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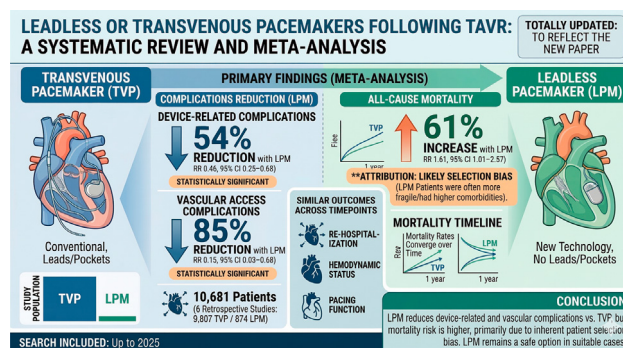
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Leadless or Transvenous pacemakers following TAVR: A systematic review and meta-analysis

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GRAPHICAL ABSTRACT



ARTICLE INFO

ABSTRACT

Introduction: Transcatheter aortic valve replacement (TAVR) is frequently associated with conduction disturbances and arrhythmias, often requiring permanent pacemaker (PPM) implantation in an elderly, high-bleeding-risk population. Leadless pacemakers (LPMs) reduce pocket and lead-related complications and have demonstrated noninferior safety compared with transvenous pacemakers (TVP) in non-TAVR populations. However, comparative data in the post-TAVR setting are lacking.

Methods: We systematically searched Pubmed, Cochrane, Embase, Web of Sciences and Scopus for studies comparing LPM vs. TVP following TAVR. Random effects models were used to calculate risk ratios (RRs) with 95% confidence

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intervals (CIs) for all-cause mortality, device-related complications, re-hospitalization and vascular access site complications. Statistical analysis was performed with R software, version 4.2.3.

Results: Six retrospective studies comprising 10,681 patients were included, of whom 874 (7.56%) underwent LPM implantation. Compared with TVP, LPM was associated with a significant reduction in device related complications (RR 0.46; 95% CI 0.25–0.83; $p < 0.011$) and vascular access site complications (RR 0.15; 95% CI 0.03–0.68; $p = 0.011$). There was no significant difference in re-hospitalization (RR 0.82; 95% CI 0.23–3.12; $p = 0.76$). LPM was associated with a higher risk of all-cause mortality (RR 1.61; 95% CI 1.01–2.57; $p = 0.047$).

Conclusions: Among these six retrospective studies, LPM use following TAVR was associated with fewer device-related and vascular access complications compared with TVP, albeit with a higher risk of all-cause mortality at 2 years. However, this finding likely reflects a selection bias in non-adjusted baseline characteristics rather than device inferiority. No significant differences were observed in re-hospitalization between the two strategies. Prospective studies are required to confirm or refute these findings