing Threshold: 0.6 (SD 0.4) V at 0.2 ms (jugular) versus 0.5 (SD 0.3) V at 0.2 ms (femoral), p=0.722</p>	<p>Complications (Total): 2 (jugular) versus 16 (femoral), p<0.01</p> <ul style="list-style-type: none"> Pericardial Effusion: 1 (jugular) versus 1 (femoral)

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		<p>Baseline Sensing Amplitude: Not reported Final Sensing Amplitude: 10 (SD 4.4) mV (jugular) versus 9.9 (SD 4.4) mV (femoral), p=0.799</p> <p>Baseline Impedance: Not reported Final Impedance: 772.3 (SD 218.6) ohms (jugular) versus 705.8 (SD 142.3) ohms (femoral), p=0.011</p> <p>Pacing Threshold (Day 1): 0.6 (SD 0.5) V at 0.2 ms (jugular) versus 0.5 (SD 0.4) V at 0.2 ms (femoral), p=0.446</p> <p>Sensing Amplitude (Day 1): 10.9 (SD 4.2) mV (jugular) versus 10.8 SD 4.4 mV (femoral), p=0.865</p> <p>Impedance (Day 1): 695.7 (SD 205.6) ohms(jugular) versus 662.9 (SD 131.4) ohms (femoral), p=0.188</p> <p>Pacing Threshold (Day 14): 0.6 SD 0.4 V at 0.2 ms (jugular) versus 0.6 SD 0.4 V at 0.2 ms (femoral), p=0.963</p> <p>Sensing Amplitude (Day 14): 11.4 (SD 4.4) mV (jugular) versus 11.7 (SD 4.3) mV (femoral), p=0.771</p> <p>Impedance (Day 14): 611.1 (SD 143.7) ohms (jugular) versus 605.6 (SD 96.7) ohms (femoral), p=0.675</p>	<ul style="list-style-type: none"> • Device Dislocation: 1 (jugular) versus 0 (femoral) • Arterial Injuries: 0 (jugular) versus 2 (femoral) • Major Groin Hematomas: 0 (jugular) versus 13 (femoral) <p>Positioning Success Rate (First Attempt): 70% (jugular)</p> <p>Device Deployment Attempts: Median 1 (range 1 to 8) (jugular)</p> <p>No bailout femoral access needed in jugular group: 100% success with jugular approach, no conversions</p> <p>No significant procedural discomfort or vagal reactions observed in jugular group: 0 reported cases</p> <p>No mortality reported in either group during follow-up: 0 deaths in both groups</p>

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		<p>Electrical Parameters Stability: No statistically significant changes over follow-up (14 days), jugular and femoral groups showed similar electrical behavior</p> <p>Procedure Time: 42.4 (SD 18.5) min (jugular) versus 48.94 (SD 21.04) min (femoral), p=0.02</p> <p>Fluoroscopy Time: 4.7 (SD 5.2) min (jugular) versus 7.7 (SD 7.8) min (femoral), p=0.001</p> <p>Fluoroscopy Dose: 828.7 (SD 1264.5) cG × cm² (jugular) versus 842.8 (SD 1006.3) cG × cm² (femoral), p=0.930</p>	<p>Faster participant mobilisation post-procedure compared to femoral approach: Immediate mobilisation in jugular group, compared to delayed mobilisation in femoral group</p> <p>Lower vascular complication risk with ultrasound-guided jugular puncture: Ultrasound used in all jugular cases, reducing risk of access-site complications</p> <p>Radiation Exposure: Fluoroscopy time and radiation dose were statistically significant and lower in the jugular group, contributing to overall procedural safety</p>
Tjong, 2018	Right ventricular leadless pacing	<p>HRQoL: Evaluated using the Short-Form-36 (SF-36) questionnaire.</p> <p>Baseline to 3 Months Improvement:</p> <ul style="list-style-type: none"> • Physical Functioning: Mean increase: 6.2 points; SD not specified. p-value ≤ 0.0001. • Role Physical: Mean increase: 11.3 points; SD not specified. p ≤ 0.0001. • Mental Health: Mean increase: 4.7 points; SD not specified. p ≤ 0.0001. 	<p>Activity Restrictions:</p> <ul style="list-style-type: none"> • 49% rated discharge instructions as less restrictive than traditional pacemaker systems. • 47% rated them equally restrictive, and only 4% found them more restrictive.

IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

First author, date	System	Efficacy outcomes	Safety outcomes
		<ul style="list-style-type: none"> Other domains showed significant increases (exact p-values and means for each domain are not detailed). <p>Baseline to 12 Months Improvement: Continued improvements in SF-36 scores:</p> <ul style="list-style-type: none"> Physical Component Scale: Mean at baseline: 36.3; SD 9.0. Mean at 3 months: 38.7; SD 9.1; $p < 0.001$. Mean at 12 months: 38.6; SD 9.4; $p < 0.001$. Mental Component Scale: Mean at baseline: 47.3; SD 12.5. Mean at 3 months: 50.9; SD 11.6; $p < 0.001$. Mean at 12 months: 50.7; SD 12.2; $p < 0.001$. <p>Implant Success Rate:</p> <ul style="list-style-type: none"> 720 successfully implanted out of 726 attempts (99% success rate). 	
Cabanas-Grandío, 2020	Right ventricular leadless pacing	<p>Physical Function at 6 months:</p> <ul style="list-style-type: none"> LP group: 63; SD 27 TVP group: 42; SD 26 $p < .001$ <p>Role Physical at 6 months:</p> <ul style="list-style-type: none"> LP group: 64; SD 43 	<p>Chest discomfort at 6 months:</p> <ul style="list-style-type: none"> LP group: 18% TVP group: 39% $p = .032$ <p>Restriction in physical activities because of chest discomfort at 6 months:</p> <ul style="list-style-type: none"> LP group: 11%

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		<ul style="list-style-type: none"> • TVP group: 36; SD 45 • p=.004 <p>Mental Health at 6 months:</p> <ul style="list-style-type: none"> • LP group: 75; SD 22 • TVP group: 65; SD 23 • p=.017 	<ul style="list-style-type: none"> • TVP group: 37% • p=.004 <p>Discomfort in the area of intervention at 6 months:</p> <ul style="list-style-type: none"> • LP group: 13% • TVP group: 35% • p=.017
Ueyama, 2024	Right ventricular leadless pacing	<p>In-Hospital (short-term) outcomes (part of primary outcomes):</p> <p>Length of stay (days)</p> <ul style="list-style-type: none"> • Median: Both 4.0 days • IQR: LPs: 2 to 8, TVPs: 2 to 7 • Adjusted mean difference: 1 day (95% CI: 0.2 to 1.4) • p=0.005 	<p>In-Hospital (short-term) outcomes (part of primary outcomes):</p> <p>Overall complications</p> <ul style="list-style-type: none"> • LPs: 7% • TVs: 10% • p=0.014 <p>Device-related complications</p> <ul style="list-style-type: none"> • LPs: 1% • TVPs: 2% • p=0.015 <p>Other complications (e.g. hematoma, cardiac arrest, pericarditis, etc.)</p> <ul style="list-style-type: none"> • LPs: 3% • TVPs: 5% • p=0.014

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First author, date	System	Efficacy outcomes	Safety outcomes
			<p>In-hospital death</p> <ul style="list-style-type: none"> • LPs: 2% • TVPs: 1% • p=0.17 <p>Long-term outcomes:</p> <p>All-cause death</p> <ul style="list-style-type: none"> • Adjusted HR: 1.1 • 95% CI: 1 to 1.3 • p=0.15 <p>Heart failure hospitalisation</p> <ul style="list-style-type: none"> • sdHR: 0.9 • 95% CI: 0.7 to 1.1 • p=0.24 <p>Infective endocarditis</p> <ul style="list-style-type: none"> • sdHR: 1 • 95% CI: 0.4 to 2.2 • p=0.95 <p>Device-related complications</p> <ul style="list-style-type: none"> • sdHR: 0.4 • 95% CI: 0.2 to 0.6 • p<0.001 <p>Sensitivity Analyses LPs vs TVPs (AF cohort)</p> <ul style="list-style-type: none"> • All-cause death HR: 0.9 (95% CI: 0.7 to 1.2), p=0.57

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First author, date	System	Efficacy outcomes	Safety outcomes
			<ul style="list-style-type: none"> • Device-related complications sdHR: 1 (95% CI: 0.4 to 2.4), p=0.97 <p>LPs vs TVPs (non-AF cohort)</p> <ul style="list-style-type: none"> • All-cause death HR: 1.2 (95% CI: 0.9 to 1.6), p=0.23 • Device-related complications sdHR: 0.2 (95% CI: 0.1 to 0.7), p=0.017
Nair, 2025	Right atrial leadless pacing (either as a single chamber pacing or as part of a dual chamber leadless pacing)	<p>Implantation success: 100% (75/75) Total procedure duration: mean 36.3 minutes. LP implant duration (from insertion to removal of catheter): mean 21.6 minutes. De novo implants procedure time (which did not include existing transvenous hardware removal): mean 32.3 minutes.</p> <p>Device positioning: Right atrial appendage base: 82.7% Posterior base of appendage: 42.7% Anterior base of appendage: 33.3% Free wall: 12.0% Mid-to-deep appendage: 3.0% Bachmann's bundle: 1.3%.</p>	<p>Acute procedural complications: 0</p> <p>Repositioning rate: 5.3% (4/75) (in 1 person repositioning was done because leadless pacemaker could not be released from the catheter and in 3 people repositioning was done twice because of inadequate electric parameters). No repositioning needed in 94.7% (71/75).</p> <p>30-day complications: 0 There were no perforations, device dislodgements, pacing or sensing changes needing reintervention, groin haematomas, vascular</p>

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		<p>Device performance, mean (SD): Pacing capture threshold (PCT) during prefixation=1.1 (1.1) volts improved at discharge to 0.6 (0.6) volts, p<0.001. 91.5% of people had PCT 3.0 volts or less at release and this improved at discharge to 98.6%.</p> <p>Sensed amplitudes during prefixation=2.1 (1.0) millivolts improved by discharge to 2.9 (1.5) millivolts, p<0.001. 94.7% of people had sense amplitude 1.0 millivolts or higher at LP release and this improved at discharge to 100%.</p> <p>Pacing impedance at prefixation=315 (44) ohms and remained stable at mapping, release and discharge at 329 (46) ohms</p>	<p>complications, pericardial effusions or tamponade.</p>
von Felten, 2025	Right atrial leadless pacing (either as a single chamber pacing or as part of a dual chamber leadless pacing)	<p>Implantation success: 100% (45/45)</p> <p>Median procedure time Overall: 30 minutes (IQR 25 to 35) Atrial device (AR) only (n=14): 25 minutes De novo dual chamber system (DR) (n=22): 35 minutes DR upgrade (from ventricular device-VR to DR) (n=9): 30 minutes</p> <p>Device positioning: AR: 100% at right atrial appendage base</p>	<p>Procedure related complications Device repositioning: 0 Acute complications: 0</p> <p>Complications (at median 21 days): Pericardial effusion (managed conservatively): 4.4% (2/45)</p> <p>Device dislodgements or dislocations: 0</p>

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		<p>VR: 67.7% Midseptal; 22.5% inferoseptal, 9.7% anteroseptal.</p> <p>Electric performance</p> <p>Median impedance</p> <p>AR: was 340 ohms (IQR 290 to 380, n=45) at implantation, which improved to 310 ohms (IQR 295 to 340, n=44) at follow-up (median 21 days).</p> <p>VR: was 820 ohms (IQR 757.5 to 1140, n=28) at implantation, which improved to 710 ohms (IQR 555 to 850, n=31) at follow-up.</p> <p>Median sensing</p> <p>AR: was 1.5 millivolts (IQR 1.0 to 2.3, n=44) at implantation, which improved to 3.75 millivolts (IQR 2.7 to 4.7, n=44) at follow-up.</p> <p>VR: was 5.25 millivolts (IQR 3.6 to 7.9, n=26) at implantation, which improved to 10.1 millivolts (IQR 8.41 to 2.9, n=24) at follow-up.</p> <p>Median PCT</p> <p>AR: was 1.875 volts/0.4 ms (IQR 1.5 to 3.47, n=38) at implantation which improved to 0.5 volts/0.4 ms (IQR 0.5 to 0.5, n=41) at follow-up.</p> <p>VR: was 1.26 volts/0.4ms (IQR 0.75 to 2.93, n=28) at implantation, which improved to 0.5 volts/0.4ms (IQR 0.43 to 0.53, n=31) at follow-up.</p> <p>Median estimated battery life (at follow-up: median 21 days)</p>	

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		<p>AR: 6.8 years (IQR 5.3 to 11.2) VR: 10.4 years (IQR 9 to 12.2). AR versus DR: (11.9 years, IQR 10.5 to 14.1 versus 5.8 years, IQR 5.1 to 6.9, p=0.001).</p> <p>Implant to implant communication (in 29 people with DR system at mean 21 days) Median implant to implant throughput achieved: 88% (IQR 80 to 94) for atrial to ventricular and 87% (IQR 71 to 95) for ventricular to atrial.</p> <p>The median implant to implant setting level was 5 (IQR 4 to 5) in the AR and 4 (IQR 4 to 5) in the VR.</p>	
Knops, 2023 (Aveir DR i2i Study, NCT05252702)	Dual chamber leadless pacing	<p>Atrial capture threshold:</p> <ul style="list-style-type: none"> Baseline: Not provided 90 Days: 0.8 (SD 0.7) V <p>Atrial sensing amplitude (P-wave amplitude):</p> <ul style="list-style-type: none"> Baseline: Not provided 90 Days: 3.6 (SD 1.9) mV <p>AV synchrony success:</p> <ul style="list-style-type: none"> Baseline: Not applicable 90 Days: 97% (95% CI: 95.4 to 99.3, p<0.001) <p>Successful device implantation rate:</p> <ul style="list-style-type: none"> At Procedure: 98% (295/300) <p>Mean atrial pacing capture threshold:</p> <ul style="list-style-type: none"> 90 Days: 0.8 (SD 0.7) V 	<p>Freedom from device- or procedure-related serious adverse events:</p> <ul style="list-style-type: none"> 90 Days: 90% (95% CI: 87 to 94%, p<0.001) <p>Incidence of device- or procedure-related complications:</p> <ul style="list-style-type: none"> 90 Days: 10% (29 out of 300, 35 events total) <p>Incidence of AF:</p> <ul style="list-style-type: none"> 90 Days: 3% (9), 5 people had prior history. <p>Incidence of pericardial effusion:</p> <ul style="list-style-type: none"> 90 Days: 1% (2), 1 needed pericardiocentesis

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First author, date	System	Efficacy outcomes	Safety outcomes
		<p>Mean P-wave amplitude:</p> <ul style="list-style-type: none"> 90 Days: 3.6 (SD 1.9) mV <p>Mean AV synchrony percentage:</p> <ul style="list-style-type: none"> 90 Days: At least 95% across all postures and activities <p>Overall AV synchrony across multiple postures and gaits:</p> <ul style="list-style-type: none"> Sitting: 98% (95% CI: 97 to 99%) Supine: 97% (95% CI: 95 to 98%) Left lateral recumbent: 97% (95% CI: 96 to 99%) Right lateral recumbent: 97% (95% CI: 96 to 99%) Standing: 98% (95% CI: 98 to 99%) Normal walk: 98% (95% CI: 98 to 99%) Fast walk: 98% (95% CI: 97% to 99%) 	<p>Incidence of device dislodgement (intraprocedural and postprocedural):</p> <ul style="list-style-type: none"> Intraprocedural: 2% (5) Postprocedural: 2% (5), occurring at 26 SD 17 days after implantation. <ul style="list-style-type: none"> Incidence of complete AV block at 90 Days: 1 Incidence of loss of implant-to-implant communication at 90 Days: 1 Intermittent capture in the ventricular LP at 90 days: 1 Incidence of access site bleeding at 90 Days: 1 Incidence of retroperitoneal hematoma at 90 Days: 1 Incidence of heart failure at 90 Days: 1 Incidence of syncope at 90 Days: 1, resulted in distal phalanx fracture. Incidence of pleural effusion at 90 Days: 1

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First author, date	System	Efficacy outcomes	Safety outcomes
			<ul style="list-style-type: none"> • Incidence of urinary retention at 90 Days: 3 • Incidence of oral pain at 90 Days: 1, led to tooth extraction. • Device revision procedures (retrieval and reimplantation) at 90 Days: 8 revision procedures performed; 6 received new pacemakers. <p>Mortality rate (all-cause deaths) at 90 Days: 4 deaths (1%)</p> <ul style="list-style-type: none"> • Causes: Cardiac arrest (2), malignancy (1), sepsis (1) <p>None were device- or procedure-related.</p>
Knops, 2025 (Aveir DR i2i Study, NCT05252702)	Dual chamber leadless pacing	<p>Implantation success (with established implant to implant communication): 98.3% (295/300) Unsuccessful atrial implants: n=2 Inadequate implant to implant communication: n=3.</p> <p>Primary performance endpoint: Atrial capture threshold 3.0 volts or less at 0.4 ms and sensing amplitude P-wave 1.0 millivolts or higher at 12 months: 92.8% (95% CI: 89.7 to 95.8). Performance goal: >80.0% (p<0.001).</p>	<p>Primary Safety Endpoint: 12-month complication-free rate: 88.6% (95% CI 84.5 to 91.8) Performance goal: more than 76.5% (p<0.001). 3-month complication-free rate: 90.3%.</p>

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		<p>Atrial electrical performance success at 3 months: 90.2%.</p> <p>Atrial device performance at 12 months, mean (SD): Capture threshold: 0.83 (0.62) volts at 0.4 ms P-wave amplitude: 3.51 (1.87) millivolts Impedance: 312 (48) ohms, decline from 331 (68) ohms at implantation.</p> <p>Implant to implant communication at 12 months: Ventricular-to-atrial success: 87.5% Atrial-to-ventricular success: 90.3% AV synchrony success at 3 months: 97.3%.</p> <p>Battery longevity at 12 months, mean (SD): Atrial device remaining longevity: 5.4 (4.0) years (95% CI 4.9 to 5.9) Ventricular device remaining longevity: 10.3 (5.5) years (95% CI 9.6 to 11.0) Programming-specific longevity: • <u>Single-chamber mode sub-cohort (18.5%):</u> Atrial: mean 8.9 years (95% CI 6.7 to 11.1) Ventricular: mean 18.1 years (95% CI 15.9 to 20.4). • <u>Dual-chamber mode only:</u> Atrial: mean 4.7 years (95% CI 4.4 to 5.0)</p>	<p>Complication rate at 12 months: 11.3% (n=34/300, 41 events).</p> <p>Timing of complications: Within 2 days: 68.3% of all complications (28 events, n=24 people) 3 to 90 days: 7 additional complications (7 people) 91 to 365 days: 6 new complications (6 people, 2.0%).</p> <p>Complications: 11.3% (41 events in 34 people) Cardiac arrhythmia (mostly AF): 3.3% (n=10) Device dislodgement: 3.4% Intra-procedural dislodgement: 1.7% (n=6) Post-procedural dislodgement: 1.7% (n=5) Capture threshold issues: 1.3% (n=4) Pericardial effusion: 0.7% (n=2) Urinary retention: 1.0% (n=3) Threshold elevation: n=2 Heart failure: n=2</p>

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		<p>Ventricular: mean 8.7 years (95% CI 8.3 to 9.1).</p> <p>Indication specific longevity:</p> <ul style="list-style-type: none"> • Sinus node dysfunction: atrial 5.3 years, ventricular 11.6 years • AV block: atrial 5.8 years, ventricular 7.9 years. 	<p>Oral pain: n=1</p> <p>Pleural effusion: n=1</p> <p>Presyncope: n=1</p> <p>Syncope: n=1</p> <p>Haematoma: n=1</p> <p>Access site bleeding: n=1</p> <p>Oversensing: n=1</p> <p>Inappropriate magnet mode: n=1 (firmware updated).</p> <p>Device revisions (all successful): n=14</p> <p>LP replacement in 9</p> <p>CRT-P device in 2</p> <p>Transvenous dual chamber in 1</p> <p>No replacement device in 2</p> <p>Indications for revision were atrial device dislodgement (in 6), suboptimal implant-to-implant communication (in 1), and intermittent ventricular capture (in 1), threshold elevation of one or both devices (in 3), a change in medical condition (in 2), and mechanical dislodgement of the atrial device during cardiac surgery (in 1).</p> <p>Deaths (not procedure or device related): 2.7% (8/300)</p>

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			4 were within 90 days and 4 happened between 251 and 341 days.
Reddy, 2025 (Aveir DR i2i Study, NCT05252702)	Dual chamber leadless pacing	<p>Battery longevity at 12 months (values are shown as median and IQR):</p> <p>Atrial leadless pacemaker (ALP) remaining longevity: 4.3 years [3.5, 5.1]</p> <p>ALP total longevity: 5.3 years [4.4, 6.1]</p> <p>Ventricular leadless pacemaker (VLP) remaining longevity: 9.1 years [6.8, 10.7]</p> <p>VLP total longevity: 9.9 years [7.7, 11.7].</p> <p>Programmed parameters at 12 months</p> <p>DDD mode: 65.2% (197/302)</p> <p>DDDR mode: 33.4% (101/302)</p> <p>DDI/DDIR mode: 1.4% (4/302)</p> <p>Median base rate: mean 60 beats per minute [IQR 50, 60]</p> <p>Rate-response disabled: 65.6% (198/302)</p> <p>ALP pulse amplitude: mean 1.25 volts [IQR 1.25, 2.0] (87.7% at 0.4 ms pulse width)</p> <p>VLP pulse amplitude: mean 1.5 volts [IQR 1.25, 2.0] (93.7% at 0.4 ms pulse width)</p> <p>ALP-to-VLP implant to implant communication (i2i) setting: mean 5 [IQR 4, 6] out of 7</p> <p>VLP-to-ALP i2i setting: mean 5 [IQR 4, 6] out of 7</p>	<p>Device revisions before 12 months: 5.4% (24/446)</p> <p>Dislodgement: n=13 (11 VLP and 2 ALPs)</p> <p>Capture threshold elevation: n=7 (in 2 ALP, 4 VLP and both in 1 person).</p> <p>Implant to implant communication issue: n=1</p> <p>Upgrade to CRT-P: n=2.</p>

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		<p>Device Performance at 12 months (values are shown as median and IQR):</p> <p>ALP pacing percentage: 20.5% [3.0, 56.0] VLP pacing percentage: 15.0% [2.0, 80.0] ALP event rate: 67.9 events per minute [61.0, 74.9] VLP event rate: 67.0 events per minute [60.3, 73.4] ALP impedance: 310 ohms [280, 340] VLP impedance: 600 ohms [500, 702].</p> <p>Longevity impact factors:</p> <p>Base rate, pulse amplitude, pacing percentage, event rate, impedance, and i2i setting level all exhibited significant correlations with ALP and VLP longevities (p<0.001). Programming i2i setting levels below 7 produced the greatest longevity savings.</p>	

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Procedure technique

Most procedures were done using femoral vein access, but jugular vein access was also used.

Final device positioning differed between groups in the RCT of 51 people (Garweg 2023). None of the LPs were placed at the ventricular apex, whereas 6 out of 24 (25%) TVPs needed apical placement because of inadequate pacing parameters in non-apical positions.

In the systematic review and meta-analysis (Oliveira 2023) of 21 studies, LP devices included the Micra (Medtronic, Minnesota) in 15 studies, Nanostim device in 2 studies, both Micra and Nanostim in 3 studies, while 1 study did not specify the LP device used.

Most studies used single-chamber LPs but the studies by Knops (2023, 2025) Reddy (2025), and von Felten (2025) used a dual-chamber LP. Dual-chamber LP may need alternative access strategies compared to single-chamber implantation. The Aveir DR i2i (Abbott Medical) dual-chamber LP system was implanted percutaneously via the femoral vein.

Efficacy

Successful Implantation

This outcome was reported in 12 studies and ranged from 98 to 100% for LPs.

A randomised controlled trial of 51 people reported a 100% implantation success rate in both LP and TVP groups. The first-attempt success rate was statistically significantly higher in the LP group (96%; 26 out of 27) compared to the conventional pacemaker group (63%; 15 out of 24, $p < 0.001$). Despite this difference, the median total implantation time was similar between groups (LP: 35 minutes, IQR: 31 to 45; TVP: 35 minutes, IQR: 20.3 to 47.8, $p = 0.999$). Venous access time was statistically significantly longer in the LP group (17 minutes,

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IQR: 14 to 19) compared to the TVP group (7 minutes, IQR: 6 to 14, $p < 0.001$), likely because of additional procedural steps needed for LP implantation, such as routine RV angiography and the use of temporary pacing guide wires in 18 people (Garweg 2023).

In the meta-analysis by Mhasseb (2025), the overall rate of successful implantation was 99% (95% CI 98 to 100%) in the LP group and 98% (95% CI 97 to 99%) in the TVP group ($p = 0.07$). The authors noted that TVP implantation was associated with a higher rate of procedural complications, which contributed to early implantation failures.

The 5-year follow-up of the Micra PAR study (El-Chami 2024) reported a 99% implantation success rate, with the Micra VR successfully implanted in 1,792 out of 1,809 people. Similarly, in the PACES registry study by Shah (2023), which included 63 children and young people, the implantation success rate was 98% (62 out of 63).

A retrospective study of young adults (Strik 2023) involving 35 people aged 18 to 40 years reported a 100% successful implantation rate for the Micra VR LP, with no technical failures or abandoned procedures. Similarly, a prospective observational study (Amrani 2020) including 129 elderly people found no statistically significant difference in success rates between age groups, with implantation being successful in 98% (40 out of 41) of people aged 90 or above and 99% (87 out of 88) in people younger than 90 ($p = 0.58$).

A propensity score-matched retrospective cohort study (Panico 2024) of people using haemodialysis reported implantation success rates of 99% for LPs and 100% for TVPs.

In a prospective study of 200 people (Molitor 2024), comparing jugular versus femoral vein approaches, the success rate was 100% (100 out of 100) with jugular vein access. Success rate in the femoral group was not reported.

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In the prospective study of 720 people (Tjong 2018), 99% people had successful LP implantation.

For dual-chamber LP implantation, a prospective study (Knops 2023) of 300 people reported an implantation success rate of 98% (295 out of 300), based on achieving effective implant-to-implant communication.

For atrial pacing implantation alone, a prospective study (Nair 2025) of 75 people with sinus node dysfunction reported 100% successful implantation, placed predominantly in the right atrial appendage base (83%). The total procedure duration was 36 minutes. Prefixation mapping made repositioning unnecessary in 95% of implants.

In a prospective study of 45 people who had an atrial leadless pacemaker either as a standalone therapy or as part of a dual chamber leadless pacemaker system, an atrial leadless pacemaker was implanted successfully in all without device repositioning or dislocation (von Felten 2025). The median procedure time was 35 minutes.

Adequate Pacing Performance

The randomised controlled trial of 51 people comparing LPs with TVPs reported similar VP percentages at 12 months (LP: 58% versus TVP: 62%, $p=0.744$). However, paced QRS duration was statistically significantly shorter in the LP group (median 158 ms, IQR: 146 to 166) than in the conventional pacemaker group (164 ms, IQR: 158 to 178, $p=0.024$). Additionally, pacing efficiency was superior in the LP group, with a statistically significant lower mean pacing threshold at 12 months (0.4 V versus 0.7 V, $p<0.001$) and higher mean R-wave sensing (14.2 mV versus 10.4 mV, $p=0.021$), (Garweg 2023).

Similarly, a meta-analysis of 21 studies by Oliveira (2025) found that LPs demonstrated a statistically significant lower pacing capture threshold than TVPs, with a mean difference (MD) of -0.2 V (95% CI -0.2 to -0.2 V, $p<0.01$). No

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statistically significant difference in impedance was observed (MD 32.6 ohms, 95% CI -22.5 to 87.8 ohms, $p=0.25$).

The ability of LPs to achieve AV synchrony was specifically assessed in a systematic review and meta-analysis of 8 observational studies by Wu (2023). The pooled AV synchrony proportion across these studies was 79% (95% CI 72 to 86%), with individual study results ranging from 63% to 89%. Additionally, programming optimisation led to an 11% improvement in synchrony (95% CI 7 to 16%, $p<0.01$), demonstrating the adaptability of LPs in improving pacing performance over time.

Long-term observational studies further support these findings. The Micra PAR 5-year follow-up study (El-Chami 2024), involving 1,809 people, documented stable pacing capture thresholds, with initial values of 0.7 V at 0.2 ms at implant, which remained consistent at 0.7 at 0.2 ms at 60 months. Pacing impedance declined from 727 ohms at implantation to 533 ohms at 60 months, while sensing amplitude improved from 10.7 mV to 13.1 mV over the same period. Additionally, the Micra AV CED registry study (El-Chami 2024), which included 118,110 people, demonstrated that AV synchrony with LP ranged between 80% and 84%, over a 2-year follow-up period.

Findings from paediatric and younger adult populations also indicated stable electrical performance over time. The retrospective PACES study (Shah 2023) involving 63 children and young people reported that capture thresholds decreased over time, with an initial mean of 0.8 V at 0.2 ms, which declined to 0.7 V at 1 to 4 months, and 9 to 12 months. Similarly, in the retrospective study of young adults (aged 18 to 40 years) by Strik (2023), the pacing efficacy endpoint was met in 97% of people at 6 months, with 1 person having a pacing threshold above 2 V. Additionally, mean R-wave amplitude increased from baseline to 6 months (1.4 mV, $p<0.01$), while impedance decreased (-89 ohms, $p<0.01$), which

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was statistically significant. At 2 years, 91% of population maintained a pacing threshold below 1 V.

Among an elderly population, findings were similarly positive. The prospective observational study (Amrani 2020) reported that 99% of people aged 90 or above had a pacing threshold below 1.5 V at 0.2 ms, demonstrating electrical stability with no statistically significant differences compared to the younger cohort. The propensity score-matched retrospective cohort study of people on haemodialysis found that LPs maintained stable electrical parameters, with a mean pacing threshold of 0.5 V at implantation, remaining consistent over a median follow-up of 24 months (Panico 2024).

The impact of venous access approach on pacing performance was evaluated in a prospective study (Molitor 2024) of 200 people, comparing jugular and femoral approaches. Pacing thresholds for the jugular approach remained stable over time, measured at 0.6 V at implantation, Day 1, and Day 14. These values were comparable to those observed with the femoral approach, which showed thresholds of 0.5 V at implantation and Day 1, and 0.61 V at Day 14. Sensed amplitudes in the jugular group increased from 10.0 mV at implantation to 10.9 mV on Day 1 and 11.4 mV on Day 14, closely matching the femoral group, which recorded 9.9 mV, 10.8 mV, and 11.7 mV at the same time points. No deterioration in electrical performance was observed. Lead impedance was initially higher in the jugular group at 772.3 ohms; SD 218.6 ohms at implantation, compared to 705.8 ohms; SD 142.3 ohms in the femoral group ($p=0.011$), but differences diminished over time, with values of 695.7 ohms (SD 205.6) versus 662.9 ohms (SD 131.4) on Day 1 ($p=0.188$) and 611.1 ohms (SD 143.7) versus 605.6 ohms (SD 96.7) on Day 14 ($p=0.675$), indicating comparable long-term electrical performance between the 2 approaches.

The performance of dual-chamber LPs was assessed in a prospective single-group study (Knops 2023) of 300 people, evaluating atrial capture threshold and

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sensing amplitude. At 3 months, 90% of population met predefined criteria for adequate atrial capture threshold (less than or equal to 3.0 V at 0.4 ms) and atrial sensing amplitude (P-wave more than or equal to 1 mV) (95% CI 86.8 to 93.6, $p < 0.001$). The mean atrial capture threshold was 0.8 V (SD 0.7), and mean P-wave amplitude was 3.6 mV (SD 1.9), indicating stable pacing function. Long-term follow-up at 12 months (Knops 2025), confirmed that the primary performance end point was achieved in 92.8% of people (95% CI, 89.7 to 95.8; $p < 0.001$).

The pacing performance of single chamber atrial leadless pacemaker alone was assessed in the study of 75 patients with isolated sinus node dysfunction (Nair 2025). The analysis showed significant improvement in capture threshold and sensed amplitude from leadless pacemaker release to patient discharge (early post implant period). In the prospective study of 45 patients who had an atrial leadless pacemaker either as a standalone therapy or as part of a dual chamber leadless pacemaker system, sensing, impedance, and stimulation thresholds of the atrial and ventricular device remained stable or improved over a median follow-up of 21 days. Median implant-to-implant communication throughput was 88% for atrial to-ventricular and 87% for ventricular-to-atrial transmission, indicating reliable device to device communication.

6 minute Walk Test (6MWT)

In the randomised controlled trial of 51 people, there was no significant decline in 6MWT distance over 12 months in either group ($p = 0.577$), and the difference between LP and TVP groups at 12 months was also not statistically significant ($p = 0.088$) (Garweg 2023).

Cardiac Function

A key finding from the RCT study (Garweg 2023) was the preservation of tricuspid valve function in LP population. Over the study period, tricuspid regurgitation statistically significantly worsened in the TVP group ($p = 0.001$),

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whereas it remained stable in the LP group ($p=0.195$). By 12 months, there was no progression of tricuspid regurgitation in 58% of those in the LP group compared with 13% of those in the TVP group ($p=0.009$). Additionally, at 12 months, tricuspid regurgitation worsened in 70% of the TVP population but in only 31% of the LP group ($p=0.009$). The difference for mitral regurgitation was not statistically significant ($p=0.304$).

A notable difference was observed in NT-proBNP levels, a biomarker for heart failure progression. At baseline, levels were comparable between groups (LP: 1176 pg/dl, IQR: 603 to 2357; TVP: 907 pg/dl, IQR: 410.5 to 2345.8, $p=0.355$). By 12 months, NT-proBNP levels had increased in the TVP group but had decreased in the LP group. The final median NT-proBNP level was 970.0 pg/dl (IQR: 536.0 to 1453.5) in the LP group compared to 1394.0 pg/dl (IQR: 1030.0 to 2245.5) in the TVP group ($p=0.041$). Interaction analysis confirmed a statistically significant overall difference between groups ($p=0.013$).

Length of Hospital Stay

In the prospective study of 129 elderly individuals (Amrani 2020), hospital stay was similar across age groups, with a median of 3.0 days in both the people aged 90 and more and less than 90 years. The IQR was 2 to 5.5 and 1 to 9 days, respectively, with no significant difference ($p=0.95$).

In the propensity score-matched study of people on haemodialysis (Panico 2024), those who had LPs had a statistically significantly shorter hospital stay (mean: 6.8 days) compared to those with TVPs (mean: 11.2 days, $p=0.0014$).

The retrospective cohort study by Ueyama (2024) including 10,338 people who had TAVR reported that the median length of stay was 4 days for both LP and TVP groups. The IQR was slightly wider for LPs (2 to 8 days) compared to TVPs (2 to 7 days). The length of stay was significantly longer with leadless pacemakers compared to transvenous pacemakers (adjusted mean difference 0.8 days; 95% CI: 0.2 to 1.4; $p=0.005$).

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Health-related Quality of Life

The prospective multi-centre clinical trial of 720 people (Tjong 2018) evaluated HRQoL using the Short-Form-36 (SF-36) questionnaire, revealing significant improvements from baseline to 3 months post-implantation of the LPs.

Specifically, Physical Functioning improved by an average of 6.2 points ($p \leq 0.0001$), Role Physical increased by 11.3 points ($p \leq 0.0001$), and Mental Health rose by 4.7 points ($p \leq 0.0001$). Continued improvements were observed at 12 months, with the Physical Component Scale showing mean scores of 36.3 (SD 9.0) at baseline, 38.7 (SD 9.1) at 3 months ($p < 0.001$), and 38.6 (SD 9.4) at 12 months ($p < 0.001$). The Mental Component Scale recorded mean scores of 47.3 (SD 12.5) at baseline, 50.9 (SD 11.6) at 3 months ($p < 0.001$), and 50.7 (SD 12.2) at 12 months ($p < 0.001$).

In the retrospective study of 106 people (Cabanas-Grandio 2020), in terms of physical functioning, the LP group scored an average of 63 with a standard deviation of 27, while the TVP group had a lower average score of 42 (SD 26), yielding a statistically significant difference ($p < .001$). Similarly, for role physical, the LP group scored an average of 64 (SD 43) compared to 36 (SD 45) in the TVP group, with $p = .004$ indicating a statistically significant difference. Mental health scale for LP group had an average score of 75 (SD 22), contrasted with the TVP group's average of 65 (SD 23), resulting in a statistically significant p -value of .017. These metrics were assessed using the SF-36 questionnaire.

Device Durability

The RCT by Garweg (2023), reported higher impedance values in the LP group suggesting lower current drain and potentially extended battery longevity. At 12 months, pacing impedance was 661.2 ohms (SD 133.1) in the LP group versus 447.4 ohms (SD 121.8) in the TVP group ($p < 0.001$). Furthermore, pacing thresholds remained statistically significantly lower in the LP group at all time points ($p < 0.001$).

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The meta-analysis by Mhasseb (2025) reported that LPs had a lower incidence of generator malfunction than TVPs (LogOR=-0.5, p=0.13). Battery longevity was also evaluated, with a median projected lifespan of 6.8 years, and a 12.1-year median battery life. Battery depletion was reported in less than 1% of LPs, indicating a high degree of durability.

Long-term observational data further support these findings. The Micra PAR 5-year follow-up study (El-Chami 2024) reported that at 5 years, the projected median battery longevity was 6.8 years, with 84% of people having at least 5 additional years of battery life remaining. Device durability remained high, with only 2% of devices needing replacement because of elevated pacing thresholds or battery depletion.

Among paediatric and younger populations, LPs also demonstrated favourable long-term performance. The Children PACES registry study (Shah 2023), which included 63 people, projected battery longevity using Monte Carlo methods, estimating that 90% of the 55 people with available follow-up data would exceed 8 years of battery life. The retrospective study (Strik 2023) of young adults undergoing LP implantation, with an average follow-up of 26 months; SD 15 months (range: 6 to 60 months), indicated stable device performance, with no reported instances of pacemaker failure, extraction, or retrieval during the study period.

The prospective study of 129 elderly individuals (Amrani 2020) reported that LPs had optimal electrical performance, with no reported device failures, dislodgements, migrations, or malfunctions over a 2-year follow-up period. During the 3-month follow-up after implantation, 93% of people aged less than 90 years and all people aged 90 or above maintained stable pacing thresholds of less than 1.5 V.

A prospective study (Reddy 2025) evaluating dual chamber pacemakers in 302 people (with primary indications of sinus node dysfunction [58%] and IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

atrioventricular block [27%] reported that median remaining battery life at 12 months was 4.3 years for atrial leadless pacing and 9.1 years for ventricular leadless pacing; total estimated longevity was 5.3 years (for atrial leadless pacing) and 9.9 years (for ventricular leadless pacing). Lower programming i2i setting levels below 7 provided the longevity savings. Base rate, pulse amplitude, pacing percentage, event rate, impedance, and i2i setting level were all statistically significantly correlated with ALP and VLP longevity ($p < 0.001$).

The prospective study of 45 people (von Felten 2025) who had an atrial leadless pacemaker either as a standalone therapy or as part of a dual chamber leadless pacemaker system, reported that the estimated median battery life of the atrial device was statistically significantly longer in single chamber mode compared to dual chamber settings (11.9 years versus 5.8 years, $p = 0.001$).

Safety

Cardiac perforation

The meta-analysis by Mhasseb (2025) reported that cardiac perforation was statistically significantly higher in the LP group than the TVP group. Among the 10 studies included in the analysis, 8 studies documented a greater risk of perforation in LPs (LogOR=1, $p < 0.001$). However, Oliveira (2025), in a separate meta-analysis, found no statistically significant difference in myocardial perforation rates between LPs and TVPs (OR=1.8, 95% CI 0.5 to 6.5, $p = 0.39$).

Findings from large observational studies support the low absolute incidence of cardiac perforation. The Micra PAR 5-year follow-up study (El-Chami 2024) reported 1 case of cardiac perforation among 1,809 people. Similarly, the retrospective PACES registry study (Shah 2023) recorded 1 case of cardiac perforation with pericardial effusion in a 7-year-old, 19 kg child, where the device had been deployed at the RV apex. This complication led to cardiac tamponade, which was successfully managed with pericardiocentesis, allowing the device to remain in place without further issues.

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In elderly populations, the prospective study of 129 people (Amrani 2020) documented 1 case of cardiac perforation occurring in a person aged under 90 years. This complication was observed early in the implantation experience of the clinical team, suggesting that operator experience may play a role in procedural safety.

The propensity score-matched retrospective cohort study (Panico 2024) of people on haemodialysis found that cardiac perforation was not commonly reported in either LP or TVP groups. 1 case of haemopericardium was recorded in the LP group, potentially because of perforation, though no statistically significant difference was observed compared to the TVP group (0% incidence, $p=0.07$).

Cardiac tamponade

The meta-analysis by Mhasseb (2025) reported a 0.33% cumulative incidence of cardiac tamponade in those who had LPs, consistent with findings (0.33% cumulative incidence) from the Oliveira (2025) study, which found a statistically significantly increased risk in the LP group compared to the TVP group (OR 3.8, 95% CI 2.4 to 5.8, $p<0.01$). Observational data from the Micra PAR follow-up study (El-Chami 2024), included 6 cases of cardiac tamponade (less than 1%) among 1,809 people.

Pericardial effusion

The meta-analysis of 21 studies by Oliveira (2025) reported a statistically significantly higher risk of pericardial effusion in the LP group compared to the TVP group (OR 2.5; 95% CI 1.4 to 4.4, $p<0.01$). The systematic review and meta-analysis by Wu (2023) reported 4 cases of pericardial effusion in their study cohort ($n=464$).

The occurrence of pericardial effusion was consistently low across studies, with 1 case reported in each of the Micra PAR 5-year follow-up study (El-Chami 2024), the children PACES registry (Shah 2023), and both the jugular and IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

femoral approach groups in a prospective study of 200 people (Molitor 2024). These findings suggest that pericardial effusion remains a rare complication, regardless of population or venous access approach.

In the prospective single-group study (Knops 2023) of 300 people who had dual-chamber LPs, pericardial effusion was reported in 2 people (1%), with 1 needing pericardiocentesis, while the other was managed conservatively.

In the prospective study of 45 people who had an atrial leadless pacemaker either as a standalone therapy or as part of a dual chamber leadless pacemaker system, 2 people (4%) developed pericardial effusions. Both were self-limiting and were managed conservatively (von Felten 2025),

Pulmonary oedema

In the Micra PAR 5-year follow-up study including 1,809 people (El-Chami 2024), there was 1 report of pulmonary oedema during the follow-up period.

Atrial Fibrillation (AF)

The Micra PAR 5-year follow-up study (El-Chami 2024) reported that AF was more common in people who had LPs compared to historical TVP cohorts, though precise incidence rates were not reported.

In a prospective study (Knops 2023) involving 300 people implanted with dual-chamber LPs, AF was the most common arrhythmic complication, occurring in 9 people (3%). Of these, 5 people had a prior history of atrial arrhythmias. In 8 people, AF occurred either during or immediately after implantation of the atrial LPs. All AF cases were successfully managed with pharmacological or electrical cardioversion.

Device failure (dislodgement, migration, embolisation, malfunction, battery issues)

The meta-analysis by Mhasseb (2025) reported that device dislodgement was lower in the LP group than in the TVP group. Among the 10 studies assessing this outcome, 8 documented a statistically significantly higher risk of dislodgement in TVPs (LogOR=-1.1, $p<0.001$). Lead dislodgement was less common in the LP group (0.1%) compared to the TVP group (1%, $p<0.001$) and there were a 70% lower odds of pacing failure because of lead dislodgement in the LP group compared to the TVP group (OR=0.3, 95% CI: 0.2 to 0.4).

Additionally, generator malfunction was more frequent in TVPs (LogOR=-0.5, $p=0.13$), though this difference was not statistically significant. Similarly, a meta-analysis by Oliveira (2025) found that people who had LPs were at lower risk of lead dislodgement compared to those with TVPs (OR 0.3, 95% CI 0.2 to 0.6, $p<0.01$), a finding attributed to the absence of transvenous leads in LPs. 1 case of device dislodgement was reported in the systematic review by Wu (2023).

The Micra PAR 5-year follow-up study (El-Chami 2024) of 1,809 people documented 2 cases of device dislocation without embolisation (less than 1%) and 1 case of embolisation during implantation. Additionally, battery depletion in the presence of elevated thresholds was reported in 12 people. In the larger Micra AV CED registry study (El-Chami 2024) of 118,110 people, device-related complications were statistically significantly lower in LP population (219 out of 7,552; 3%) compared to TVP population (7,518 out of 110,558; 7%, $p<0.0001$). Dislodgement was observed in 1% (38 out of 7,552) of LP population versus 3% (3,095 out of 110,558) of TVP population ($p<0.0001$), and mechanical failure occurred in 1% (60 out of 7,552) versus 2% (1,658 out of 110,558) ($p<0.0001$).

The propensity score-matched retrospective study of people on haemodialysis found that lead-related complications were higher in the TVP population (Panico 2024). Lead fractures and dislodgements were observed exclusively in those who had TVPs (9%), whereas no cases of lead dislodgement, migration, embolisation, IP overview: leadless cardiac pacemaker implantation for bradyarrhythmias

or battery malfunction were reported in the LP group (HR 0.4, 95% CI 0.2 to 0.9, $p=0.0093$). The prospective study (Molitor 2024) of 200 people comparing venous access sites reported only 1 case of device dislocation in the jugular approach group, which was the only device-related complication documented in that study. In the retrospective cohort study of 10,338 people who had TAVR as well as pacemaker implantation (Ueyama 2024), in-hospital device-related complications were 1% for LPs and 2% for TVPs ($p=0.015$), with fewer long-term device-related complications (sdHR 0.4; 95% CI: 0.2 to 0.6; $p<0.001$) and the differences in groups were statistically significant. In the AF cohort, device-related complications were not statistically significant between LPs and TVPs (sdHR 1; 95% CI: 0.4–2.4; $p=0.97$). The non-AF cohort showed fewer complications with LPs compared to TVPs (sdHR 0.2; 95% CI: 0.1 to 0.7; $p=0.017$) and the difference was statistically significant.

In the prospective single-group study of 300 people evaluating the safety and performance of dual-chamber LPs, there were 6 cases of intraprocedural dislodgement (5 atrial and 1 ventricular pacemaker) (Knops 2023). Additionally, postprocedural dislodgement was observed in 5 cases, all involving the atrial LPs, at an average of 26 days: SD 17 days (range, 0 to 40 days) after implantation. In 4 of these cases, the device migrated outside the right atrium to the right ventricle ($n=3$) or the right pulmonary artery ($n=1$). All dislodged devices were successfully retrieved, and in 3 cases, reimplanted.

Repeat surgery (for device retrieval and revisions)

The meta-analysis by Mhasseb (2025) found that reintervention rates were significantly lower in the people who had LPs than in those with TVPs. Among the 19 included studies, 7 specifically examined reintervention outcomes, all of which reported a higher likelihood of device revision or extraction in the TVP group (LogOR=-0.7, $p<0.001$). The primary reasons for reintervention in TVPs included lead-related complications and system failures.

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The Micra PAR 5-year follow-up study (El-Chami 2024) of 1,809 people reported an all-cause system revision rate of 5% (95% CI: 4% to 6%) over 5 years. The primary drivers of system revision were device upgrades (41%) and elevated pacing thresholds (31%). Similarly, the Micra AC CED study (El-Chami 2024), which included 118,110 people, found that device-related reinterventions were lower in LP population (264 out of 7,552; 4%) compared to TVP population (6,191 out of 110,558; 6%) ($p < 0.0001$), which was statistically significant. Furthermore, device removals occurred in 53 out of 7,552 LP population (less than 1%), while the rate of upgrade from LP to a TVP pacemaker was 1% (106 out of 7,552), indicating that while LPs need fewer system revisions overall, device upgrades still occur in a small proportion.

The retrospective study of 63 children and young people (aged 21 and under; Shah 2023) reported 1 case of device retrieval and replacement because of high pacing thresholds at 1-month post-implantation. The retrospective cohort study of people on haemodialysis (Panico 2024) found that repeat procedures were more common in those who had TVP because of lead-related complications. Reinterventions for lead dysfunction occurred in 9% of people with TVPs compared to 0% of those with LPs (HR 0.4, 95% CI 0.2 to 0.9, $p = 0.0093$).

The prospective single-group study of 300 people implanted with dual-chamber LPs, reported 8 revision procedures within 90 days (Knops 2023). Of these, 6 involved successful percutaneous retrieval followed by new pacemaker implantation, while 2 people did not have a replacement atrial pacemaker at the investigator's discretion.

Venous thromboembolism

The meta-analysis by Mhasseb (2025) indicated a higher risk of thromboembolic events in people who had LPs with a LogOR of 0.5 (95% CI: -0.3 to 1.2; 6 studies; $I^2 = 97\%$). However, this association did not reach statistical significance. The Micra PAR study (El-Chami 2024) reported 2 cases of venous

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thrombosis (less than 1%) among 1,809 people, comprising 1 case of deep vein thrombosis (DVT) and 1 case of pulmonary embolism (PE). The Micra AV CED registry study (El-Chami 2024), which included 118,110 people, found comparable rates of embolism and thrombosis between LP recipients (15 out of 7,552; 0.2%) and TVP population (221 out of 110,558; 0.2%), with no statistically significant difference between the groups ($p=0.9015$).

The retrospective multicentre study of 63 children and young people (Shah 2023) reported 1 case of a non-occlusive femoral venous thrombus identified post-implantation. This was successfully treated with enoxaparin for 2 months, with complete resolution confirmed on follow-up imaging.

A propensity score-matched retrospective cohort study (Panico 2024) of people on haemodialysis reported that VTE incidence was slightly higher in the people who had TVPs (13%) compared to those who had LPs (8%). This difference was not statistically significant (HR 1, 95% CI 0.4 to 2.2, $p=0.92$).

In the prospective study of 300 people who had dual-chamber LP implantation, a single case of pulmonary embolism occurred 28 days post-implantation. This event was excluded from the primary safety analysis as it was attributed to COVID-19 rather than the pacemaker itself.

Vascular complications

The Micra PAR 5-year follow-up study (El-Chami 2024) reported a low incidence of vascular complications, with 12 cases (0.7%) of groin puncture-related issues, including AVF (less than 1%), vascular pseudoaneurysm (less than 1%), and vessel puncture site haematoma (less than 1%). Similarly, the retrospective study of young adult population by Strik (2023) found minimal vascular complications, with no major adverse events reported.

The prospective observational study (Amrani 2020) of an elderly population reported a 2% incidence of vascular complications ($n=2$), comprising a single

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case of femoral pseudoaneurysm and 1 haematoma, both of which were deemed unrelated to the LP device itself. Similarly, the retrospective cohort study of a propensity score-matched haemodialysis population (n=384) found that vascular complications were more common in TVP population than in LP population, with 8 cases (9%) occurring in the people who had TVP implantation compared to 2 cases (2%) in the LP population (HR 4.25, 95% CI 0.88 to 20.39, p=0.07).

The prospective study of 200 individuals reported that the femoral approach was associated with a higher rate of complications, with 2 people having femoral artery injury (2%) and 13 major groin haematomas (13%). No vascular complications were observed in the jugular approach group (Molitor 2024).

In the prospective single-arm study of 300 people with dual-chamber LPs, there was 1 report each of vascular access site bleeding and retroperitoneal haematoma (Knops 2023).

Bleeding

The RCT of 51 people by Garweg (2023) reported a single case of pocket haematoma in the TVP group, which led to prolonged hospitalisation. The Micra PAR study of 1,809 people (El-Chami 2024), reported 1 case of retroperitoneal haemorrhage. The Children PACES registry study (Shah 2023) reported minor bleeding at the femoral venous access site in 3 people (5%), all of which resolved with manual compression. 1 person developed a femoral haematoma that needed no further intervention.

The retrospective propensity score-matched study of people on haemodialysis (Panico 2024) reported similar rates of bleeding events in both LP and TVP groups. 6 cases (7%) were recorded in the people who had TVPs, compared to 4 cases (5%) in the LP population (HR 0.7, 95% CI 0.2 to 2.4, p=0.52). In the prospective study of 300 individuals implanted with dual-chamber LPs, bleeding-related complications were minimal, with 1 case of access site bleeding and 1 case of retroperitoneal haematoma (Knops 2023).

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Infections

The meta-analysis by Mhasseb (2025) assessed infection rates across 11 studies and found that while infection risk was lower in those who had LPs compared to those with TVPs, the difference did not reach statistical significance (LogOR=-0.6, p=0.27). Similarly, Oliveira (2025) conducted a separate meta-analysis evaluating infection rates and found no statistically significant difference between LPs and TVPs (OR 0.5, 95% CI 0.2 to 1.4, p=0.18).

In the Micra PAR 5-year follow-up study (El-Chami 2024), infection rates remained low, with 9 cases reported among 1,809 people. Of these, 5 were classified as major complications, including sepsis, abdominal wall infection, and catheter site infection, all of which were managed successfully with antibiotic therapy. No cases needed device removal because of infection. In the Micra AV CED study (El-Chami 2024), which analysed data from 7,552 LP recipients, 45 device-related infections were documented (1%). This rate was lower than that observed in the dual-chamber TVP cohort (p<0.0001). Furthermore, device-related infections were statistically significantly lower in the LP group (1%; 45 out of 7,552, p<0.0001). The impact of pacemaker type on infection risk has also been examined in high-risk populations. In a retrospective propensity score-matched study of people on haemodialysis, Panico (2024) reported a statistically significantly higher infection rate among the people who had TVP implantation. Device-related infections occurred in 9% of TVP population, whereas no infections were documented in the LP population (HR 0.4, 95% CI 0.2 to 0.9, p=0.0093).

Mortality

The RCT by Garweg (2023) reported 3 deaths during the study period between 9 and 11 months after implantation—1 in the LP group and 2 in the TVP group. These deaths were attributed to non-cardiac causes (2 because of cancer and 1 because of pulmonary infection) and were not related to the device itself.

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The systematic review and meta-analysis by Inoue (2024) demonstrated a statistically significantly higher pooled mortality rate among people who had simultaneous LP implantation and CIED removal (23%, 95% CI: 16% to 32%, $I^2=0\%$, $p=0.72$) compared to post-extraction LP implantation (9%, 95% CI: 4% to 16%, $I^2=21\%$, $p=0.27$), with a statistically significant difference between these groups ($p=0.008$). Temporal trends indicated an estimated 1-month mortality rate of 3%, which was lower than the 7% observed in the simultaneous implantation population. By 186 days, mortality increased to 9% in the post-extraction implantation group, compared to 21% in the simultaneous implantation population.

The impact of pacemaker type on all-cause mortality has also been evaluated in meta-analyses. The meta-analysis by Mhasseb (2025), analysing 13 of 19 included studies, found a higher risk of mortality associated with TVPs, but this did not reach statistical significance (Cohen's $d=-0.1$, 95% CI: -0.2 to 0.01). Similarly, found no statistically significant difference in overall mortality between the people who had LPs and TVPs, with ORs and HRs consistently non-significant across different analytical approaches: overall analysis (OR 1.4, 95% CI 0.7 to 3.2, $p=0.35$), multivariate-adjusted analysis (OR 1.3, 95% CI 0.7 to 2.8, $p=0.43$), and time-to-event analysis (HR 1.1, 95% CI 0.9 to 1.3, $p=0.53$). This review also documented 1 death following LP implantation; however, the cause was not specified, making it unclear whether the event was device- or procedure-related.

The Micra PAR 5-year follow-up study (El-Chami 2024) reported 676 deaths among 1,809 people, corresponding to a 5-year mortality rate of 40%. Notably, 5 procedure-related deaths were identified, including 2 attributed to cardiac perforation. In a broader cohort analysis, the Micra AV CED study (El-Chami 2024) involving 118,110 people reported statistically significant higher all-cause mortality in LP population (2,567 of 7,552; 34%) compared to TVP population (26,305 of 110,558; 24%), yielding a HR of 1.5 (95% CI: 1.4 to 1.6, $p<0.0001$). A

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sensitivity analysis adjusting for 6-month survival confirmed persistence of this increased mortality risk (adjusted HR: 1.4, 95% CI: 1.3 to 1.5).

The retrospective study of young adult people (n=35) recorded 3 deaths over a mean follow-up of 26 months, however none were related to LP implantation or the device (Strik 2023). There were 2 deaths in people with severe pre-existing conditions needing intubation and sedation, while the third resulted from malignancy. In the prospective observational study of an elderly population (Amrani 2020), 29 deaths were reported, with a mortality rate of 32% among those aged more than 90 years (n=13) compared to 18% in those younger than 90 years (n=16). Importantly, all deaths in this cohort were attributed to non-cardiovascular causes, with no device-related mortality reported.

In the propensity score-matched cohort study of people on haemodialysis (Panico 2024), the HR for mortality in the LP population compared to TVP was 0.7 (95% CI: 0.5 to 1, p=0.045), indicating a statistically significant reduction in mortality risk.

The prospective study of 300 people with dual-chamber LPs reported 4 deaths during follow-up, occurring between 46- and 86-days post-implantation (Knops 2023). The mean age of these people was 74 years. Causes of death included cardiac arrest (n=2), malignancy (n=1), and sepsis (n=1), with none attributed to the device or implantation procedure. In the retrospective cohort study of 10,338 people who had TAVR as well as pacemaker implantation (Ueyama 2024), there were no statistically significant differences in groups regarding all-cause death, with an adjusted HR of 1.1 (95% CI: 1 to 1.3; p=0.15) and in-hospital death (2% versus 1%; p=0.17). In the AF cohort, there was no statistically significant difference in all-cause death between LPs and TVPs (HR 0.9; 95% CI: 0.7 to 1.2; p=0.57). Similarly, in the non-AF cohort, LPs and TVPs showed no statistically significant difference in all-cause death (HR 1.2; 95% CI: 0.9 to 1.6; p=0.23).

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Pacemaker syndrome

In the large prospective registry study, El-Chami (2024) followed 1,809 people with LPs over 5 years and reported pacemaker syndrome incidence of less than 1% (n=7). Similarly, in a retrospective study of 35 young adults by Strik (2023), 1 person experienced pacemaker syndrome, presenting with intermittent chest discomfort and light-headedness, attributed to retrograde P-wave conduction during VP. This issue was managed successfully by lowering the lower rate limit of the pacemaker without necessitating device removal or replacement.

Cardiomyopathy

In the large prospective registry study of 1,809 people by El-Chami (2024) pacing-induced cardiomyopathy occurred in 5 people over 5 years.

Pericarditis

The Micra AV CED study, also led by El-Chami (2024), evaluated a larger cohort of 7,552 LP population compared to 110,558 TVP population. Pericarditis was reported in 2% of LP population and 2% of TVP population (p=0.6876), indicating no significant difference.

Overall complication rate

The systematic review and meta-analysis by Oliveira (2025) reported overall complications were significantly lower in the comparison group, with an OR of 0.6 (95% CI: 0.5 to 0.8; p<0.01). Procedure-related adverse events were assessed in a systematic review by Wu (2023), which included 7 studies and reported an overall complication rate of 6%. The Micra AV CED study by El-Chami (2024), evaluated a larger cohort of 7,552 LP population compared to 110,558 TVP population. In this study, overall complication rates were statistically significantly lower in the LP population (5% versus 10%, p<0.0001), with fewer device-related complications such as dislodgement and infections. The retrospective cohort study of 10,338 people who had TAVR and pacemaker implantation (Ueyama

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2024) reported that overall complication rates were statistically significant between LP and TVP groups (7% versus 10%; $p=0.014$).

Activity Restrictions

In the prospective multi-centre clinical trial of 720 people (Tjong 2018), it is reported that 49% of people rated them as less restrictive compared to TVPs. Additionally, 47% of people felt that the discharge instructions were equally restrictive, while only a small minority of 4% found them to be more restrictive.

At six months post-implantation in the retrospective study of 106 people (Cabanas-Grandio 2020), only 11% of people in the LP group reported restrictions in physical activities because of chest discomfort, compared to 37% in the TVP group. This difference ($p=.004$) was statistically significant.

Other device- or procedure-related adverse events

The RCT of 51 people by Garweg (2023) reported a statistically significant higher radiation dose in the LP group because of the use of biplane RV angiography, with reported values of 334.9 mGy (IQR: 219.6 to 444.9) compared to 9.2 mGy (IQR: 3 to 28.3) in the conventional group ($p<0.001$).

The meta-analysis by Mhasseb (2025) reviewed various complications, including pneumothorax, haemothorax, and haematoma. While the odds of major complications were lower for LPs than for TVPs (LogOR=-0.3), this difference was not statistically significant ($p=0.14$). Similarly, Oliveira (2025) found no significant difference between LPs and TVPs in terms of tricuspid regurgitation (OR 1.2, 95% CI 0.6 to 2.3, $p=0.69$) or haematoma (OR 1, 95% CI 0.6 to 1.9, $p=0.96$). The study found that pneumothorax was statistically significantly lower in the LP group compared to the TVP group (OR 0.3, 95% CI 0.2 to 0.5, $p<0.01$).

The systematic review by Wu (2023), which included 7 studies and reported 1 case of elevated pacing threshold, 2 cases of atrial undersensing, and 5 unspecified complications. The review also identified ventricular pause and

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oversensing-induced tachycardia as potential synchrony algorithm-related complications, though only 2 cases were reported across the entire dataset.

In the Micra AV CED study (El-Chami 2024), which evaluated a larger cohort of 7,552 LP population compared to 110,558 TVP population, the rate of upgrades to cardiac resynchronisation therapy (CRT) was similar between the 2 groups (1.6% versus 1.7%, $p=0.40$).

The PACES children registry study of 63 people reported a complication rate of 16%. Among these complications, 1 person developed right bundle branch block post-implantation, which resolved spontaneously within a week, while another experienced attenuation of measured R waves 4 days post-implantation, improving after a 5-day course of oral steroids. There were no reported cases of worsening tricuspid valve regurgitation, thromboembolic events, or arrhythmias beyond those previously described.

The retrospective cohort study by Panico (2024) examined a propensity score-matched population of 384 hemodialysis population implanted with either LPs or TVPs. The study found that central venous stenosis and vascular access complications were more common in those who had TVPs. Interventions related to haemodialysis vascular access were needed in 33% of TVP population compared to 19% of LP population (HR 0.6, 95% CI 0.4 to 1.1, $p=0.09$), which was not statistically significant.

In the prospective single-group study (Knops 2023) assessing the safety and efficacy of dual-chamber LPs in 300 people 35 device- or procedure-related serious adverse events occurred in 29 people (10%). The primary safety endpoint (freedom from device or procedure related events within 90 days) was met in 271 people (90%; 95% CI, 87 to 94%; $p<0.001$), exceeding the predefined safety threshold of 78%. Long-term follow-up (Knops 2025) confirmed sustained safety, with a Kaplan-Meier 12-month complication-free rate of 89% (95% CI, 84.5 to 91.8; $p<0.001$). The retrospective cohort study by Ueyama (2024)

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including 10,338 people who had TAVR reported that there were no statistically significant differences between those who had LPs and those who had TVPs in heart failure hospitalisation (sdHR 0.9; 95% CI: 0.7 to 1.1; p=0.24) or infective endocarditis (sdHR 1; 95% CI: 0.4 to 2.2; p=0.95).

Anecdotal and theoretical adverse events

Expert advice was sought from consultants who have been nominated or ratified by their professional society or royal college. They were asked if they knew of any other adverse events for this procedure that they had heard about (anecdotal), which were not reported in the literature. They were also asked if they thought there were other adverse events that might possibly occur, even if they had never happened (theoretical).

They listed the following theoretical adverse events:

- Rapid battery depletion because of high pacing thresholds or exit block
- Long-term difficulty or inability to extract chronically implanted devices

10 professional expert questionnaires for this procedure were submitted. Find full details of what the professional experts said about the procedure in the [specialist advice questionnaires for this procedure](#).

Validity and generalisability

- Sample sizes varied widely, from small studies like Garweg's RCT (n=51) and a young adult study (n=35) to large analyses such as Oliveira's meta-analysis (n=47,229). Smaller studies lacked statistical power, while larger ones included heterogeneous populations.
- Only the 5-year Micra PAR study includes UK data (El-Chami 2024). The rest are from the US, France, Switzerland, the Netherlands, or other non-UK European and North American centres.

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- Follow-up durations ranged from 90 days (dual-chamber LP study) to over 5 years (Micra PAR), providing some insight into long-term outcomes. Long-term data are particularly valuable for this procedure.
- Bias was common, with most studies being observational. Meta-analyses by Inoue and Mhasseb found publication bias, especially regarding adverse events. Many studies, such as the Micra AV CED and Micra PAR, were industry-funded, raising concerns about conflict of interest despite transparency in methodology.
- Procedural variation was also notable. While Garweg's RCT used standard protocols, others, like the jugular versus femoral study, tested alternative access routes. Device differences (Micra, Nanostim, Abbott dual-chamber LP) made direct comparisons difficult because of varying algorithms and fixation methods.
- Results were often conflicting—LPs were associated with reduced infection risk in some studies, but not consistently across pooled data. Reported AV synchrony for LP also varied, with lower rates in real-world settings than in trials, likely because of differences in programming and population selection.
- Key evidence gaps remain in long-term outcomes beyond 5 years, LP retrieval and replacement, and patient-reported outcomes. Ongoing trials may help address these gaps, particularly for new dual-chamber LPs and alternative implantation techniques, focusing different subgroups.

Any ongoing trials

- [Danish Randomized Trial on Leadless vs Transvenous Pacing \(DANVERS\)](#) (NCT05856799); RCT; Denmark; n=80; completion date August 2025
- [The leadless MICRA AV versus DDD pacing study \(LEAVE DDD\)](#) (NCT05498376); RCT (open label); Switzerland; n=100; completion date December 2027
- [Aveir VR coverage with evidence development post-approval study \(CED\)](#) (NCT05336877); observational (case-control); US; n=8,744; completion date January 2028

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- [Longitudinal coverage with evidence development study on Micra leadless pacemakers \(Micra CED\)](#) (NCT03039712); observational (cohort); US; n=37,000; completion date June 2027
- [Key factors of leadless pacemaker implantation with implantation site, complications and prognosis](#) (NCT05761821); observational (cohort); China; n=300; completion date December 2024
- [Micra transcatheter pacing system post-approval registry](#) (NCT02536118); observational (cohort, patient registry); worldwide; n=3100; completion date August 2025
- [International leadless pacemaker registry \(i-LEAPER\)](#) (NCT05528029); observational; Belgium, Italy, Switzerland; n= 2000; completion date December 2024
- [Aveir AR coverage with evidence development \(CED\) study \(ARRIVE\)](#) (NCT06100770); observational; US; n=586; completion date January 2031
- [A Safety and Effectiveness Monitoring in France for AVEIR VR LP and AVEIR AR LP \(France LEADLES\)](#) (NCT06262295); observational (patient registry); France; n=600; completion date September 2028
- [Aveir dual-chamber leadless pacemaker real-world evidence post-approval study](#); observational; USA; n= 1805; completion date January 2030
- [Aveir single-chamber leadless pacemaker real-world evidence post-approval study](#) (NCT05270499); observational (patient registry); US; n= 2100; completion date February 2034

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Existing assessments of this procedure

- [UK Expert Consensus Statement for the Optimal Use and Clinical Utility of Leadless Pacing Systems on Behalf of the British Heart Rhythm Society](#). A UK expert panel used a modified Delphi method to assess how LPs can be better utilised. They developed 36 survey statements and distributed them to LP implanters. The consensus process required a 25% response rate and at least 75% of statements meeting a 66% agreement threshold. 31 statements reached consensus, with 23 gaining 90% and above agreement. Based on these results, seven recommendations were proposed to help expand LP use and improve population outcomes.
- [British Heart Rhythm Society Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults: January 2024 Update](#). LP may be recommended for people at high risk of infection, those with end-stage renal disease, previous device infections, anatomical barriers to transvenous systems, immunocompromised population, those on biological or immunosuppressive therapies, or receiving radiotherapy near the device site. It may also be considered for people with congenital heart disease or those under 40 years of age, particularly when atrioventricular synchrony is clinically important.

Related NICE guidance

Interventional procedures

- [Laser sheath removal of pacing leads](#) (2004) NICE health technology guidance 36 (formerly interventional procedure guidance 63; recommendations: recommended only in people for whom standard methods of removal are ineffective)

Clinical guidelines

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- [AF: diagnosis and management](#) (2021) NICE guideline 196

Technology appraisals

- [Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure \(review of TA95 and TA120\)](#) (2014) NICE technology appraisal guidance 314
- [Dual chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without AV block \(part review of technology appraisal guidance 88\)](#) (2014) NICE technology appraisal guidance 324
- [Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or AV block](#) (2005) NICE technology appraisal guidance 88

Professional societies

- British Heart Rhythm Society (BHRS)
- British Cardiovascular Intervention Society
- British Cardiovascular Society.

Evidence from people who have had the procedure and patient organisations

NICE received 2 [submissions from patient organisations](#) about LPs and 1 patient commentary from a person who had this procedure.

The views of patient organisations were consistent with the published evidence and the opinions of the professional experts.

Company engagement

NICE asked companies who manufacture a device potentially relevant to this procedure for information on it. NICE received 2 completed submissions. These

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were considered by the interventional procedures technical team, and any relevant points have been taken into consideration when preparing this overview.

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Appendix A: Methods and literature search strategy

Methods and literature search strategy

NICE has identified studies and reviews relevant to LP implantation for bradyarrhythmias from the medical literature.

Search strategy design and peer review

This search report is informed by the [Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension \(PRISMA-S\)](#).

A NICE information specialist ran the literature searches on 17 January 2025 and updated on 21 July 2025. See the [search strategy history](#) for the full search strategy for each database. Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The principal search strategy was developed in MEDLINE ALL (Ovid interface). It was adapted for use in each of the databases listed in [table 4a](#), taking into account the database's size, search functionality and subject coverage. The MEDLINE ALL strategy was quality assured by a NICE senior information specialist. All translated search strategies were peer reviewed to ensure their accuracy. The quality assurance and peer review procedures were adapted from the [Peer Review of Electronic Search Strategies \(PRESS\) 2015 evidence-based checklist](#).

Review management

The search results were managed in EPPI-Reviewer version 5 (EPPI-R5). Duplicates were removed in EPPI-R5 using a 2-step process. First, automated deduplication was done using a high-value algorithm. Second, manual deduplication was used to assess low probability matches. All decisions about inclusion, exclusion and deduplication were recorded and stored.

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Limits and restrictions

The CENTRAL database search removed trial registry records and conference material. The Embase search excluded conference material and when updated in July 2025 also excluded additional clinical trial records added to Embase.

English language limits were applied to the search when possible, in the database. This is standard NICE practice for review topics.

Main search

Table 4a Main search results

Database	Date searched	Database platform	Database segment or version	Number of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	17/01/2025	Wiley	Issue 01 of 12, January 2025	13
Cochrane Database of Systematic Reviews (CDSR)	17/01/2025	Wiley	Issue 01 of 12, January 2025	0
Embase	17/01/2025	Ovid	1974 to January 16, 2025	768
INAHTA International HTA Database	17/01/2025	https://database.inahta.org/	-	11
MEDLINE ALL	17/01/2025	Ovid	1946 to January 16, 2025	628

Update search

There were no changes to the search strategies between the original and the updates.

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Table 4b Update search results

Database	Date searched	Database platform	Database segment or version	Number of results downloaded
Cochrane Central Register of Controlled Trials (CENTRAL)	21/07/2025	Wiley	Issue 07 of 12, July 2025	0
Cochrane Database of Systematic Reviews (CDSR)	21/07/2025	Wiley	Issue 07 of 12, July 2025	0
Embase (clinical trials excluded)	21/07/2025	Ovid	1974 to July 20, 2025	127
INAHTA International HTA Database	21/07/2025	https://database.inahta.org/	-	0
MEDLINE ALL	21/07/2025	Ovid	1946 to July 21, 2025	90

Search strategy history**MEDLINE ALL search strategy**

1 arrhythmias, cardiac/ or bradycardia/ or heart block/ or AV block/ or bundle-branch block/ or sick sinus syndrome/ or AF/ 180361

2 (bradycardia* or bradyarrhythm*).tw. 27494

3 ((cardiac* or heart* or AV*) adj2 (arrhythmia* or block*)).tw. 44907

4 (abnormal* adj2 (heart* or cardiac* or AV*) adj2 rhythm*).tw. 593

5 ((heart* or cardiac* or AV*) adj2 rhythm* adj2 (disease* or disorder*)).tw. 1705

6 (Atrial adj2 Fibrillat*).tw. 100250

7 Bundle* branch* block*.tw. 10944

8 ((slow* or reduc* or low*) adj2 (heart* or cardiac*) adj2 (rate* or beat* or rhythm*)).tw. 10925

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9 ((sinus* or sinotrial*) adj2 (syndrome or dysfunction* or disease*)).tw. 10418

10 or/1-9 272016

11 Cardiac Pacing, Artificial/ or Pacemaker, Artificial/ 46791

12 (leadless or wireless).tw. 24704

13 11 and 12 837

14 LPMS.tw. 237

15 ((leadless or wireless) adj4 (pacemak* or pacin*)).tw. 1212

16 ((leadless or LP*) adj2 implant*).tw. 508

17 or/13-16 1643

18 10 and 17 517

19 (micra* adj4 leadless adj4 pacemaker*).tw. 148

20 (micra* adj4 pacemaker* adj4 implant*).tw. 84

21 (micra* adj4 transcatheter adj4 pacing).tw. 104

22 (Aveir* adj4 leadless adj4 pacemaker).tw. 27

23 (Aveir* adj4 (AR or VR or DR)).tw. 28

24 or/19-23 269

25 18 or 24 657

26 limit 25 to english language 628

Embase search strategy

1 heart arrhythmia/ or bradycardia/ or heart block/ or AV block/ or heart bundle branch block/ or sick sinus syndrome/ or AF/ 430409

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- 2 (bradycardia* or bradyarrhythm*).tw. 40864
- 3 ((cardiac* or heart* or AV*) adj2 (arrhythmia* or block*)).tw. 63468
- 4 (abnormal* adj2 (heart* or cardiac* or AV*) adj2 rhythm*).tw. 886
- 5 ((heart* or cardiac* or AV*) adj2 rhythm* adj2 (disease* or disorder*)).tw. 2122
- 6 (Atrial adj2 Fibrillat*).tw. 179782
- 7 Bundle* branch* block*.tw. 17516
- 8 ((slow* or reduc* or low*) adj2 (heart* or cardiac*) adj2 (rate* or beat* or rhythm*)).tw. 15265
- 9 ((sinus* or sinotrial*) adj2 (syndrome or dysfunction* or disease*)).tw. 15317
- 10 or/1-9 515425
- 11 heart pacing/ or artificial heart pacemaker/ 48312
- 12 (leadless or wireless).tw. 29115
- 13 11 and 12 624
- 14 LPMS.tw. 296
- 15 ((leadless or wireless) adj4 (pacemak* or pacin*)).tw. 2098
- 16 ((leadless or LP*) adj2 implant*).tw. 928
- 17 or/13-16 2631
- 18 10 and 17 1050
- 19 (micra* adj4 leadless adj4 pacemaker*).tw,dm,dv. 365
- 20 (micra* adj4 pacemaker* adj4 implant*).tw,dm,dv. 222
- 21 (micra* adj4 transcatheter adj4 pacing).tw,dm,dv. 245
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22 (Aveir* adj4 leadless adj4 pacemaker).tw,dm,dv. 40

23 (Aveir* adj4 (AR or VR or DR)).tw,dm,dv. 65

24 or/19-23 658

25 18 or 24 1382

26 (conference abstract* or conference review or conference paper or conference proceeding).db,pt,su. 6126021

27 25 not 26 813

28 limit 27 to english language 768

Cochrane Library (CDSR and CENTRAL) search strategy

#1 MeSH descriptor: [Arrhythmias, Cardiac] explode all trees 14039

#2 MeSH descriptor: [Bradycardia] explode all trees 708

#3 MeSH descriptor: [Heart Block] explode all trees 793

#4 MeSH descriptor: [AV Block] explode all trees 140

#5 MeSH descriptor: [Bundle-Branch Block] explode all trees 255

#6 MeSH descriptor: [Sick Sinus Syndrome] explode all trees 198

#7 MeSH descriptor: [AF] explode all trees 7522

#8 (bradycardia* or bradyarrhythm*) 9308

#9 ((cardiac* or heart* or AV*) near/2 (arrhythmia* or block*)) 11190

#10 (abnormal* near/2 (heart* or cardiac* or AV*) near/2 rhythm*) 140

#11 ((heart* or cardiac* or AV*) near/2 rhythm* near/2 (disease* or disorder*)) 198

#12 (Atrial near/2 Fibrillat*) 17629

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#13 Bundle* branch* block* 1050

#14 ((slow* or reduc* or low*) near/2 (heart* or cardiac*) near/2 (rate* or beat* or rhythm*)) 3510

#15 ((sinus* or sinotrial*) near/2 (syndrome or dysfunction* or disease*)) 1361

#16 {or #1-#15} 41287

#17 MeSH descriptor: [Cardiac Pacing, Artificial] explode all trees 1944

#18 MeSH descriptor: [Pacemaker, Artificial] explode all trees 1018

#19 #17 or #18 2446

#20 (leadless or wireless) 1642

#21 #19 and #20 18

#22 LPMS 8

#23 ((leadless or wireless) near/4 (pacemak* or pacin*)) 46

#24 ((leadless or LP*) adj2 implant*) 19

#25 {or #21-#24} 83

#26 #16 and #25 29

#27 (micra* near/4 leadless near/4 pacemaker*) 8

#28 (micra* near/4 pacemaker* near/4 implant*) 6

#29 (micra* near/4 transcatheter near/4 pacing) 4

#30 (Aveir* near/4 leadless near/4 pacemaker) 0

#31 (Aveir* near/4 (AR or VR or DR)) 0

#32 {or #27-#31} 12

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#33 #26 OR #32 33

#34 "conference":pt or (clinicaltrials or trialsearch):so 801159

#35 #33 NOT #34 13

INAHTA HTA Database search strategy

1	"Arrhythmias Cardiac"[mh]	60
2	"Bradycardia"[mh]	13
3	"Heart Block"[mh]	5
4	"AV Block"[mh]	2
5	"Bundle-Branch Block"[mh]	1
6	"Sick Sinus Syndrome"[mh]	4
7	"AF"[mh]	156
8	(bradycardia* or bradyarrhythm*)	24
9	((cardiac* or heart* or AV*) and (arrhythmia* or block*))	145
10	(abnormal* and (heart* or cardiac* or AV*) and rhythm*)	16
11	((heart* or cardiac* or AV*) and rhythm* and (disease* or disorder*))	19
12	(Atrial and Fibrillat*)	183
13	Bundle* branch* block*	3
14	((slow* or reduc* or low*) and (heart* or cardiac*) and (rate* or beat* or rhythm*))	213
15	((sinus* or sinotrial*) and (syndrome or dysfunction* or disease*))	26

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16	#15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1	532
17	"Cardiac Pacing Artificial"[mh]	47
18	"Pacemaker Artificial"[mh]	61
19	(leadless or wireless)	50
20	#18 OR #17	81
21	#20 AND #19	12
22	LPMS	0
23	((leadless or wireless) and (pacemak* or pacin*))	12
24	((leadless or LP*) and implant*)	11
25	#24 OR #23 OR #22 OR #21	19
26	#25 AND #16	9
27	(micra* and leadless and pacemaker*)	5
28	(micra* and pacemaker* and implant*)	2
29	(micra* and transcatheter and pacing)	5
30	(Aveir* and leadless and pacemaker)	0
31	(Aveir* and (AR or VR or DR))	0
32	#31 OR #30 OR #29 OR #28 OR #27	6
33	#32 OR #26	11

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Inclusion criteria

The following inclusion criteria were applied to the abstracts identified by the literature search.

- Publication type: clinical studies were included with emphasis on identifying good quality studies. Abstracts were excluded if they did not report clinical outcomes. Reviews, editorials, and laboratory or animal studies, were also excluded and so were conference abstracts, because of the difficulty of appraising study methodology, unless they reported specific adverse events not available in the published literature.
- People with bradyarrhythmias.
- Intervention or test: leadless cardiac pacemakers.
- Outcome: articles were retrieved if the abstract contained information relevant to the safety, efficacy, or both.

If selection criteria could not be determined from the abstracts the full paper was retrieved.

Potentially relevant studies not included in the main evidence summary are listed in [Appendix B: Other relevant studies](#).

Find out more about [how NICE selects the evidence for the committee](#).

Appendix B: Other relevant studies

Other potentially relevant studies that were not included in the main evidence summary ([tables 2 and 3](#)) are listed in table 5 below.

Observational studies on ventricular pacing with fewer than 30 people were excluded.

Table 5 additional studies identified

Study	Number of people and follow up	Direction of conclusions	Reason study was not included in main evidence summary
Afzal MR, Daoud EG, Cunnane R, et al. (2018) Techniques for successful early retrieval of the Micra transcatheter pacing system: A worldwide experience. Heart Rhythm 15(6): 841–846	n=40 (29 with full procedural details) Follow-up duration for delayed retrievals: median 46 days (range 1 to 95 days)	Early retrieval of LP is feasible and safe. All retrievals (immediate and delayed) were successful with no serious complications. Most common reasons were elevated pacing thresholds and infections.	Only successful retrievals were included; limited generalisability because of small sample size, retrospective nature, and absence of a comparator group.
Alhuarrat M, Kharawala A, Renjithlal S, et al. (2023) Comparison of in-hospital outcomes and complications of leadless pacemaker and traditional transvenous pacemaker implantation. EP Europace 2023; euad269.	n=35,430 admissions; LP group: n=7780; TVP group: n=27,650; in-hospital outcomes only	LP population had significantly higher in-hospital mortality (aOR 1.6), vascular complications (aOR 7.5), venous thromboembolism (aOR 3.7), cardiac complications (aOR 1.8), device thrombus (aOR 5.0), and transfusion need (aOR 1.5) compared to TVP population. TVP population was more likely to experience pulmonary complications (aOR 0.7) and device	Covered in systematic reviews included in evidence summary.

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		revisions (aOR 0.4). Differences may reflect higher comorbidity burden in LP group.	
Agarwal S, Patel HP, Asad ZUA et al. (2025) Real-World Outcomes of Leadless Pacemaker Implantation After Transvenous Lead Removal for Infected Cardiac Implantable Electronic Devices in the United States. <i>Am J Cardiol.</i> 2025 253:10-13.	Ventricular pacing, single chamber Retrospective analysis of data from national readmissions database between 2016 and 2021. 41,058 people had leadless pacemakers and of these 3,244 had the device after transvenous lead removal for Cardiac Implantable Electronic Devices (CIED) infection. Follow-up 180 days.	These findings suggest that while leadless pacemaker implantation following transvenous lead removal is associated with higher procedural complexity, it remains a viable and safe option in this high-risk population and provides important real-world context to guide clinical decision-making.	More comprehensive studies are included in the summary of evidence.
Ando K, Inoue K, Harada T, et al. (2023) Safety and Performance of the Micra VR Leadless Pacemaker in a Japanese Cohort – Comparison with Global Studies <i>Circulation Journal</i> 87(12): 1809–1816	n=300 Follow-up: mean 7.23; SD 2.83 months	Micra VR implantation was highly successful with a low acute (30 day) major complication rate of 3%, consistent with global trial data. No procedure- or device-related deaths occurred. Frailty scores improved post-implantation.	Limited to a non-randomised observational study with a relatively short follow-up period. More robust evidence from randomised controlled trials or meta-analyses was prioritised for the main summary.
Arps K, Li B, Allen JC Jr, et al. (2023)	n=54; median follow-up echocardiogram	LP implantation was not associated with worsening tricuspid	Small, single-center cohort with short-term follow-

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<p>Association of leadless pacing with ventricular and valvular function.</p> <p>J Cardiovasc Electrophysiol 34(11):2233–2242.</p>	<p>at 8.9 months (IQR 4.5 to 14.5)</p>	<p>regurgitation in the short term. There was a significant decline in LVEF (mean decrease: 52% to 48%, p=0.0019) and TAPSE (1.8 cm to 1.6 cm, p=0.0437), indicating a reduction in biventricular function. 24% of people experienced a 10% or more drop in LVEF, consistent with known effects of RV pacing.</p>	<p>up; observational nature limits ability to determine causality for observed ventricular function decline.</p>
<p>Bahbah A, Sengupta J, Kapphahn-Bergs M, et al. (2024)</p> <p>A comparison of procedure-related adverse events between two right ventricular leadless pacemakers.</p> <p>Journal of Cardiovascular Electrophysiology 35(12): 2397–2401</p>	<p>n=10,940 (Micra VR), n=5,990 (AVEIR VR)</p> <p>Follow-up duration not specified; adverse events reviewed from 2022 to 2024</p>	<p>Micra VR and AVEIR VR showed similar rates of major adverse clinical events (p=0.387) and procedure-related complications (including death and perforation). However, AVEIR VR had a higher rate of device dislodgement (p<0.001), while Micra VR had more unacceptable pacing thresholds requiring replacement (p=0.001). Design-related differences may account for these outcomes.</p>	<p>The study is based on retrospective analysis of adverse event reports from the MAUDE database, which may be subject to reporting biases and lacks the controlled conditions of prospective clinical trials. Therefore, more robust, randomised controlled studies were prioritised in the main evidence summary.</p>
<p>Bahbah A, Sengupta J, Witt D, et al. (2024)</p> <p>Device dislodgement and embolization associated with a new leadless pacemaker.</p> <p>Journal of Cardiovascular Electrophysiology</p>	<p>n=5,990 (AVEIR VR, over 21 months)</p> <p>n=72,237 (Micra VR, over 8 years)</p> <p>Follow-up: Device approval periods: AVEIR VR (Apr 2022 to Dec 2023), Micra</p>	<p>Dislodgement and/or embolisation (D/E) occurred in less than 1% of both AVEIR VR cases and Micra VR cases (p<0001). Most AVEIR D/E events (60%) occurred during implantation, commonly because of release mechanism or fixation issues.</p>	<p>Data based on passive post-market surveillance (MAUDE), with known limitations in voluntary reporting accuracy and absence of clinical adjudication or</p>

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35(12): 2483–2486	VR (2016 to Apr 2024)		comparator control.
Beccarino NJ, Choi EY, Liu B, et al. (2023) Concomitant leadless pacing in pacemaker-dependent patients undergoing transvenous lead extraction for active infection: Mid-term follow-up. Heart Rhythm 20(6): 853–860.	n=86, undergoing LP implantation at the time of transvenous lead extraction for active CIED infection; median follow-up 163 days (IQR 57 to 403)	Concomitant LP implantation during TLE for active infection was associated with no procedural complications and no recurrent infections during follow-up. Despite a 29% mortality rate, most deaths were unrelated to infection.	Covered by systematic reviews included in main evidence summary.
Bertelli M, Toniolo S, Ziacchi M, et al. (2022) Is Less Always More? A Prospective Two-Centre Study Addressing Clinical Outcomes in Leadless versus Transvenous Single-Chamber Pacemaker Recipients. J Clin Med 11(20): 6071.	n=344 (LP: n=72; TVP: n=272); follow-up duration not explicitly stated but included both acute and long-term complications	No statistically significant difference in complication rates between LP and TVP groups. Higher mortality in the TVP group attributed to older age and comorbidities. LP implantation was preferentially used in people with higher bleeding/infection risk, difficult venous access, or active lifestyle.	Covered by systematic review included in the main evidence summary.
Bhatia NK, Kiani S, Merchant FM, et al. (2021) Life cycle management of Micra transcatheter pacing system: Data from a high-volume center. Journal of Cardiovascular	n=302 Follow-up: mean 1105.5; SD 529.3 days (3 years)	LP was durable with low complication rates over long-term follow-up. 6% of people required system modification—either extraction (n=11) or abandonment (n=12)—mainly because of CRT upgrade, threshold issues, or battery depletion. All extractions and	Study focuses on long-term device management rather than long-term safety and efficacy outcomes and includes a limited number of extraction/abandonment cases.

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Electrophysiology 32(2): 484–490		abandonments were successful without long-term complications.	
Bodin A, Clementy N, Bisson A, et al. (2022) Leadless or Conventional Transvenous Ventricular Permanent Pacemakers: A Nationwide Matched Control Study. J Am Heart Assoc 11(16): e025339.	n=42,315 total (LP: 1487; TVP: 40,828); matched cohort: n=1344 per group; mean follow-up 6.2; SD 8.7 months	LP recipients had lower all-cause and cardiovascular mortality within 30 days post-implantation compared to TVP recipients. During midterm follow-up, there were no significant differences between LP and TVP groups in all-cause mortality, cardiovascular death, or infective endocarditis after matching for baseline comorbidities.	Covered by systematic review included in the main evidence summary.
Bongiorni MG, Della Tommasina V, Barletta V et al. (2019) Feasibility and long-term effectiveness of a non-apical Micra pacemaker implantation in a referral centre for lead extraction. EP Europace 21(1): 114–120.	n=52 Follow-up: mean 13; SD 9 months	LP implantation was successful in 52 people, with 60% receiving non-apical implants. Non-apical placement was feasible and had no adverse impact on electrical performance. Pacing thresholds remained optimal in 94% of people. No device-related adverse events occurred during follow-up, demonstrating safety and long-term stability even in high-risk population.	Relatively small sample size and single-centre design More comprehensive, multicentre studies with larger cohorts and randomised controlled designs were prioritised in the main evidence summary.
Breeman KTN, Oosterwerff EFJ, de Graaf MA, et al. (2023) Five-year safety and efficacy of leadless pacemakers in a Dutch cohort. Heart Rhythm 20(8): 1128–1135	n=179 (93 Nanostim, 86 Micra VR) Follow-up: mean 44; SD 26 months (3.7 years); up to 5 years	LPs demonstrated good long-term safety and performance. The 5-year major complication rate was 4% when excluding Nanostim advisory-related events, and 27% when including them. Capture threshold was less or equal to 2 V and stable in 98% of people.	Includes people implanted with the discontinued Nanostim device; results may not reflect outcomes relevant to currently used LPs.

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		No infections or late complications occurred.	
Cantillon DJ, Exner DV, Badie N, et al. (2017) Complications and Health Care Costs Associated with Transvenous Cardiac Pacemakers in a Nationwide Assessment. JACC: Clinical Electrophysiology 3(11): 1296–1305.	n = 72,701 (mean age 75; SD 12 years; 55% men) Follow-up: Mean 1.5; SD 1.1 years; outcomes tracked up to 3 years	TVP complications were more frequent than previously reported, with an overall 3-year complication rate of 15 to 16%. Key findings include: Acute complications (within 30 days): 8% in single-chamber TVP, 9% in dual-chamber TVP Most common: thoracic trauma (4%, cost: \$70,114), lead revision (4%, cost: \$9,296), and infection (1%, cost: \$80,247) Long-term complications (1 to 36 months): 6% (single-chamber) and 6% (dual-chamber)	Focused on health systems and healthcare costs.
Cantillon DJ, Dukkupati SR, Ip JH, et al. (2018) Comparative study of acute and mid-term complications with leadless and transvenous cardiac pacemakers. Heart Rhythm 15(7): 1023–1030.	n=718 LP (LEADLESS II) vs. n=1436 TVP (matched); complications assessed at less than or at 1 month (short-term) and between 1 to 18 months (mid-term).	LP recipients had significantly fewer overall complications (HR 0.4; 95% CI 0.3 to 0.6), with reduced short-term (6% vs 9%) and mid-term (1% versus 5%) complications. LCPs had higher rates of pericardial effusion (2% versus 0.3%; p=.005) but fewer infectious, lead-related, and pocket-related events. No thoracic trauma events occurred in the LP group.	Covered in systematic review included in the main evidence summary.
Carretta DM, Tomasi L, Tondo C et al. (2025) Leadless Micra pacemakers:	Ventricular pacing, single chamber	Leadless pacemakers appear to have a median expected longevity ranging from 14 to 17 years. Having a	Projected battery longevity estimates calculated.

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estimating long-term longevity. A real word data analysis. Int J Cardiol. 426:133062.	Prospective multicentre registry. n=391 people who had single chamber leadless pacemaker. Follow-up median 33.9 months.	stimulation threshold less than or equal to 1 volt at 0.24 ms seems to be an excellent predictor of increased longevity.	
Cha MJ, Park SJ, Cho Y et al. (2025) Safety and Performance of the Micra VR Leadless Pacemaker in a South Korean Cohort: A Comparison to Global Studies. Korean Circ, 55(6):526-537. doi: 10.4070/kcj.2024.0317. Epub 2025 Feb 13.	Ventricular pacing, single chamber Prospective registry n=100 people had Micra VR leadless pacemaker implantation at 8 centres. Follow-up 12 months.	In a South Korean cohort, the Micra VR leadless pacemaker was implanted with a high success rate and low major complication rate.	More comprehensive studies are included in the summary of evidence.
Chopra M, Hsieh JC, Mueller W et al. (2025) Incidence of pacing-induced cardiomyopathy: left bundle branch area pacing versus leadless pacing. J Interv Card Electrophysiol.	Ventricular pacing, single chamber Comparative case series People who had either a leadless pacemaker (n=25) or a permanent pacemaker with a left bundle branch area pacing (n=70, LBBAP) lead for atrioventricular block between 2021 and 2023 were included.	In people who are not candidates for cardiac resynchronisation, who need a high burden of ventricular pacing, LBBAP may lead to a lower incidence of pacemaker included cardiomyopathy than right ventricular septal pacing with a leadless pacemaker.	More comprehensive studies are included in the summary of evidence.

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	Follow-up of 14 months.		
Chinitz L, Ritter P, Khelae SK, et al. (2018) Accelerometer-based atrioventricular synchronous pacing with a ventricular leadless pacemaker: Results from the Micra atrioventricular feasibility studies. Heart Rhythm 15(9): 1363–1371.	n=64 across 12 centers in 9 countries; median 6 months post-implant (range 0 to 41.4 months); evaluation over 30 minutes of pacing.	Accelerometer-based atrial sensing algorithm achieved high atrioventricular synchrony (AVS) during pacing: 87% average AVS overall, 80% in high-degree AV block, and 94% in intrinsic conduction. AVS was significantly better during AV algorithm pacing than VVI pacing in high-degree block (p<.001).	Covered in systematic review included in the main evidence summary.
Chinitz LA, El-Chami MF, Sagi V, et al. (2023) Ambulatory atrioventricular synchronous pacing over time using a leadless ventricular pacemaker: Primary results from the AccelAV study. Heart Rhythm 20(1): 46–54.	n=152 enrolled; primary analysis subset: n=54 with complete AV block and normal sinus function; follow-up at 1 and 3 months	In people with complete AV block and normal sinus function, LP achieved mean resting AVS of 85% and ambulatory AVS of 75% at 1 month. Optimisation improved ambulatory AVS to 83% (p<.001). AVS remained stable at 3 months, and quality of life improved significantly (p=.031). No device upgrades were needed during the follow-up.	Covered by systematic review included in the main body evidence summary.
Crossley GH, Piccini JP, Longacre C, et al. (2023) Leadless versus transvenous single-chamber ventricular pacemakers: 3 year follow-up of the Micra CED study.	n=6,219 (LP n=2,202; TVP n=4,017); 3-year follow-up	LP recipients had lower adjusted 3-year risks of chronic complications (HR 0.8, 95% CI 0.7 to 0.9; p<.001), device-related reintervention (HR 0.5, 95% CI 0.4 to 0.7; p<.001), and device-related infection (HR 0.4, 95% CI 0.2 to 0.8; p=.005) compared with TVP recipients. No	Covered by systematic review included in the main evidence summary.

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<p>J Cardiovasc Electrophysiol 34(4): 1015–1023.</p>		<p>significant difference in 3-year all-cause mortality was observed (HR 1, 95% CI 0.9 to 1.1; p=.73).</p>	
<p>Crossley GH, Longacre C, Higuera L, et al. (2024) Outcomes of patients implanted with an atrioventricular synchronous leadless ventricular pacemaker in the Medicare population. Heart Rhythm 21(1): 66–73.</p>	<p>n=7471 LP recipients; n=107,800 dual-chamber TVP recipients; outcomes assessed at 30 days and 6 months</p>	<p>LP recipients had higher comorbidity burden (mean Charlson Index 4.9 versus 3.8) but similar unadjusted 30-day complication rates (9% vs 9%). After adjustment, LP was associated with significantly lower 30-day (9% versus 11%) and 6-month complication rates (HR 0.5; 95% CI 0.4 to 0.6) and reinterventions (HR 0.5; 95% CI 0.4 to 0.6). Higher mortality in LP group attributed to baseline health differences.</p>	<p>Covered by Mhasseb (2025) systematic review included in the main evidence summary.</p>
<p>Darlington D, Brown P, Carvalho V, et al. (2022) Efficacy and safety of leadless pacemaker: A systematic review, pooled analysis and meta-analysis. Indian Pacing and Electrophysiology Journal 22(2): 77–86</p>	<p>18 studies included n=2,496 (LP recipients) Follow-up duration varied across studies</p>	<p>LPs demonstrated high implant success rates (96 to 100%) with low adverse event rates. Device/procedure-related death rate was less than 1%; overall complication rate 3%; pericardial tamponade 1%. Other complications such as pericardial effusion, dislodgement, revision, malfunction, infection, and access site complications occurred in less than 1% of people. No significant differences found between LPs and TVPs for:</p> <ul style="list-style-type: none"> • Haematoma (RR 0.7, 95% CI 0.2 to 2.2) • Pericardial effusion (RR 0.6, 	<p>More updated and comprehensive studies have been included in the main evidence summary.</p>

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		<p>95% CI 0.2 to 2.3)</p> <ul style="list-style-type: none"> • Device dislocation (RR 0.3, 95% CI 0.1 to 1.7) • Any complication (RR 0.4, 95% CI 0.2 to 1.1) • Death (RR 0.5, 95% CI 0.2 to 1.4) 	
<p>Defaye P, Klug D, Anselme F, et al. (2018)</p> <p>Recommendations for the implantation of leadless pacemakers from the French Working Group on Cardiac Pacing and Electrophysiology of the French Society of Cardiology.</p> <p>Archives of Cardiovascular Disease 111(1): 53–58.</p>	<p>Not applicable (guideline document); consensus formed based on expert experience and early clinical trials.</p>	<p>Recommended cautious use of LPs because of limited long-term data and complication risk. Identified groups most suitable for LP: those with no venous access, high infection risk, prior endocarditis, or cosmetic preferences. Advocated for implantations only in high-expertise centers with cardiac surgery facilities. Advised that only board-certified electrophysiologists with sufficient volume (more than 20 LPs/year) perform these procedures. Highlighted risks: tamponade, vascular injury, device migration, and lack of extraction experience. Stressed mandatory surveillance via national registry and outlined minimum training and implantation volumes to ensure safety.</p>	<p>Not an empirical study; guideline based on expert consensus rather than original research data.</p>
<p>Denman RA, Lee G, Phan K, et al. (2018)</p>	<p>n=79 Follow-up: median 355 days</p>	<p>Implantation was successful in 96% of people. Electrical performance remained excellent over follow-up</p>	<p>Single-centre study with small sample size and limited generalisability;</p>

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Leadless Permanent Pacing: A Single Centre Australian Experience. Heart, Lung and Circulation 28(11): 1677–1682	(range; 9 to 905 days)	with a median R-wave of 11.2 mV, capture threshold of 0.5 V at 0.2 ms, and impedance of 754 ohm. No people required revision or were readmitted for device-related complications. 1 case of acute dislodgement was successfully managed. 5 deaths (7%) occurred, all unrelated to the device.	lacks comparator arm or stratification across different risk groups.
Doshi RN, Ip JE, Defaye P, et al. (2024) Chronic wireless communication between dual-chamber leadless pacemaker devices. Heart Rhythm, published online ahead of print on October 19, 2024.	n=399 Follow-up: at implant, discharge, 1, 3, and 6 months	Aveir DR dual-chamber LPs demonstrated more than 90% success in implant-to-implant (i2i) wireless communication (A-to-V and V-to-A) throughout 6 months. People with less than 70% success at implant showed marked improvement by 1 month, decreasing to only 5% by 6 months. Improvements were linked to reprogramming and post-implant device adaptation.	The study focuses on device communication metrics rather than clinical outcomes such as complications, mortality, or pacing efficacy; thus, it is not directly comparable with safety and performance endpoints in the main summary.
Duray GZ, Ritter P, El-Chami M, et al. (2017) Long-term performance of a transcatheter pacing system: 12-Month results from the Micra Transcatheter Pacing Study. Heart Rhythm 14(5): 702–709	n=726 (Micra) Follow-up: 12 months for safety, 24 months for electrical performance	At 12 months, freedom from major complications was 96% (95% CI: 92 to 97; p<0.0001), meeting the prespecified performance goal. The risk of major complications was 48% lower than with TVPs (HR 0.5; 95% CI: 0.6 to 0.8; p=0.001). Device performance remained stable through 24 months with projected battery life of 12.1 years.	Earlier results already incorporated into broader summaries; this study includes historical comparator data and device-specific outcomes rather than direct head-to-head comparison within a randomised framework.
El-Chami MF, Soejima K,	n=720 (Micra) n=16 developed 21 serious	Serious infections (bacteraemia or endocarditis) occurred in	Focused specifically on rare post-implant

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<p>Piccini JP et al. (2019) Incidence and outcomes of systemic infections in patients with leadless pacemakers: Data from the Micra IDE study. Pacing and Clinical Electrophysiology 42(8): 1105–1110.</p>	<p>infectious events (SIEs) Follow-up after SIE: mean 13.1; SD 9.1 months</p>	<p>2% of people (16/720), on average 4.8 months post-implant. All events were adjudicated as unrelated to the device or procedure. Most infections involved gram-positive organisms and resolved with antibiotics, with no persistent bacteraemia observed.</p>	<p>infectious events; small number of cases limits generalisability and does not evaluate broader safety or efficacy outcomes of the device.</p>
<p>El-Chami MF, Johansen JB, Zaidi A, et al. (2019) Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry. J Cardiovasc Electrophysiol 30(4): 569–574.</p>	<p>n=105 people with prior CIED infection who underwent Micra implant attempt less than or at 30 days after device explant; mean follow-up 8.5; SD 7.1 months</p>	<p>LP was successfully implanted in 99% of people with recent CIED infection. No LP removals because of infection were reported. Most people received IV antibiotics pre-implant (91%) and/or post-implant (42%). 2 persons died from sepsis, but no reinfections involved the LP system.</p>	<p>Covered by systematic review included in the main evidence summary.</p>
<p>El-Chami MF, Bonner M, Holbrook R, et al. (2020) Leadless pacemakers reduce risk of device-related infection: Review of the potential mechanisms. Heart Rhythm 17(8): 1393–1397.</p>	<p>More than 3000 (across clinical trials referenced); follow-up durations vary across studies included</p>	<p>LPs demonstrate a markedly lower rate of infection compared to TVPs (0.00% versus 1 to 2% in trials with over 3000 people). Proposed mechanisms include absence of subcutaneous pocket and leads, minimal skin/glove contact during implantation, smaller size, implantation in a lower-flow cardiac</p>	<p>Narrative review — not a primary study or systematic review/meta-analysis; mechanism-focused without formal comparative data analysis.</p>

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		environment, and biocompatible materials.	
<p>EI-Chami MF, Garweg C, Iacopino S et al. (2022)</p> <p>Leadless pacemaker implant, anticoagulation status, and outcomes: Results from the Micra Transcatheter Pacing System Post-Approval Registry. Heart Rhythm 19(2): 228–234.</p>	<p>n=1,795 (with documented anticoagulation status)</p> <p>Follow-up: 30 days post-implant</p>	<p>implantation was safe across all perioperative anticoagulation (AC) strategies: non-AC (n=585), interrupted AC (n=795), and continued AC (n=415). Major complication rates were 3%, 3%, and 2% respectively. Implant success exceeded 99% in all groups. Vascular or pericardial effusion events did not significantly differ among AC strategies, suggesting continued AC does not increase procedural risk.</p>	<p>Focused specifically on procedural safety relative to anticoagulation management, rather than overall clinical outcomes or long-term device performance.</p>
<p>EI-Chami MF, Clementy N, Garweg C et al. (2019)</p> <p>Leadless pacemaker implantation in hemodialysis patients: Experience with the Micra transcatheter pacemaker. JACC: Clinical Electrophysiology 5(2): 162–170.</p>	<p>n=201, on hemodialysis (7% of 2,819 total)</p> <p>Follow-up: mean 6.2 months (range 0 to 26.7 months)</p>	<p>LP implantation was successful in 98% (197/201) of people having haemodialysis. The median procedure time was 27 minutes. There were 4 implant failures and 3 procedure-related deaths. No device-related infections or removals occurred. People included in this study had multiple comorbidities, and 72% were deemed unsuitable for TVPs.</p>	<p>A more recent study including people on haemodialysis has been included in table 2.</p>
<p>EI-Chami MF, Bockstedt L, Longacre C et al. (2022)</p> <p>Leadless vs. transvenous single-chamber ventricular pacing in the Micra CED study: 2-year follow-up.</p>	<p>n=6,219 (LP) vs. n=10,212 (TVP)</p> <p>Follow-up: 2 years</p>	<p>LP group had significantly fewer reinterventions (adjusted HR 0.6, 95% CI 0.5 to 0.9, P=0.003) and chronic complications (adjusted HR 0.7, 95% CI 0.6 to 0.8, P<0.0001) compared to TVP population. Adjusted all-cause mortality did not</p>	<p>A more recent publication from the same study has been included in the main evidence summary.</p>

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European Heart Journal 43(12): 1207–1215.		differ (HR 1, 95% CI 0.9 to 1, P=0.4).	
El-Chami MF, Al-Samadi F, Clementy N et al. (2018) Updated performance of the Micra transcatheter pacemaker in the real-world setting: a comparison to the investigational study and a transvenous historical control. <i>Heart Rhythm</i> 15(12): 1800–1807.	n=1817 (Micra PAR); mean follow-up 6.8; SD 6.9 months Comparators: n=726 (IDE study) and n=2667 (TVP control group)	The major complication rate in Micra PAR was 3% at 12 months (95% CI 2% to 3%). Compared to TVPs, LPs had a 63% lower risk of major complications (HR 0.4, 95% CI 0.3 to 0.5, p<0.001). There were no battery or telemetry issues, and pacing thresholds remained stable.	A more recent publication from PAR study has been included in the main evidence summary.
Fagerlund BC, Harboe I, Giske L et al. (2018) The Micra™ Transcatheter Pacing System, a leadless pacemaker, in patients indicated for single-chamber ventricular pacemaker implantation: a single technology assessment. Norwegian Institute of Public Health.	Clinical review included data from 3 large multi-site trials (total n=1,575) and 3 smaller case series. Follow-up: up to 24 months (efficacy), 10-year horizon for cost-effectiveness model.	LP achieved satisfactory pacing thresholds in 93 to 97% of people at 12 to 24 months. Major complications occurred in 2 to 4% of people, with 4 reported device/system-related deaths. Compared to historical controls, LPs had a lower complication rate, but evidence was rated low to very low certainty because of study design (single arm) and indirectness.	More recent systematic reviews have been included in the main evidence summary.
Fouad M, Abdelsayed K, Tabassum S et al. (2025) Comparative analysis of leadless versus	Ventricular pacing, single chamber Retrospective propensity-score	In the absence of heart failure, leadless pacemaker was associated with fewer rates of mechanical complications and cardiac-related	More comprehensive studies are included in the summary of evidence.

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transvenous pacemakers in non-heart failure patients: A Multicenter US retrospective study. J Cardiovasc Electrophysiol. 36(6):1362-1376	matched study comparing leadless pacemakers (n=1,158) with transvenous pacemakers (n=1,158) in people without heart failure. Follow-up 12 months.	haemodynamic instability. However, late mortality was higher with leadless pacemakers. Hospitalisation rates and reintervention rates were comparable between both groups.	
Gangannapalle M, Monday O, Rawat A, et al. (2023) Comparison of Safety of Leadless Pacemakers and Transvenous Pacemakers: A Meta-Analysis. Cureus 15(9): e45086	This meta-analysis encompassed 17 studies comparing LPs and TVPs. The total number of people and specific follow-up durations varied across the included studies.	LPs were associated with a lower risk of total complications, device-related complications, pneumothorax, endocarditis, and need for reintervention compared to TVPs. However, the risk of pericardial effusion was significantly higher in the LP group.	Comprehensive and more recent meta-analyses have been included in the main evidence summary.
Garg A, Koneru JN, Fagan DH, et al. (2020) Morbidity and mortality in patients precluded for transvenous pacemaker implantation: Experience with a leadless pacemaker. Heart Rhythm 17(12): 2056–2063	n=2,817, undergoing Micra implantation; 546 (19%) were precluded from TVP implantation Follow-up: 36 months	People precluded from TVP had higher acute mortality (3% vs 1%, p=0.022) and 36-month mortality (38% vs 21%, p<0.001) than no precluded people.	Although informative for high-risk subpopulations, the comparative arm is not randomised, and the elevated mortality likely reflects baseline comorbidities rather than device performance, limiting its applicability for general evidence synthesis.
Garg J, Shah K, Bhardwaj R et al. (2023) Adverse events associated with Aveir™ VR	n=64 adverse event reports included (from post-FDA approval until January 2023)	Most common complications included high threshold/noncapture (28%), stretched helix (17%), and device	Brief communication: this study is based on voluntarily reported adverse

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leadless pacemaker: a Food and Drug Administration MAUDE database study. Journal of Cardiovascular Electrophysiology 34(9): e15932.	No follow-up duration specified; real-world device surveillance study	dislodgement (16%). Serious adverse events included 5 cases of pericardial effusion requiring pericardiocentesis and 2 deaths (3%). The study highlights rare but serious safety concerns with the Aveir™ VR LP.	events from a regulatory database without denominator data or follow-up, limiting its comparability to prospective clinical trials or registries.
Garweg C, Chinitz L, Marijon E, et al. (2024) A leadless ventricular pacemaker providing atrioventricular synchronous pacing in the real-world setting: 12-Month results from the Micra AV post-approval registry. Heart Rhythm 21(10): 1939–1947	n=801 (LP), with 12-month follow-up Comparison: Historical cohort of 2667 people with TVPs	LP showed a significantly lower major complication rate at 12 months compared to transvenous dual-chamber pacing (4% vs 9%; HR 0.4, 95% CI 0.3 to 0.6 p<0.001) and a lower system revision rate (2% vs 6%; HR 0.3, 95% CI 0.13 to 0.5; p<0.001). Median AV synchrony index was 79% in high burden paced population.	This real-world observational registry lacks a direct comparator group within the study itself, limiting its suitability for inclusion in the main evidence summary prioritising controlled or randomised studies.
Garweg C, Vandenberg B, Jentjens S, et al. (2020) Bacteraemia after leadless pacemaker implantation. Journal of Cardiovascular Electrophysiology 31(9): 2440–2447	n=155, with LP implantation Median follow-up after bacteraemia: 263 days (range: 15 to 1134)	Bacteraemia occurred in 15 people (10%) at a median of 226 days post-implantation. FDG PET/CT in 6 people showed no evidence of infection involving the pacemaker. No cases of LP related endocarditis were identified, and all infections resolved with antibiotics.	Small single-centre retrospective study with a limited number of events and lack of control group; not prioritised for inclusion in main evidence summary focused on broader or comparative outcomes.
Garweg C, Vandenberg B, Foulon S, et al. (2020) Leadless pacemaker for	n=170 LPs (54 post-valve intervention vs 116 controls);	LP implantation was successful in all people, including the 54 with prior cardiac valve interventions (aortic, mitral, or multiple	Broader registry study has been added in the main evidence summary.

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<p>patients following cardiac valve intervention.</p> <p>Arch Cardiovasc Dis 113(12): 772–779.</p>	<p>Median follow-up: 12 months</p>	<p>valves). No major procedural complications occurred. Both valve intervention and control groups showed similar reduction in LVEF over 12 months, which correlated with the amount of right ventricular pacing.</p>	
<p>Garweg C, Vandenberg B, Foulon S, et al. (2019)</p> <p>Leadless pacing with Micra TPS: A comparison between right ventricular outflow tract, mid-septal, and apical implant sites.</p> <p>Journal of Cardiovascular Electrophysiology 30(10): 2002–2011</p>	<p>n=133 Mean follow-up: 13; SD 11 months</p>	<p>LP implantation was successful in all. across RV outflow tract (n=45), mid-septal (n=58), and apical (n=30) sites. RVOT pacing was associated with the narrowest QRS duration (142 ms vs. 159 ms mid-septal vs. 181 ms apical; p<0.001). No pericardial effusion occurred. 2 major complications were reported in the apical group. Electrical performance (pacing threshold, R-wave amplitude) was stable across all positions.</p>	<p>This single-centre, non-randomised observational study with modest sample size offers valuable insights into implantation site differences but lacks comparative clinical outcomes beyond electrical parameters, limiting its inclusion in the main evidence summary.</p>
<p>Garweg C, Ector J, Voros G, et al. (2018)</p> <p>Monocentric experience of leadless pacing with focus on challenging cases for conventional pacemaker.</p> <p>Acta Cardiologica 73(5): 459–468</p>	<p>n=66 Follow-up: mean 10.4; SD 6.1 months (range 1 to 23 months)</p>	<p>LP was successfully implanted in 99% of people, with stable electrical performance at follow-up. Mean pacing capture threshold was 0.6 V, impedance 580 Ohms, and R-wave sensing 10.6 mV. 1 major and 3 minor adverse events were reported. No dislodgement, infection, or pericardial effusion occurred. The device was also effective in anatomically challenging population.</p>	<p>Single centre with small sample size and non-comparative design limits generalisability and strength of evidence compared to larger multicentre or controlled trials.</p>

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<p>Grubman E, Ritter P, Ellis CR, et al. (2017)</p> <p>To retrieve, or not to retrieve: System revisions with the Micra transcatheter pacemaker.</p> <p>Heart Rhythm 14(12): 1801–1806.</p>	<p>n=989 (LP group) vs. n=2667 (TVP group); up to 24 months follow-up</p>	<p>The 24-month revision rate for LP was 1%, statistically significantly lower than the 5% revision rate in the TVP group (75% relative risk reduction; $p < 0.001$). No LP revisions were because of dislodgement or device-related infection. Most LP devices were disabled and left in situ; percutaneous retrieval was successful up to 14 months post-implant.</p>	<p>Broader registry studies have been included in the main evidence summary.</p>
<p>Gul EE, Baudinaud P, Waldmann V, et al. (2024)</p> <p>Leadless pacemaker implantation following tricuspid interventions: multicenter collaboration of feasibility and safety.</p> <p>J Interv Card Electrophysiol 67(5): 1241–1246.</p>	<p>n=40 with prior tricuspid valve interventions. Mean follow-up: 10 months</p>	<p>All people successfully received LPs after tricuspid valve surgery or intervention. No acute complications were observed. Electrical parameters (pacing threshold: 1.4; SD 1.2 V, impedance: 772; SD 245 Ohm, R-wave: 6.9; SD 5.4 mV) remained stable through follow-up. There were 4 deaths, not procedure related.</p>	<p>Broader registry study has been prioritised in the main body evidence.</p>
<p>Gulletta S, Schiavone M, Gasperetti A, et al. (2023)</p> <p>Peri-procedural and mid-term follow-up age-related differences in leadless pacemaker implantation: Insights from a multicenter</p>	<p>n=1154; 2 cohorts: younger (50 or less in years, 6%) and older (more than 50 years); mid-term follow-up duration not explicitly stated</p>	<p>In younger people, LPs were primarily chosen because of preference (47% versus 6%, $p < 0.001$), while in older population, infectious (68%) and vascular concerns (16%) were more common indications. Periprocedural complication rate was 4% with no significant age-related difference. Younger people had</p>	<p>Age-based subgroup analysis with limited representation of younger people (6% of cohort).</p>

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European registry. Int J Cardiol 371:197–203.		higher pacing thresholds at discharge and follow-up (0.6 V versus 0.5 V, $p=0.004$), though device performance remained acceptable in both groups.	
Gill J, Harb A, Varghese J et al. (2025) Safety of Leadless Pacemaker Insertion in Nonagenarians. J Innov Card Rhythm Manag. 16(5):6272-6277.	Ventricular pacing, single chamber Retrospective analysis of data from National Readmission Database for people who had leadless pacemaker insertion between 2017 and 2020.	Study demonstrates that leadless pacemaker insertion could be safe in the very elderly population. However, study likely demonstrates survivorship bias, as people in the nonagenarian group had fewer overall comorbidities. Despite adjustment for known comorbidities, there remain confounders that are difficult to account for. Age itself does not seem to be a risk factor for worse outcomes in this population.	More comprehensive studies are included in the summary of evidence.
Hadadi CA, Lee KW, Lo M, Rashtian M et al. (2025) Commercial implant experience of a helix-fixation dual-chamber leadless pacemaker. J Cardiovasc Electrophysiol. 36(7):1559-1566.	Dual-chamber pacing Multicentre registry study. $n=175$ people with sinus node dysfunction, AV node ablation was implanted with dual-chamber leadless pacemaker. Follow-up 30 days	The initial commercial experience of the helix-fixation, dual-chamber LP system demonstrated safe and efficient implantation with clinically acceptable electrical metrics and minimal acute complications.	More comprehensive studies are included in the summary of evidence. Short term follow-up (30 days), limited to initial commercial rollout without comparator group.
Haddadin F, Majmundar M, Jabri A, et al. (2022) Clinical outcomes and predictors of	$n=7,821$ Follow-up: In-hospital and 30-day outcomes	Immediate procedure-related complications occurred in 8% of people. Specific complications included pericardial effusion (2%),	Shorter follow up duration might not capture long term safety and efficacy outcomes.

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<p>complications in patients undergoing leadless pacemaker implantation.</p> <p>Heart Rhythm 19(8): 1289–1296</p>		<p>pericardiocentesis (1%), vascular complications (2%), and device dislodgment.</p>	<p>Studies with longer follow up period have been assessed in the main evidence summary.</p>
<p>Hai JJ, Fang J, Tam CC, et al. (2019)</p> <p>Safety and feasibility of a midseptal implantation technique of a leadless pacemaker.</p> <p>Heart Rhythm 16(6): 896–902</p>	<p>n=51</p> <p>Follow-up: Median 218.7 days</p>	<p>Midseptal LP implantation was successfully achieved in 90% of people using fluoroscopic guidance (RAO, LAO, and lateral views).</p>	<p>Small, single-centre feasibility study with a short follow-up duration and limited generalisability; primarily technical in nature rather than focused on comparative safety or efficacy outcomes.</p>
<p>Hauser RG, Gornick CC, Abdelhadi RH, et al. (2021)</p> <p>Major adverse clinical events associated with implantation of a leadless intracardiac pacemaker.</p> <p>Heart Rhythm 18(7): 1132–1139</p>	<p>n=363 major adverse clinical events (MACE) for Micra (LP) vs. n=960 MACE for CapSureFix (TVP)</p> <p>Timeframe: 2016–2020 (retrospective database review; no population-level follow-up duration)</p>	<p>LPs was associated with significantly more serious events: deaths (26% versus 2%), tamponade (79% versus 23%), and rescue thoracotomies (27% versus 5%) compared to TVPs (all $p < 0.001$).</p>	<p>Although highlighting critical safety signals, this study is based solely on voluntary manufacturer-reported adverse event data from the MAUDE database, which lacks denominator data, standardised event adjudication, and clinical detail, limiting its reliability for inclusion in formal evidence summaries.</p>
<p>Hindricks G, Doshi R, Defaye P, et al. (2024)</p> <p>Six-month electrical</p>	<p>n=381; follow-up duration: 6 months post-implant</p>	<p>The Aveir DR dual-chamber LP showed stable and improving electrical performance over 6 months. Capture thresholds significantly</p>	<p>Short-term follow-up (6 months) in an early experience cohort; long-term outcomes and</p>

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<p>performance of the first dual-chamber leadless pacemaker.</p> <p>Heart Rhythm 2024;21(1):66–73.</p>		<p>decreased in both atrial (2.4 V to 0.8 V) and ventricular (0.8 V to 0.6 V) devices. Sensed amplitudes increased (atrial: 1.8 mV to 3.4 mV; ventricular: 8.8 mV to 11.7 mV). Impedance remained stable in the atrial device and decreased in the ventricular device. Performance did not vary by implant location. These results suggest robust and reliable pacing and sensing for dual-chamber LPs.</p>	<p>comparative effectiveness data with dual LP has been included in the main evidence summary.</p>
<p>Huang J, Bhatia NK, Lloyd MS, et al. (2023)</p> <p>Outcomes of leadless pacemaker implantation after cardiac surgery and transcatheter structural valve interventions.</p> <p>J Cardiovasc Electrophysiol 34(11): 2216–2222.</p>	<p>n=78; mean follow-up: 1.3; SD 1.1 years</p>	<p>LPs were successfully implanted in post-surgical and post-transcatheter valve intervention group, with device electrical performance over medium-term follow-up. Mean RVP burden decreased significantly (from 74% to 48%; $p<.001$). LVEF showed a modest decline (from 55% to 52%; $p<.001$). 6 people (8%) required conversion to TVPs—four because of need for cardiac resynchronisation and two for dual-chamber pacing. No device-related safety issues were highlighted.</p>	<p>Broader registry study has been added in the main summary evidence.</p>
<p>Huang J, Bhatia NK, Lloyd MS, et al. (2024)</p> <p>Impact of omitting the intravenous heparin bolus on outcomes of</p>	<p>n=621 LP implantations; 326 with heparin bolus, 243 without, 52 excluded because of</p>	<p>No statistically significant differences were observed between heparin bolus and no-bolus groups in terms of procedural complications (hematoma,</p>	<p>Operators chose anticoagulation strategy, possibly reflecting population-level confounders not fully adjusted.</p>

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leadless pacemaker implantation. J Cardiovasc Electrophysiol 35(6):1212-1216.	unknown status; median follow-up: 14.3 months	pseudoaneurysm, cardiac perforation, thrombus formation), 30-day readmission or mortality, or implant electrical parameters.	
Hofer D, Regoli F, Saguner AM, et al. (2023) Efficacy and Safety of Leadless Pacemaker Implantation in Octogenarians. Cardiology 148(5): 441–447	n=220 (of which 124 were 80 years or more) Follow-up: Not explicitly stated; included procedural and post-implant follow-up measurements	Implantation in octogenarians was found to be safe and effective, with a high success rate (99%) and a low major complication rate (3%). Procedural time and radiation exposure were slightly higher in people more or equal to 80 years, but post-procedural outcomes and device performance were comparable to younger people.	While relevant for older adults, the study's retrospective design, limited follow-up duration, and non-comparative structure reduce its strength for informing this evidence summaries.
Ip JE, Rashtian M, Exner DV, et al. (2024) Atrioventricular Synchrony Delivered by a Dual-Chamber Leadless Pacemaker System. Circulation 150(6): 439–450	n=464 enrolled; n=384 evaluable (83%) Follow-up: 3 months post-implantation	Achieved a mean atrioventricular (AV) synchrony of 98% across all evaluated beats and postures, outperforming atrial-to-ventricular and ventricular-to-atrial i2i communication success rates (both 94%; p<0.001). AV synchrony more than 95% was maintained consistently across various postures (sitting, standing, supine, lateral recumbency), activity levels (walking, fast walking), implantation indications, AV event types, and heart rates including more than 100 bpm.	The study's follow-up period was limited to 3 months, which may not capture long-term performance and safety outcomes, which restricts its inclusion in evidence summaries prioritising long-term comparative data from randomised or controlled observational studies.
Ip J (2024) Minimizing for Maximum Benefit: An Illustrative Case-Series of Atrial	Atrial pacing Case series N=4	This first report case-series of atrial LPs describes and discusses the potential use-case scenarios of recently approved helix-fixation	More comprehensive studies included in table 2.

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<p>Only Leadless Pacing. https://doi.org/10.1111/pace.15138</p>		<p>atrial LPs. The article highlights important concepts regarding their use, including implantation techniques, programming, battery conservation, and the low rate of progression of AV block in people implanted with AAI(R) pacemakers.</p>	
<p>Ip JE, Cheung JW, Liu CF et al. (2025) Maximizing battery longevity of leadless pacemaker systems by optimizing individualized programming. Heart Rhythm 2025:1–2.</p>	<p>Case series n=217 people were implanted with Aveir LP systems: 100 dual-chamber LPs, 17 atrial-only and 100 ventricular-only LPs. Follow-up was 21 months.</p>	<p>This study (on first generation leadless pacing systems in only 17 atrial implants) reported increased total projected longevity. These findings can be attributable to performance and patient specific programming.</p>	<p>Similar findings have been reported in studies included in the overview.</p>
<p>Jelisejevas J, Regoli F, Hofer D, et al. (2024) Leadless Pacemaker Implantation in Patients with a Prior Conventional Pacing System. CJC Open 6(4): 649–655</p>	<p>n=257</p> <ul style="list-style-type: none"> • Group 1: n=233 (no prior CPS) • Group 2: n=24 (prior CPS, 20 required lead extraction) <p>Follow-up: Mean 12.5; SD 9.3 months</p>	<p>Implantation was successful and safe in people with prior conventional pacing systems (CPS). There were no major complications in the prior CPS group, including those who underwent lead extraction because of infection. No infections were recorded post-LP implantation, even when LP implantation followed device-related infection. Electrical parameters at implant and follow-up were comparable between groups. Major complications occurred in 3% of the full cohort (none in the prior CPS group).</p>	<p>Despite its relevance, the study's small subgroup size for prior CPS people (n=24), retrospective design, and limited generalisability restrict its inclusion in main evidence summaries prioritising large-scale or prospective comparative studies.</p>

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<p>Jelisejevas J, Regoli F, Hofer D, et al. (2023) Leadless Pacemaker Implantation, Focusing on Patients With Conduction System Disorders Post-Transcatheter Aortic Valve Replacement: A Retrospective Analysis. CJC Open 6(2Part A): 96–103.</p>	<p>n=257 (26 with post-TAVR bradycardia; 231 non-TAVR controls); follow-up duration not explicitly reported, but complications assessed within 30 days post-implantation.</p>	<p>The implantation success rates were 100% in TAVR and 99% in non-TAVR groups. No significant differences were found in pacing parameters (sensing, impedance, and threshold) at implantation or during follow-up. The major complication rate was similarly low (4% in TAVR versus 3% in non-TAVR).</p>	<p>Broader registry study has been prioritised in the main summary evidence.</p>
<p>Jelisejevas J, Breitenstein A, Hofer D, et al. (2021) Left femoral venous access for leadless pacemaker implantation: patient characteristics and outcomes. Europace 23(9): 1456–1461</p>	<p>n=143 (125 right femoral access, 18 left femoral access) Follow-up: Mean 15; SD 11.5 months</p>	<p>Left femoral venous access for LP implantation was safe and effective, with procedural success and device parameters comparable to the conventional right-sided approach. All 5 major complications (4%) occurred with right-sided access. Left-sided access was more commonly used following transfemoral TAVI (42% versus 8%, P=0.003).</p>	<p>While informative, the small sample size for left-sided access (n=18) and single-centre retrospective design limit generalisability</p>
<p>Katsuki T, Nagashima M, Kono H, et al. (2022) Clinical outcome for heart failure hospitalizations in patients with leadless pacemaker.</p>	<p>n=929 (368 LPs vs. 561 TVPs) Median follow-up: 1.7 years (IQR 0.8–2.6 years)</p>	<p>People with LPs had a significantly higher risk of heart failure hospitalisation than those with conventional pacemakers (adjusted HR 1.7; 95% CI 1.1 to 2.6; p=0.01).</p>	<p>The study's retrospective design and observational nature limit the ability to establish causality between pacemaker type and heart failure hospitalisation. Additionally, the median follow-up duration of 1.7</p>

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Journal of Arrhythmia 38(5): 730–735			years may not be sufficient to capture long-term outcomes associated with different pacemaker types.
<p>Kempa M, Mitkowski P, Kowalski O, et al. (2021)</p> <p>Expert opinion of a Working Group on Leadless Pacing appointed by the National Consultant in Cardiology and the Board of the Heart Rhythm Section of the Polish Cardiac Society.</p> <p>Kardiologia Polska 79(5): 604–608.</p>	Not applicable (policy and guidance document; no population cohort analysed)	Endorsed LPs as a safe and effective alternative to traditional TVPs, particularly when infection risk or venous access issues exist. Highlighted positive outcomes from international clinical trials confirming LP safety and efficacy. Provided Polish-specific guidance including - indications and contraindications for LP use, emphasis on procedural expertise and proper center accreditation for implantation and called for formal reimbursement frameworks in Poland to increase access.	This is an expert consensus document providing recommendations for clinical practice in Poland, not an original empirical study with a population cohort.
<p>Khan MZ, Nguyen A, Khan MU, et al. (2024)</p> <p>Association of chronic kidney disease and end-stage renal disease with procedural complications and inpatient outcomes of leadless pacemaker implantations across the United States.</p>	<p>n=29,005 LP implantations (CKD: n=5,245 [18.1%]; ESRD: n=3,790 [13.1%])</p> <p>In-hospital outcomes only (no post-discharge follow-up)</p>	CKD and ESRD were significantly associated with increased inpatient mortality.	Focused only on in-hospital outcomes.

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<p>Khan MZ, Nassar S, Nguyen A, et al. (2024) Contemporary trends of leadless pacemaker implantation in the United States. Journal of Cardiovascular Electrophysiology 35(7): 1351–1359</p>	<p>Data from 2016–2020, showing growth from 3,230 LP implants (2016–2017) to 11,815 implants (2020) Follow-up: In-hospital outcomes only</p>	<p>LP implantations steadily increased in the US over the study period. Adjusted in-hospital mortality significantly declined (2018: aOR 0.6; 2019: aOR 0.5; 2020: aOR 0.5, all $p < 0.01$) compared to 2016 to 2017.</p>	<p>Trend study, not aligned with the objective of this overview.</p>
<p>Kiani S, Black GB, Rao B, et al. (2019) Outcomes of Micra leadless pacemaker implantation with uninterrupted anticoagulation. Journal of Cardiovascular Electrophysiology 30(8): 1313–1318</p>	<p>n=170 (OAC group: n=26; Off-OAC group: n=144) Follow-up: Not explicitly stated, complete in-hospital and procedural data</p>	<p>Implantation with uninterrupted anticoagulation (OAC) was safe and feasible. The composite complication rate was similar between OAC and Off-OAC groups (4% versus 1%; $P=0.761$), with no significant difference in length of stay (1.3; SD 2.6 vs 2.3; SD 3.4 days; $P=0.108$).</p>	<p>Focused on a specific subset of population, also the sample size is smaller.</p>
<p>Kiani S, Black GB, Rao B, et al. (2019) The Safety and Feasibility of Same-Day Discharge After Implantation of MICRA Transcatheter Leadless Pacemaker System.</p>	<p>n=167 (Same-day discharge [SD] group: n=25; Hospitalised overnight [HD] group: n=142) Follow-up: 45 days</p>	<p>Same-day discharge after LP implantation was safe and feasible. No major complications occurred in the SD group vs. 4% in the HD group ($P=1.00$), with similar rates of individual complications such as access site issues, pericardial effusion, dislodgement, or device revision.</p>	<p>The study did not capture long term safety and efficacy outcomes.</p>
<p>Kiblboeck D, Blessberger H, Ebner J, et al. (2024) Feasibility, timing and outcome of leadless cardiac pacemaker implantation in</p>	<p>n=48, undergoing CIED extraction (38 for infection, 10 for dysfunction); median follow-up 15 months (IQR 12 to 41)</p>	<p>LP implantation was feasible in 98% of people undergoing CIED extraction, with 67% receiving the LP in a single procedure. Complete CIED removal was achieved in 92% overall and 97% of</p>	<p>Covered in the systematic review included in the main evidence body.</p>

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<p>patients undergoing cardiac implantable electronic device extraction.</p> <p>Clin Res Cardiol 2024 Aug 12. doi: 10.1007/s00392-024-02516-0</p>		<p>infected cases. In-hospital mortality was 6%, and 1-year survival was 85%. No LP-related mortality or recurrent infections occurred during follow-up.</p>	
<p>Knops RE, Tjong FVY, Neuzil P, et al. (2015)</p> <p>Chronic performance of a leadless cardiac pacemaker: 1-year follow-up of the LEADLESS trial.</p> <p>Journal of the American College of Cardiology 65(15): 1497–1504</p>	<p>n=31 (implanted with LPs)</p> <p>Follow-up: 12 months</p>	<p>Demonstrated stable electrical performance at 6 and 12 months, with mean pacing thresholds of 0.40; SD 0.3 V (6 months) and 0.43; SD 0.3 V (12 months), R-wave amplitudes of 10.6; SD 2.6 mV and 10.3; SD 2.2 mV, and impedance of 625; SD 205 ohms and 627; SD 209 ohms, respectively.</p>	<p>Small sample size and single-arm design without comparator group limits generalisability and prevents comparative assessment with conventional pacing systems.</p>
<p>Kowlgi GN, Tseng AS, Tempel ND, et al. (2022)</p> <p>A real-world experience of atrioventricular synchronous pacing with leadless ventricular pacemakers.</p> <p>J Cardiovasc Electrophysiol 33(5):982–993.</p>	<p>n=56 with LP implants;</p> <p>minimum follow-up 3 months</p>	<p>65% of people achieved atrial synchronous ventricular pacing (AVP) equal or more than 70%. Higher AV synchrony was associated with lower BMI, fewer comorbidities (e.g., heart failure), and prior cardiac surgery.</p>	<p>Covered by systematic review included in the main evidence summary.</p>
<p>Lenormand T, Abou Khalil K, Bodin A et al. (2023)</p> <p>Comparison of first- and second-generation</p>	<p>n=93 (45 first-generation Micra VR, 48 second-generation Micra AV)</p> <p>Follow-up: At least 1 year</p>	<p>Second-generation Micra AV pacemakers achieved atrioventricular synchrony (median AV-synchronous beats: 78%) and were associated with significantly lower</p>	<p>Focused on head-to-head comparison between device generations rather than broader safety/effectiveness</p>

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<p>leadless pacemakers in patients with sinus rhythm and complete atrioventricular block.</p> <p>Journal of Cardiovascular Electrophysiology 34(8): 1730–1737.</p>		<p>incidence of pacemaker syndrome (0% versus 11% in Micra VR group, $p=0.02$).</p>	<p>ss outcomes. Small sample size and short-term follow-up limit generalisability.</p>
<p>Lenormand T, Abou Khalil K, Bodin A et al. (2023)</p> <p>Leadless cardiac pacing: Results from a large single-centre experience.</p> <p>Archives of Cardiovascular Disease 116(6-7): 316–323.</p>	<p>n=400 (328 Micra VR, 72 Micra AV)</p> <p>Follow-up: Median 16 months (694 person-years)</p>	<p>Implantation success was 100%. At 30 days, perioperative complication rate was 4%, and 88% of people were discharged the next day.</p>	<p>Single-centre retrospective study without a comparator group or stratified outcome data; limits generalisability.</p>
<p>Li B, Allen JC, Arps K, et al. (2022)</p> <p>Leadless pacemaker implantation after lead extraction for cardiac implanted electronic device infection.</p> <p>J Cardiovasc Electrophysiol 33(3): 464–470.</p>	<p>n=39; mean follow-up 24.8; SD 14.7 months</p>	<p>LP implantation following extraction of infected cardiac devices was associated with low complication rates and no recurrence of infection during the 2-year follow-up. Among 3 major complications (8%), none were infections.</p>	<p>Covered in systematic review included in main evidence summary.</p>
<p>Loring Z, North R, Hellkamp AS, et al. (2020)</p> <p>VVI pacing with normal QRS duration and ventricular function: MOST trial findings</p>	<p>n = 1284 (subset of the original 2010 MOST participants)</p> <p>Inclusion: LVEF more than 35%, QRS duration less than 120 ms, no prior ICD or</p>	<p>VVIR pacing, typical of most LPs, does not increase the risk of death, stroke, or heart failure hospitalisation compared to DDDR pacing.</p> <p>However, it significantly increases the risk of</p>	<p>Focused on pacing mode effects in LP-eligible populations, particularly highlighting the AF risk tradeoff with VVIR mode</p>

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relevant to leadless pacemakers. Pacing and Clinical Electrophysiology 43(12): 1545–1553.	ventricular arrhythmias Follow-up: 4 years	new-onset AF, especially in people without a history of AF.	pacing typical in current LP devices.
Lago-Quinteiro JR, Reyes-Santias F, Antelo M et al. (2025) Single-chamber pacemakers: with or without leads? Cost-effectiveness and cost-utility analyses. Ann Med. 57(1):2512108.	Ventricular pacing, single chamber Retrospective observational study of 403 people implanted with a conventional (n=244) or leadless pacemaker (n=159). Study compared cost-effectiveness and cost-utility.	Leadless pacemakers have fewer complications than conventional pacemakers and, although the device itself is more expensive, the leadless pacemaker is more cost-effective in around 90% of cases.	Focused on costs
Leal MA, Sheldon T, Escalante K et al. (2025) Device longevity of a leadless pacemaker family. Future Cardiol. 21(10):753-75.	Ventricular pacing, single chamber Retrospective modelling and simulation study using real world data (644 people for Micra VR/VR2; 999 people for Micra AV/AV2).	Modelling of the Micra leadless pacemakers projected meaningful improvements in device longevity and an increase in the number of people served with a single device.	Projected battery longevity estimates.
Mararenko A, Udongwo N, Pannu V, et al. (2023) Intracardiac leadless versus transvenous permanent	n=21,782 (mean age 81.1 years, 46% female); follow-up focused on 30-day readmissions and in-hospital outcomes	No significant difference in 30-day readmission (HR 1.1, 95% CI 0.9 to 1.4) or inpatient mortality (HR 1.4, 95% CI 0.7 to 2.6) between LP and TVP groups. Length of stay was slightly longer	Covered in systematic review included in main evidence summary.

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pacemaker implantation: Impact on clinical outcomes and healthcare utilization. J Cardiol 82(5):378–387.		for LP recipients (0.5 days; $p < 0.001$).	
Martínez-Sande JL, García-Seara J, Rodríguez-Mañero M et al. (2017) The Micra Leadless Transcatheter Pacemaker. Implantation and Mid-term Follow-up Results in a Single Center. Revista Española de Cardiología (English Edition) 70(4): 275–281.	n=30 (65 years or more); Mean follow-up: 5.3; SD 3.3 months (range up to more than 1 year in 4 people)	Successful implantation was achieved in all. Electrical pacing and sensing parameters remained stable from implantation through follow-up. 1 moderate pericardial effusion occurred without tamponade; otherwise, no severe complications were observed.	Small single-centre study with limited follow-up duration and generalisability. Also, concurrent procedures were assessed.
Martínez-Sande JL, García-Seara J, González-Melchor L, et al. (2021) Conventional single-chamber pacemakers versus transcatheter pacing systems in a "real world" cohort of patients: A comparative prospective single-center study. Indian Pacing Electrophysiol J 21(2):89–94.	n=443 (LP: n=198, TVP: n=245); mean follow-up 22.3; SD 15.9 months	LP recipients had significantly fewer overall complications compared to TVP groups (HR 0.4, 95% CI 0.2 to 1; $p = 0.013$), with a 96% probability of lower risk in Bayesian analysis. No significant differences in major complications (LP 3% versus TVP 6%; $p = 0.1761$) or mortality.	Covered in systematic review included in the main body evidence.
Mitacchione G, Schiavone M,	n=1179 (64% male); after	There were no statistically significant	While sex-specific findings are

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<p>Gasperetti A, et al. (2023) Sex differences in leadless pacemaker implantation: A propensity-matched analysis from the i-LEAPER registry. Heart Rhythm 20(10):1429–1435.</p>	<p>matching, n=738 (1:1 matched); median follow-up: 25 months (IQR 24 to 39)</p>	<p>sex differences in major complication rates (HR 2.03; 95% CI 0.7 to 5.8; p=.190) or all-cause mortality (HR 1; 95% CI 0.4 to 2.4; p=.96). LP performance was similar between men and women, although women had slightly higher pacing impedance at implant and follow-up (670 ohms vs 616 ohms at 24 months; p=.014), remaining within acceptable ranges. Women were underrepresented among LP recipients.</p>	<p>valuable, the analysis was exploratory and not powered to detect small differences in adverse outcomes. No impact on safety or efficacy was observed despite impedance variation.</p>
<p>Molina-Lerma M, Cózar-León R, García-Fernández FJ, Calvo D. (2024) Spanish pacemaker registry. 21st official report of Heart Rhythm Association of the Spanish Society of Cardiology (2023). Rev Esp Cardiol (Engl Ed) 77(11):947–956.</p>	<p>112 hospitals participated 24,343 LP implantations reported in 2023 No specific population-level follow-up data provided</p>	<p>Marked 48% increase in reported device implantations compared to 2022. LPs saw an 18% rise, with 963 devices implanted. AV block remained the top indication; atrial tachyarrhythmia with slow ventricular response ranked second for the first time.</p>	<p>This is a national registry report summarising implantation trends and system use in Spain, not a clinical trial or comparative study measuring population outcomes.</p>
<p>Molina-Linde JM, Díaz-Infante E, Tercedor-Sánchez L, et al. (2023) The VR leadless pacemaker: Results of an expert panel using the RAND/UCLA method.</p>	<p>Involved expert evaluation of 256 clinical scenarios, 64 for people with AF, 192 for people in sinus rhythm. Follow-up not applicable; no population-level outcome data</p>	<p>The panel created appropriateness criteria for VR LP implantation. Limitation of vascular access via the superior vena cava was the strongest predictor for recommending LPs in both groups. Additional relevant variables included: life expectancy, risk of infection,</p>	<p>It provides expert-based recommendations rather than empirical outcome data.</p>

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Pacing Clin Electrophysiol 46(5):358–364.		presence of prosthetic valves, LVEF and population mobility and exercise capacity.	
Manzo G, Giannola G, Nigro G et al. (2025) Outcomes of Micra leadless pacemaker implants in centers with and without cardiac surgery. J Cardiovasc Electrophysiol. 36(7):1512-1519	Ventricular pacing, single chamber Retrospective cohort study. n=1,899 people who had a Micra pacemaker at 23 centres. People were divided into 2 groups: those implanted in centres with cardiac surgery (n=1,025) and those without (n=874) Follow-up 12 months	The Micra leadless pacemaker can be safely and effectively implanted in centres without cardiac surgery capabilities, broadening access to this technology across diverse clinical settings.	More comprehensive studies are included in the summary of evidence.
Mitacchione G, Schiavone M, Gasperetti A et al (2025) Leadless pacemakers in patients with different stages of chronic kidney disease: Real-world data from the updated i-LEAPER registry. Heart Rhythm. 22(2):325-331.	Ventricular pacing, single chamber Registry study People were divided into 3 groups according to chronic kidney disease (CKD) stage. n=1,748 people enrolled, 33% were in CKD stage G3a/G3b and 9.4% were in CKD stage G4/G5.	In a real-world setting, people with advanced CKD who had leadless pacemaker implantation were underrepresented. Although all-cause mortality was higher in end-stage CKD, periprocedural complications and leadless pacemaker performance were overall comparable between normal kidney function and different stages of CKD, except for higher values of pacing threshold in people with CKD up to first-month follow-up.	More comprehensive studies are included in the summary of evidence.
Mekary W, Vijayvargiya S, Mouawad C et al.	Atrial, ventricular or	A modular pacing approach for leadless pacing was adopted.	Short term follow-up.

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<p>(2025) A Modular Approach for Leadless Pacing. J Cardiovasc Electrophysiol. doi: 10.1111/jce.16740. Epub ahead of print</p>	<p>dual-chamber pacing</p> <p>Retrospective case series n=89 people who had AVEIR leadless pacemaker implantation (37 single-chamber atrial AVEIR, 34 single-chamber ventricular AVEIR, and 18 dual-chamber devices). Follow-up median 4.7 months.</p>	<p>This strategy focuses on minimising the amount of hardware in the heart. This reduces complications such as perforation and dislodgment while optimising battery longevity, which is affected by i2i communication.</p>	
<p>Mekary W, Anerao A, Shah AD et al. (2025) Elevated Pacing Thresholds During Atrial LP Implantation. Heart Rhythm 2025 (article in press)</p>	<p>Retrospective cohort study n=53 AVIER atrial leadless pacemakers. Follow-up 1 month</p>	<p>All people had improved pacing thresholds after 24 hours (0.8V at 0.4 ms), which remained stable during follow-up.</p>	<p>Similar outcomes reported in studies included in evidence summary.</p>
<p>Nair DG, Exner DV, Hadadi C et al. (2024) Early real-world implant experience with a helix-fixation ventricular leadless pacemaker. Journal of Interventional Cardiac Electrophysiology 67: 1539–1545.</p>	<p>n=167 Follow-up: 30 days post-implant</p>	<p>Implantation of the helix-fixation Aveir VR was successful in 99% of cases, with 98% free from acute adverse events.</p>	<p>Short-term follow-up (30 days), limited to initial commercial rollout without comparator group, and focused only on procedural outcomes.</p>
<p>Neuzil P, Exner DV, Knops RE, et al. (2025)</p>	<p>n=233 subjects with 234 retrieval attempts (mean</p>	<p>The chronic retrieval success rate for helix-fixation LPs was 88%</p>	<p>Focused on device retrieval safety and</p>

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Worldwide Chronic Retrieval Experience of Helix-Fixation Leadless Cardiac Pacemakers. J Am Coll Cardiol 85(11):1111–1120.	retrieval time = 3.2 years, range 0.2 to 9 years post-implant)	(205/234). Failures were mostly because of inability to access the docking button (86%). Retrieval-related complications occurred in 4% of people (9/233), with 11 total complications. Time since implantation (up to 9 years) did not statistically significantly affect retrieval success (p=0.71).	feasibility rather than on comparative effectiveness or long-term pacing outcomes of LPs versus TVPs.
Neuzil, Petr et al. (2024) Implantation techniques for a helix-fixation dual-chamber leadless pacemaker Heart Rhythm, Volume 21, Issue 12, 2552 - 2562	Dual-chamber pacing	With time and adherence to guidance in this article, novel dual-chamber LP implantation can become streamlined and routine, although the workflow may differ from transvenous implantation with which users are familiar.	Review on guidance for implantation procedures.
Ngo L, Nour D, Denman RA et al. (2021) Safety and Efficacy of Leadless Pacemakers: A Systematic Review and Meta-Analysis. Journal of the American Heart Association 10(13): e019212.	36 studies included Micra: n=1608 (90-day data), n=3194 (1-year data) Nanostim: variable, fewer studies Follow-up: up to 1 year	LPs showed a low pooled complication rate (less than 1% at 90 days and 2% at 1 year) and excellent pacing capture threshold maintenance (99% with less than or equal to 2V at 1 year).	More recent systematic reviews with inclusion of studies with longer follow up duration have been covered in the main evidence summary.
Nicosia A, Iacopino S, Nigro G et al. (2022) Performance of transcatheter pacing system use in relation to patients' age.	n=577 Follow-up: Not explicitly stated; electrical parameters and safety outcomes assessed at	LP implantation was found to be safe and effective across all age groups (less than 70, 70 to 77, 78 to 83, and 83 and above years). Procedural complications were rare (less than 1%)	A larger study with similar subgroup of people was included in the main evidence summary.

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Journal of Interventional Cardiac Electrophysiology 65(1): 103–110.	implant and last follow-up	and did not differ significantly by age group, despite greater frailty in older people. No cases of cardiac tamponade were reported. Electrical performance remained stable and comparable across all ages.	
Noor TA, Rana MOR, Kumari S et al. (2023) Outcomes of primary leadless pacemaker implantation: A systematic review. Annals of Noninvasive Electrocardiology 28(6): e13084.	n=1276 across 4 included studies Follow-up duration not consistently reported across all studies	LPs had shorter procedure and fluoroscopy times compared to temporary or TVPs in some studies. Major complications and mortality were not significantly different, and pacing parameters (threshold, impedance, sensing) were comparable. Hospital stay was generally shorter with LPs. The review suggests LPs may be an effective and safer alternative even in urgent/emergency pacing situations.	More recent systematic reviews have been included in the main evidence summary.
Nguyen A, Khan MZ, Sattar Y et al. (2025) Procedural complications and inpatient outcomes of leadless pacemaker implantations in rural versus urban hospitals in the United States. Clin Cardiol. 48(3): e70081	Ventricular pacing, single chamber Retrospective analysis n=29,005 (urban hospitals n=28,340, rural hospitals n=665). Follow-up: inpatient outcomes only.	Most leadless pacemaker implantations occurred in urban hospitals in the United States. Important differences in outcomes were described based on urban and rural hospital location.	More comprehensive studies are included in the summary of evidence. Focused only on in-hospital outcomes.
Oates CP, Breeman KTN, Miller MA, et al. (2024)	n=100; median follow-up duration: 10.6	Intraoperative LPs implantation during valve surgery was successful in all, with no device-	Broader registry study has been included in the

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<p>Long-Term Safety and Efficacy of Intraoperative Leadless Pacemaker Implantation During Valve Surgery. JACC: Clinical Electrophysiology 10(10): 2224–2233.</p>	<p>months (IQR: 2 to 22.7 months)</p>	<p>related complications during follow-up. At 12 months, 95% of people maintained acceptable pacing thresholds (2.0 V or lower at 0.24 ms). The cohort included 99% with tricuspid valve involvement and 78% undergoing multivalve surgery.</p>	<p>main evidence summary.</p>
<p>Oates CP, Basyal B, Whang W, et al. (2024) Trends in safety of catheter-based electrophysiology procedures in the last 2 decades: A meta-analysis. Heart Rhythm 21(9): 1718–1726.</p>	<p>n=43,914 across 174 studies Includes:</p> <ul style="list-style-type: none"> • AF ablation: n=24,057 (126 studies) • Ventricular tachyarrhythmia ablation: n=1,781 (25 studies) • LP: n=8,896 (21 studies) • Left atrial appendage occlusion: n=9,180 (18 studies) Follow-up duration not uniformly reported 	<p>Vascular complication rates remained unchanged. Results suggest that procedural safety of catheter-based electrophysiology, including LP implantation, has improved over time despite increased usage.</p>	<p>It included multiple other procedures alongside LPs.</p>

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<p>Pagan E, Gabriels J, Khodak A, et al. (2020) Safety of leadless pacemaker implantation in the very elderly. Heart Rhythm 17(12):2023–2028.</p>	<p>n=302, aged 85 years or more (LP: n=183; TVP: n=119); follow-up not specified; focused on in-hospital procedural outcomes</p>	<p>LP implantation in very elderly people was successful in 98% and associated with similar procedure-related complication rates compared to TVP (3% vs 6%, $p=0.276$). LP group had significantly shorter procedure times (35.7; SD 23 minute versus 62.3; SD 31.5-minute, $p<0.001$). No significant differences in pericardial effusion, hematoma, or lead dislodgement rates.</p>	<p>Covered in systematic review included in the main evidence summary.</p>
<p>Palmisano P, Guido A, Panico V, et al. (2021) Leadless pacemaker versus transvenous single-chamber pacemaker therapy: peri-procedural aspects, utilization of medical resources and patient acceptance. Expert Review of Medical Devices 18(5): 483–491.</p>	<p>n=154 (77 matched pairs: LP versus TVP) Follow-up: baseline, 1 week, 3 months, and 6 months</p>	<p>L-PM implantation was associated with longer procedural time (42.2;SD 16.3 vs. 28.9;SD 11.9 minutes; $p<0.001$) but lower intra- and post-operative pain, shorter hospitalisation (3.2;SD 0.5 vs. 3.5;SD 1.1 days; $p=0.034$), greater acceptance (FPAS score: 58.7;SD 7.1 vs. 40.5;SD 4.1; $p<0.001$), and better quality of life on physical and mental health scales at all timepoints.</p>	<p>Single-centre study with a relatively small sample size; findings may not be generalisable to broader populations. Outcomes such as complication rates and long-term device performance were not the primary focus.</p>
<p>Palmisano P, Iacopino S, De Vivo S, et al. (2022) Leadless transcatheter pacemaker: Indications, implantation technique and peri-procedural patient</p>	<p>n=782 Median follow-up: 20 months</p>	<p>Implantation of L-PMs was primarily chosen because of high infection risk (30% of people). The implantation success rate was 99%, with 90% of devices implanted septally.</p>	<p>Focused on per-procedural patient management.</p>

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<p>management in the Italian clinical practice.</p> <p>International Journal of Cardiology 365: 49–56.</p>			
<p>Palmisano P, Facchin D, Ziacchi M, et al. (2023)</p> <p>Rate and nature of complications with leadless transcatheter pacemakers compared with transvenous pacemakers: results from an Italian multicentre large population analysis.</p> <p>EP Europace 25(1):112–120.</p>	<p>n=2669 total (LP: n=665; TVP: n=2004); matched cohort: n=884 (442 LP versus 442 TVP); median follow-up: 39 months</p>	<p>LP group had significantly lower 12-month device-related complication rate (1% versus 2%, p=0.009). In the matched analysis, LP was associated with fewer late complications (more than 30 days; p=0.031), while early complication risk was similar (p=1.000). All LP complications occurred early, whereas 75% of TVP complications were lead- or pocket-related.</p>	<p>Covered in the systematic review included in the main evidence summary.</p>
<p>Palmisano P, Rovaris G, Della Rocca DG et al. (2025)</p> <p>Comparison of 30-day complications between a tine-based and a screw-in helix fixation single-chamber ventricular leadless pacemaker: Results of a propensity score-matched analysis from a multicenter, nationwide registry. Heart</p>	<p>Ventricular pacing, single chamber</p> <p>Prospective registry n=1,141 people who had Aveir VR (n=211) or Micra VR (n=930) implantation.</p> <p>Propensity score matched 1:1 (n=189 pairs).</p> <p>Follow-up 30 days.</p>	<p>The risk of acute device-related complications associated with Aveir VR and Micra VR leadless pacemaker implantation was similar. These findings suggest that despite differences in design, fixation mechanism, and implantation technique, these 2 devices appear to have a similar short-term safety profile.</p>	<p>More comprehensive studies are included in the summary of evidence.</p> <p>Short term follow-up.</p>

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Rhythm. 22(8): e431-e437. doi: 10.1016/j.hrthm.2025.03.1881 Epub 2025 Mar 10.			
Parulkar A, Sheikh W, Has P et al. (2025) Leadless versus single chamber pacemakers: An analysis from the national readmissions database of adverse outcomes. J Cardiovasc Electrophysiol. 36(7):1538-1547	Ventricular pacing, single chamber Retrospective cohort study Data from national readmissions database was analysed from January 2016 to December 2019	Mortality rates were higher in people having leadless pacemakers with a higher incidence of adverse outcomes in patients with dialysis dependence and pulmonary hypertension. Clinical benefits may be offset by increased risk of procedural mortality and adverse outcomes.	More comprehensive studies are included in the summary of evidence.
Piccini JP, Stromberg K, Jackson KP, et al. (2017) Long-term outcomes in leadless Micra transcatheter pacemakers with elevated thresholds at implantation: Results from the Micra Transcatheter Pacing System Global Clinical Trial. Heart Rhythm 14(5):685–691.	LP cohort: n=711 Capture (TVP) cohort: n=538 Follow-up: up to 6 months	12% LP populations had an initial pacing threshold more than 1 V at 0.2 ms pulse width. Thresholds statistically significantly decreased over time ($p<.001$), with 87% of those with high thresholds (1 to 1.5 V) and 85% of those with very high thresholds (more than 1.5 V) showing improvement by 6 months. Only 18% of people with an initial threshold more than 2 V achieved a threshold at 1 V or less at 6 months.	Primarily focuses on threshold behavior post-implant rather than broader clinical outcomes or direct device comparisons, might be informative for procedural decision-making.
Piccini JP, Stromberg K, Jackson KP, et al. (2019) Patient selection, pacing	n=720, successfully implanted with LP; 228 (32%) had non-AF indications;	The study found that 32% of LP implants were for non-AF-related indications, mainly because of expectations of infrequent pacing	The analysis was limited to the Micra IDE cohort and lacked direct comparisons with transvenous

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indications, and subsequent outcomes with de novo leadless single-chamber VVI pacing. Europace 21(11):1686–1693.	follow-up: 24 months	(66%) or advanced age (27%). Non-AF people had significantly lower VP needs (median 13%) compared to AF people (68%; $p < 0.001$). The 24-month risk of the composite outcome (cardiac failure, pacemaker syndrome, or syncope) was low (2%) and similar between groups (HR 1.4; 95% CI 0.5 to 4.2; $p = 0.59$), supporting the safety and feasibility of leadless pacing in selected non-AF population.	pacing or atrioventricular synchronous pacing outcomes
Piccini JP, El-Chami M, Wherry K, et al. (2021) Contemporaneous Comparison of Outcomes Among Patients Implanted with a Leadless vs Transvenous Single-Chamber Ventricular Pacemaker. JAMA Cardiol 6(10):1187–1195.	n=15,408 (LP: n=5746; TVP: n=9662); acute outcomes at 30 days and complications at 6 months	LP recipients had higher unadjusted acute complication rates (8% versus 7%; $p = .02$) and more pericardial effusions/perforations (1% vs 0.4%; $p = .004$). However, after adjusting for population characteristics, the overall acute complication rate was similar (8% vs 7%). LP recipients had significantly fewer 6-month complications than TVP recipients (adjusted HR 0.8; 95% CI, 0.6 to 1; $p = .02$).	Covered by the systematic review included in the main evidence summary.
Rashtian, Mayer Y. et al. (2025) Temperature-based rate response in a leadless pacemaker system Heart Rhythm, Volume 22, Issue 6, 1533 - 1540	Dual-chamber pacing	The temperature-based sensor in a dual-chamber leadless pacemaker system was shown to be effective at modulating pacing rate in response to increased metabolic demand for right ventricular and atrial devices.	Studies with more relevant outcomes are included.

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Reddy VY, Exner DV, Cantillon DJ, et al. (2015) Percutaneous implantation of an entirely intracardiac leadless pacemaker. New England Journal of Medicine 373(12): 1125–1135.	n=526 enrolled; primary cohort: n=300, with 6-month follow-up	Successfully implanted in 96% of people. In the primary cohort, the combined efficacy endpoint (maintaining an acceptable pacing threshold less or equal to 2 V at 0.4 msec and R-wave amplitude more or equal to 5.0 mV through 6 months) was met in 90% of people, and the safety endpoint (freedom from device-related serious adverse events) was met in 93% of people.	The study evaluated the Nanostim LP, which is no longer available because of safety concerns, limiting the applicability of its findings to current clinical practice.
Reddy VY, Knops RE, Sperzel J et al. (2014) Permanent leadless cardiac pacing: results of the LEADLESS trial. Circulation 129(14): 1466–1471.	n=33 Follow-up: 3 months	Implant success rate was 97% (32/33). 1 person experienced right ventricular perforation and died following a stroke; the overall complication-free rate was 94%. Pacing parameters remained stable or improved over the 3-month period.	The small sample size, Nanostim device inclusion and short follow-up period limit the generalisability of the findings.
Reddy VY, Exner DV, Doshi R, et al. (2023) LEADLESS II Investigators. 1-Year Outcomes of a Leadless Ventricular Pacemaker: The LEADLESS II (Phase 2) Trial. JACC Clin Electrophysiol. 2023 Jul;9(7 Pt 2):1187-1189.	Observational study n=210 people with standard VVI(R) pacing indications had Aveir LCP system Mean follow-up was 14.4 months.	Data demonstrate the safety and efficacy of the Aveir LCP for right ventricular pacing through 1 year of follow-up. The estimated battery longevity at 1-year post-implantation is favourable. Study limitations include an observational non-randomised trial design and a modest sample.	Research letter
Reynolds D, Duray GZ, Omar R, et al. (2016) A Leadless Intracardiac	n=725 enrolled; n=719 (99%) received successful implantation;	LPs met both prespecified safety (96% free from major complications; p<0.001 versus goal of 83%) and	Covered in the systematic review included in the main evidence summary.

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<p>Transcatheter Pacing System. New England Journal of Medicine 374(6):533–541.</p>	<p>primary safety and efficacy assessed at 6 months</p>	<p>efficacy (98% with low, stable pacing thresholds; $p < 0.001$ versus goal of 80%) targets. No device dislodgements occurred. Post hoc comparison with a TVP cohort ($n = 2667$) showed a statistically significantly lower major complication rate (HR 0.5; 95% CI, 0.3 to 0.8; $p = 0.001$).</p>	
<p>Regoli FD, Saguner AM, Auricchio A, et al. (2023) Peri-Procedural Management of Direct-Acting Oral Anticoagulants (DOACs) in Transcatheter Miniaturized Leadless Pacemaker Implantation. J Clin Med 12(14):4814.</p>	<p>$n = 392$, undergoing LP implantation; 282 on anticoagulation, including 192 on DOACs. No specific long-term follow-up duration stated, focused on peri-procedural outcomes.</p>	<p>A standardised DOAC management approach—skipping 1 dose before the procedure and resuming 6 to 24 hours afterward—was used in 115 people (Group 1A) and compared to alternative strategies in 77 (Group 1B). The incidence of major peri-procedural complications was low and similar in both groups (3% in 1A vs 4% in 1B; $p = 0.685$). Group 1A people were more likely to undergo elective implantation and had better overall clinical profiles. No significant increase in bleeding or thromboembolic events was observed with the standardised DOAC protocol.</p>	<p>While relevant for procedural safety, the study focused on anticoagulation strategy rather than comparing pacemaker systems or long-term device-related outcomes.</p>
<p>Ritter P, Duray GZ, Steinwender C, et al. (2015) Early performance of a miniaturized leadless cardiac pacemaker: the Micra Transcatheter Pacing Study.</p>	<p>$n = 140$ Follow-up: Mean 1.9; SD 1.8 months; 3-month outcomes reported in 60 people</p>	<p>Met both safety and efficacy endpoints. No unanticipated serious adverse device events were reported. Among 60 people with 3-month follow-up, all had pacing thresholds less than 2 V, with a mean threshold of 0.5; SD 0.2 V. 1 case of pericardial effusion</p>	<p>Short follow-up period and limited 3-month data on a subset ($n = 60$) reduce confidence in long-term outcomes.</p>

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European Heart Journal 36(37): 2510–2519.		occurred without tamponade.	
Roberts PR, Clémenty N, Mondoly P, et al. (2023) A leadless pacemaker in the real-world setting: Patient profile and performance over time. Journal of Arrhythmia 39(1): 1–9.	n=928 Mean follow-up: 9.7; SD 6.5 months	Confirmed a high implant success rate (100%) and a low 30-day major complication rate (3%) for LPs, consistent with earlier IDE and PAR studies. Electrical performance was stable through 12 months, with a mean pacing threshold of 0.6; SD 0.4 V.	Broader real-world studies with larger sample size have been emphasised in main evidence summary.
Roberts PR, Clementy N, Al Samadi F, et al. (2017) A leadless pacemaker in the real-world setting: The Micra Transcatheter Pacing System Post-Approval Registry. Heart Rhythm 14(9): 1375–1379.	n=795 (implant success in 792; 99.6%) Follow-up: 30 days post-implant	100% implant success rate and a low 30-day major complication rate of 1.5%. Key complications included cardiac effusion, device dislodgement, and sepsis.	The short follow-up period limits the assessment of long-term safety and efficacy outcomes.
Roberts PR, Pepper C, Rinaldi CA, et al. (2019) The use of a single chamber leadless pacemaker for the treatment of cardioinhibitory vasovagal syncope. Int J Cardiol Heart Vasc 23:100349.	n=32 Follow-up: mean 404; SD 237 days (range: 63 to 928 days)	Implantation was successful in all people, with a major complication rate of 3%. After follow-up, 87% of people were symptom-free, suggesting good efficacy. The study supports the feasibility and potential benefit of leadless pacing in this younger syncope population.	Limited sample size and observational design without a control group limit the generalisability and strength of conclusions regarding efficacy compared to conventional pacemakers or other management strategies.

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<p>Russo V, D'Andrea A, De Vivo S, et al. (2021) Single-Chamber Leadless Cardiac Pacemaker in Patients Without Atrial Fibrillation: Findings from Campania Leadless Registry. <i>Frontiers in Cardiovascular Medicine</i> 8: 781335.</p>	<p>n=140 Mean follow-up: 606.5; SD 265.9 days</p>	<p>No significant difference in perioperative complications (5%), cardiac hospitalisation (5%), syncope (4%), or all-cause mortality (8%) was observed between AF and non-AF groups. No pacemaker syndrome was reported in either group.</p>	<p>Evidence with larger sample size have been prioritised in main evidence summary.</p>
<p>Reed SD, Yang JC, Wallace MJ et al. (2024) Patient preferences for features associated with leadless versus conventional transvenous cardiac pacemakers. <i>Circ Cardiovasc Qual Outcomes</i>. 17(12): e011168.</p>	<p>Ventricular pacing, single chamber Discrete-choice experiment (DCE) survey. n=117 people who had a de novo pacemaker indication were included.</p>	<p>Latent-class analysis revealed strong patient preferences for the type of pacemaker, with a nearly equal split between recent leadless pacemaker technology and conventional transvenous pacemakers. These findings can inform shared decision-making between health care providers and patients.</p>	<p>Preference based survey.</p>
<p>San Antonio R, Chipa-Ccasani F, Apolo J, et al. (2019) Management of anticoagulation in patients undergoing leadless pacemaker implantation. <i>Heart Rhythm</i> 16(12):1849–1854.</p>	<p>n=107 (consecutive people receiving LPs between 2014 and 2018)</p>	<p>Among 107 people, 43 (40%) received anticoagulation. Anticoagulation was managed via temporary discontinuation or continuation. Only 2 people experienced complications: 1 haemorrhagic pericardial effusion and 1 saphenous vein thrombosis (not on anticoagulants).</p>	<p>Single-centre study with a modest sample size and no comparator group limits the generalisability of conclusions regarding anticoagulation safety across broader populations or different procedural techniques.</p>

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<p>Sanchez R, Nadkarni A, Buck B, et al. (2021)</p> <p>Incidence of pacing-induced cardiomyopathy (PICM) in pacemaker-dependent patients is lower with leadless pacemakers compared to transvenous pacemakers.</p> <p>Journal of Cardiovascular Electrophysiology 32(2):477–483.</p>	<p>n=198 pacemaker-dependent people (TVP: n=131; LP: n=67) with baseline LVEF equal or more than 50%; mean follow-up: TVP 592; SD 549 days, LP 817; SD 600 days</p>	<p>PICM (equal and more than 10% LVEF reduction) occurred more often in TVP recipients (14%) than LP recipients (3%; p=0.02). TVP was an independent predictor of PICM (OR: 1.1), while older age reduced the risk (OR: 0.9). Nearly all people responded to CRT, including both LP cases that developed PICM.</p>	<p>Covered by systematic review included in the main evidence summary.</p>
<p>Sasaki K, Togashi D, Nakajima I, et al. (2022)</p> <p>Clinical outcomes of non-atrial fibrillation bradyarrhythmias treated with a ventricular demand leadless pacemaker compared with an atrioventricular synchronous transvenous pacemaker: A propensity score-matched analysis.</p> <p>Circulation Journal 86(8):1283–1291.</p>	<p>n=193 total; matched cohort: n=116 (58 in each group with LP or TVP); median follow-up 733 days (IQR: 395 to 997)</p>	<p>Although late device-related adverse event rates were not statistically significantly different (0% versus 4%; p=0.155), people receiving LP had statistically significantly higher HF-related readmission (29% versus 2%; p=0.001) and a trend toward higher all-cause mortality (28% versus 4%; p=0.059) compared to TVP recipients.</p>	<p>Covered in the systematic review included in the main body evidence.</p>
<p>Schiavone M, Gasperetti A, Mitacchione G, et al. (2022)</p>	<p>n=1154 with 6% presenting from emergency departments (ED+) Periprocedural</p>	<p>Implantation for urgent bradyarrhythmias (ED+) was feasible and did not significantly increase the rate of major complications compared</p>	<p>Short-term outcomes only; limited sample size for the emergency group and no follow-up</p>

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Leadless Pacemaker Implantation in the Emergency Bradyarrhythmia Setting: Results from a Multicenter European Registry. <i>Medicina</i> 59(1): 67.	outcomes only (no long-term follow-up reported)	to elective implantations (ED-) (7% vs. 4%, $p=0.244$).	beyond the procedural period.
Semlitsch T, Loder C (2020) Leadless pacemaker for right ventricle pacing (Update 2020). Decision Support Document 97 / Update 2020. Austrian Institute for Health Technology Assessment (AIHTA).	n=2,976 across 16 new documents (3 ongoing multicentre single-arm studies, 1 multicentre case-control study, 5 monocentre case series)	The update identified limited evidence for comparative efficacy versus conventional pacemakers. However, LP showed consistent safety advantages, particularly in avoiding complications related to subcutaneous pockets and transvenous leads.	Evaluated as a policy-level update and synthesis of ongoing observational evidence rather than a new clinical study with direct comparative outcomes.
Shantha G, Brock J, Singleton MJ, et al. (2023) A comparative study of the two leadless pacemakers in clinical practice. <i>Journal of Cardiovascular Electrophysiology</i> 34(9): 1896–1903.	n=50 (25 AVEIR-VR, 25 MICRA-VR) with 8 weeks of follow-up	Both devices had 100% implant success and stable pacing parameters. AVEIR-VR had more single-attempt deployments (80% versus 60%), a higher rate of ventricular arrhythmias (20% versus 0%; $p=.043$), and a significantly longer estimated battery life (15 versus 8 years; $p=.047$). No significant procedural complications or dislodgements occurred.	Small sample size and short follow-up period; initial experience rather than long-term outcomes.
Sharma P, Guleria VS, Bharadwaj P et al., (2020)	n=35 with mean follow-up of 1.4 years	Mid-septal LP implantation resulted in the narrowest paced QRS duration (139.3	The small sample size and single-centre design may limit the

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<p>Assessing safety of leadless pacemaker (MICRA) at various implantation sites and its impact on paced QRS in Indian population. <i>Indian Heart Journal</i> 72(5): 376–382.</p>		<p>ms), while apical placement had the broadest (166.6 ms). Left ventricular ejection fraction and pacing thresholds remained stable across all groups. 2 minor complications were reported (pericardial effusion and diaphragmatic pacing).</p>	<p>generalisability of the findings.</p>
<p>Shtembari J, Shrestha DB, Awal S, et al. (2023) Comparative assessment of safety with leadless pacemakers compared to transvenous pacemakers: a systematic review and meta-analysis. <i>Journal of Interventional Cardiac Electrophysiology</i> 66(12): 2165–2175.</p>	<p>17 studies included population numbers varied (exact pooled n not reported); follow-up duration not uniformly stated across studies</p>	<p>LPs had 42% lower odds of overall complications compared to TVPs (OR 0.6, 95% CI 0.4 to 0.8). LPs showed significantly lower risks for device dislodgment (OR 0.3), re-intervention (OR 0.5), and pneumothorax (OR 0.1). However, LPs were associated with higher odds of pericardial effusion (OR 2.7). All included studies were observational.</p>	<p>More comprehensive systematic reviews and meta-analyses have been covered in the main evidence summary.</p>
<p>Soejima K, Asano T, Ishikawa T, et al. (2017) Performance of leadless pacemaker in Japanese patients vs. rest of the world: Results from a global clinical trial.</p>	<p>n=38 Japanese people (total global cohort not specified here); 12-month follow-up</p>	<p>Japanese people had no major complications and low, stable pacing thresholds over 12 months. Despite smaller body size and different procedural practices (e.g., anticoagulation, length of stay), their outcomes were comparable to people from outside Japan. Freedom from major complications at 12 months was 100% in</p>	<p>The limited sample size of the subgroups may restrict the generalisability of the findings to the entire population.</p>

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Circulation Journal 81(11): 1589–1595.		Japanese people vs. 96% in the rest of the world (P=0.211).	
Sperzel J, Burri H, Gras D, et al. (2018) Primary safety results from the LEADLESS Observational Study. Europace 20(9): 1491–1497.	n=470 (safety endpoint evaluated in 300 post-pause people); follow-up at discharge, 90 days, 180 days, and every 6 months	Freedom from serious adverse device effects (SADEs) at 6 months was 95% (95% CI: 91 to 97%) in the 300 post- pause cohort, exceeding the predefined performance goal of 86% (P<0.0001). The most common SADEs included cardiac perforation (1%), device dislodgement, and vascular complications (1%). Cardiac perforation and dislodgement decreased significantly following protocol amendments and additional training during the study pause.	Nanostim device is no longer in use because of market withdrawal, limiting current clinical applicability of findings.
Steinwender C, Khelae SK, Garweg C, et al. (2020) Atrioventricular synchronous pacing using a leadless ventricular pacemaker: Results from the MARVEL 2 study. JACC: Clinical Electrophysiology 6(1):94–106.	n=75 enrolled; n=40 with sinus rhythm and complete AV block included in the primary efficacy analysis; algorithm performance assessed over a 5 hour download period	In people with sinus rhythm and complete AV block, AV synchronous pacing using the enhanced accelerometer-based algorithm resulted in 70% or more AV synchrony in 95% of participants versus 0% during pacing (p<0.001). Mean AV synchrony rose from 27% to 89%. No pauses or oversensing-induced tachycardia episodes occurred in the full cohort.	Covered in the systematic review included in the main evidence summary.
Steinwender C, Lercher P, Schukro C, et al. (2020) State of the art: leadless ventricular	Not a clinical study; no people enrolment or follow-up Based on pooled evidence, expert	This consensus document presents recommendations from a panel of Austrian experts on indications for LP vs TVP, infection management, operator	This was a consensus-based expert opinion rather than a clinical or observational study with original

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<p>pacing: A national expert consensus of the Austrian Society of Cardiology.</p> <p>J Interv Card Electrophysiol 57(1):27–37.</p>	<p>opinion, and national practice experience in Austria</p>	<p>training requirements and technical standards for LP implantation</p> <p>It emphasises that LPs can be safely implanted with low complication rates if technical and clinical guidance is adhered to.</p>	<p>population data or comparative outcomes.</p>
<p>Sultan A, Scheurlen C, Wörmann J et al. (2024)</p> <p>First long-term outcome data for the Micra VR™ transcatheter pacing system: data from the largest perspective German cohort.</p> <p>Clinical Research in Cardiology 113(7): 1443–1450.</p>	<p>n=188; mean follow-up of 723.4; SD 598 days</p>	<p>Among 188 people, predominantly with AV block III° in AF (85%), LPs demonstrated excellent long-term safety and performance. No infections or device failures were reported. Electrical parameters remained stable over time despite increased RV pacing demand (from 17% to 87%). Battery status declined as expected (3.2 V to 3 V), consistent with longevity estimates.</p>	<p>Broader real-world registry studies have been covered in main evidence summary.</p>
<p>Sarsenbayeva A, Baimbetov A, Puodziukynas A et al. (2025)</p> <p>Systematic review and meta-analysis of acute mortality and complication rates following leadless pacemaker placement using national-level data. Medicina (Kaunas). 61(6):974</p>	<p>Ventricular pacing, single chamber</p> <p>Systematic Review and Meta-Analysis 5 studies were included.</p>	<p>The reviewed studies suggest that leadless pacemakers offer a promising alternative to transvenous pacemakers, offering a comparable short-term safety profile. Ongoing technological advancements may further enhance their applicability in clinical practice.</p>	<p>More comprehensive studies are included in the summary of evidence.</p>
<p>Sears SF, Jordan EW, Hashmath Z et al. (2025)</p>	<p>Ventricular pacing, single chamber</p>	<p>Evidence indicates that QOL is as good, if not better, than TV-PM.</p>	<p>Review</p>

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<p>Leadless Pacemakers: The "Leading Edge" of quality of life in cardiac electrophysiology . Curr Cardiol Rep. 27(1):77</p>	<p>Review includes 7 papers that report patient reported outcome measures.</p>	<p>People with L-PM report high levels of acceptance and satisfaction with aesthetic appearance (96%), recovery (91%), and level of physical activity (74%). Leadless pacemakers provide an attractive alternative.</p>	
<p>Tachibana M, Banba K, Matsumoto K, et al. (2020) The feasibility of leadless pacemaker implantation for superelderly patients. Pacing Clin Electrophysiol 43(4):374–381.</p>	<p>n=62, aged more than 85 years (TVP group: n=35; LP group: n=27); follow-up duration up to 3 months</p>	<p>Despite a higher proportion of dementia in the LP group (63% versus 37%, p=.04), complication-free rates were similar between LP and TVP groups (87% versus 93%, p=.68). LP implantation had higher initial pacing thresholds (p<.01), but these improved over 3 months. Procedure and hospitalisation durations were shorter in the LP group.</p>	<p>Covered in the systematic review included in the main body evidence.</p>
<p>Tam MTK, Cheng YW, Chan JYS, et al. (2024) Aveir VR real-world performance and chronic pacing threshold prediction using mapping and fixation electrical data. Europace 26(3): euae051.</p>	<p>n=123 Aveir VR implant attempts (122 successful, 99%) n=88 reached 3-month follow-up. Comparison with retrospective cohort of 139 LP people.</p>	<p>3-month PCT correlated with impedance during mapping and tethering (p<0.001), but not with post-fixation PCT (P>0.05). High intraoperative impedance (more than 470 ohms) predicted excellent chronic PCT with 88% sensitivity and 71% specificity. Despite higher initial high PCT rates for Aveir (12%) vs Micra (2%; P=0.004), the 3-month high PCT rates were similar (Aveir 2% vs Micra 3%; P=1.000). Complication rate was low (1.6%).</p>	<p>Focuses primarily on procedural and electrical performance characteristics (PCT prediction) of the Aveir VR device rather than direct comparative long-term safety or clinical effectiveness outcomes between different device types.</p>

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<p>Tan MC, Tan JL, Tay ST, et al. (2023) A Systematic Review of Short-Term Outcomes of Leadless Pacemaker Implantation After Transvenous Lead Removal of Infected Cardiac Implantable Electronic Device. American Journal of Cardiology 203: 444–450.</p>	<p>n=253; mean follow-up 11.3; SD 10.6 months</p>	<p>LP implantation after transvenous lead removal (TLR) of infected cardiac devices was feasible and safe, with low complication (4%) and reinfection (less than 1%) rates. The most common infection pathogen was <i>Staphylococcus aureus</i>. Concomitant LP implantation during TLR was performed in 42% of cases. Few short-term complications were noted, including hematoma, femoral AV fistula, and pericardial effusion. 1 LP-related infection occurred during follow-up.</p>	<p>Focused specifically on post-infection TLR scenarios, limiting generalisability to broader LP use cases.</p>
<p>Tjong FVY, Knops RE, Udo EO, et al. (2018) Leadless pacemaker versus transvenous single-chamber pacemaker therapy: A propensity score-matched analysis. Heart Rhythm 15(9):1387–1393.</p>	<p>n=440 (LP; n=220; TVP; n=220); median follow-up 800 days</p>	<p>When excluding PM advisory-related events, LPs had fewer complications than TVPs (1% versus 5%, $p=.02$). However, when including advisory-related complications, LPs had a higher total complication rate (11% versus 5%, $p=.063$), negating the initial advantage.</p>	<p>Covered in the systematic review included in the main evidence summary.</p>
<p>Togashi D, Sasaki K, Okuyama K, et al. (2023) Two-year Outcomes of Ventricular-demand Leadless Pacemaker Therapy for Heart Block After</p>	<p>n=39 (17 LPs, 22 TVPs); 2-year follow-up</p>	<p>Post-procedural complication rates were low and similar across groups, people with LPs had significantly higher all-cause mortality (41% versus 5%, $p<.01$) and more heart failure rehospitalisations (24% versus 0%, $p=.01$) compared to those with</p>	<p>Broader registry study with larger sample size has been prioritised in the main body evidence</p>

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<p>Transcatheter Aortic Valve Replacement. J Innov Card Rhythm Manag 14(6): 5491–5498.</p>		<p>TVPs after TAVR. No significant differences were observed in late device-related adverse events or new-onset AF.</p>	
<p>Tokavanich N, Machado C, Banga S, et al. (2023) Implant efficiency and clinical performance of Aveir™ VR and Micra™ VR leadless pacemaker: A multicenter comparative analysis of 67 patients. Pacing and Clinical Electrophysiology 46(8): 827–832.</p>	<p>n=67; follow-up at 3 and 6 months</p>	<p>Micra VR had significantly shorter electrophysiology lab time (41; SD 12 vs. 55; SD 11.5 min, p=.008) and fluoroscopy time (6.5; SD 2.2 vs. 11.5; SD 4.5 min, p<.001) compared to Aveir VR. Aveir VR showed higher initial pacing thresholds (0.7; SD 0.3 mA vs. 0.5; SD 0.18 mA, p<.001) but matched performance at 3 and 6 months. No significant differences in sensing, impedance, or pacing percentage were observed. Projected battery longevity was significantly greater in the Aveir™ VR group (18.8; SD 4.3 versus 7.7; SD 0.8 years, p<.001). Procedural complications were rare in both groups.</p>	<p>Focused on comparative implant parameters and early performance, not long-term safety or effectiveness outcomes.</p>
<p>Tolosana JM, Guasch E, San Antonio R, et al. (2020) Very high pacing thresholds during long-term follow-up predicted by a combination of implant pacing threshold and impedance in leadless transcatheter pacemakers.</p>	<p>n=110 (LP implants from 2014 to 2018); 108 successful implants Follow-up: up to 48 months (mean 24; SD 16 months)</p>	<p>Only 4% of people developed very high pacing thresholds (VHPT: more than 2 V/0.2 ms). People who developed VHPT had higher implant pacing thresholds (1; SD 0.3 V vs 0.6; SD 0.3 V; p=.003) and lower implant impedance (580; SD 59 ohms vs 837; SD 232 ohms; p=.03).</p>	<p>While valuable for hypothesis generation and identifying predictors, further validation is needed before routine clinical application.</p>

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Journal of Cardiovascular Electrophysiology 31(4):868–874.			
Tonegawa-Kuji R, Kanaoka K, Mori M, et al. (2022) Mortality and 30-Day Readmission Rates After Inpatient Leadless Pacemaker Implantation: Insights from a Nationwide Readmissions Database. Canadian Journal of Cardiology 38(11): 1697–1705.	n=137,732 total pacemaker implantations (including 5,986 LP implantations); 30-day follow-up for readmissions	The in-hospital mortality rate for LP implantations was 5%, with an overall in-hospital complication rate of 16%, and a 30-day readmission rate also at 16%. Notably, in-hospital mortality declined from 11% in early 2017 to 4% by late 2019 (P<0.001), and overall complications decreased from 21% to 13% in the same period (P<0.001).	Focused on administrative database outcomes and trends rather than device-specific performance or prospective clinical trial data.
Tam TK, Chan YS, Chan GCP, et al. (2022) Effect of Low Body Mass Index in Outcome of Micra Leadless Pacemaker Implantation. Journal of the Hong Kong College of Cardiology 30(2): 43–52.	n=147, who underwent Follow-up duration extended to 12 months post-implantation.	The composite procedure safety and efficacy outcome was achieved in 93% of people.	The study's single-centre, retrospective design and focus on a specific population subgroup may limit the generalisability of its findings.
Vaidya VR, Dai M, Asirvatham SJ, et al. (2019) Real-world experience with leadless cardiac pacing. Pacing Clin Electrophysiol 42(3): 366–373.	n=90 LP recipients (73 Micra, 17 Nanostim) matched 1:1 with 90 TVP recipients; median follow-up 62 days (IQR 28 to 169).	LPs showed comparable safety to TVPs in terms of major (0% versus 1%) and minor (8% versus 3%) complications (p>0.05). LP group had significantly lower rates of device-related revision or extraction (0% versus 5%, p=0.028) and endocarditis (0% versus	Covered in the systematic review included in the main body evidence.

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		3%, p=0.04), and no significant worsening of tricuspid regurgitation (0% versus 19%, p=0.017). Estimated device longevity was longer in the LP group (12 versus 10 years, p<0.0001).	
Valiton V, Graf D, Pruvot E, et al. (2019) Leadless pacing using the transcatheter pacing system (Micra TPS) in the real world: initial Swiss experience from the Romandie region. Europace 21(2): 275–280.	n=92; 1-year follow-up	Implantation success rate was high (98%), and pacing thresholds remained low and stable over time (median 0.4 V/0.2 ms). However, serious perioperative adverse events occurred in 7% (n=6), including 1 death, and 3 additional major events (3%) occurred during follow-up (including ventricular tachycardia and device explantation), resulting in an overall 10% major complication rate.	Limited by small sample size and regional data; initial real-world experience only, without comparator arm or long-term evaluation.
Vincent L, Grant J, Peñalver J, et al. (2022) Early trends in leadless pacemaker implantation: Evaluating nationwide in-hospital outcomes. Heart Rhythm 19(8): 1334–1342.	Nationally representative cohort: exact sample size not specified in abstract; in-hospital outcomes only.	LP use increased among older and more acutely ill people over time. From 2017 to 2019, LP-related procedural complications decreased significantly (11% to 8%; p<.001), and in-hospital mortality declined (8% to 4%; p<.001). Compared to TVP, LP had fewer procedural complications (9% versus 11%) but higher in-hospital mortality (5% versus 1%; p<.001).	Covered in the systematic review included in the main body evidence.
Wherry K, Stromberg K, Hinnenthal JA, et al. (2020) Using Medicare Claims to Identify	n=230 dually enrolled people; 30-day follow-up for acute complications	95% agreement in identifying 30-day acute complications between Medicare administrative claims (Micra CED) and physician-adjudicated	Focus was on data validation and agreement between administrative claims and

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<p>Acute Clinical Events Following Implantation of Leadless Pacemakers. Pragmatic and Observational Research 11: 19–26.</p>		<p>registry data (Micra PAR). Disagreements in reporting were limited to specific low-frequency complications such as arteriovenous fistula (50%), pulmonary embolism (67%), haemorrhage/hematoma (75%), and deep vein thrombosis (100%). No disagreements occurred in adjudicated event identification.</p>	<p>registry data rather than direct clinical outcomes or safety/effectiveness of the device.</p>
<p>Warwas S, Jędrzejczyk-Patej E, Kowalski O et al. (2025) Quality of life in patients with a leadless pacemaker versus transvenous pacemaker. <i>Kardiol Pol.</i> doi: 10.33963/v.phj.106688. Epub ahead of print.</p>	<p>Ventricular pacing, single chamber</p> <p>Prospective non-randomised study (single centre)</p> <p>People with leadless pacemakers (n=31) were matched with transvenous pacemaker group (n=31).</p> <p>Follow-up 12 months</p>	<p>Quality of life after device implantation does not differ between leadless and transvenous pacemakers.</p>	<p>More comprehensive studies are included in the summary of evidence.</p>
<p>Xu F, Meng L, Lin H, et al. (2024) Systematic review of leadless pacemaker. <i>Acta Cardiologica</i> 79(3): 284–294.</p>	<p>Included 28 studies published between 2015 and 2023, covering a total of 13,129, who underwent LP implantation. Follow-up durations ranged from 3 months to 5 years across included studies.</p>	<p>The review highlights that LPs significantly reduce complications associated with traditional TVPs, especially those related to leads and pacemaker pockets.</p>	<p>More robust systematic reviews have been covered in the main evidence summary.</p>
<p>Yan L, Zhang Y, Liu Q, et al. (2024)</p>	<p>n=112, who had LP implantation between 2020</p>	<p>Success rate was 100%. Procedure-related complications occurred in</p>	<p>Although informative, this study represents</p>

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<p>Efficacy and safety of leadless ventricular pacemaker: a single-center retrospective observational study.</p> <p>Cardiovascular Diagnosis & Therapy 14(2): 878–889.</p>	<p>and 2023. The average follow-up period was 12.4; SD 3.7 months.</p>	<p>5% of included people, including 2 cases of pericardial effusion and 3 of vascular access complications. No lead-related or pocket infections were reported. Mean pacing threshold remained stable throughout follow-up (0.5; SD 0.2 V at implant vs. 0.5; SD 0.2 V at final follow-up, P=0.72).</p>	<p>a single-centre retrospective series with limited generalisability, thus was excluded from the main summary table prioritising larger or multicentre datasets.</p>
<p>Zucchelli G, Tolve S, Barletta V, et al. (2021) Comparison between leadless and transvenous single-chamber pacemaker therapy in a referral centre for lead extraction.</p> <p>J Interv Card Electrophysiol 61(2):395–404.</p>	<p>n=200 (100 LP, 100 TVP); median follow-up: 12 months</p>	<p>LP implantation was associated with a lower acute complication rate (0% vs 7%, p=0.02) and fewer system revisions (0% vs 6%, p=0.038) compared to TVP. Both groups showed stable electrical performance, but LP demonstrated longer estimated battery longevity. 1 systemic infection occurred in the TVP group.</p>	<p>Covered in systematic review included in the main evidence summary.</p>
<p>Zucchelli G, Barletta V, Della Tommasina V, et al. (2019) Micra pacemaker implant after cardiac implantable electronic device extraction: feasibility and long-term outcomes.</p> <p>EP Europace 21(8):1229–1236.</p>	<p>n=83 total (Group 1: 23 post-extraction; Group 2: 60 naïve); median follow-up: 18 months (IQR 1 to 24 months)</p>	<p>LP implantation was feasible and safe in post-TLE people, with no significant differences in fluoroscopy time, delivery success, or electrical performance at implant and 12-month follow-up compared to naïve people. No device-related events occurred during follow-up. Majority of implants achieved non-apical placement (72%) with no significant group differences.</p>	<p>Covered in systematic review included in the main evidence summary.</p>
<p>Zhang Z, Wu Z, Luan C et al. (2025) Efficacy and safety of leadless</p>	<p>Ventricular pacing, single chamber</p>	<p>Leadless pacemaker implantation appears to be a safe and effective therapeutic option for octogenarians, including</p>	<p>More comprehensive studies are included in the</p>

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<p>pacemaker implantation in octogenarians: a single-center experience. Front Cardioasc Med. 12:1571665.</p>	<p>Case series n=154 people had leadless pacemaker implantation. (study cohort was stratified into 2 age groups: octogenarians (80 years or above, n=66) and non-octogenarians (under 80 years, n=88). Median follow-up 12 months.</p>	<p>those with more combabilities. Therefore, it should be considered a viable alternative to conventional transvenous pacemakers in this aging population.</p>	<p>summary of evidence.</p>
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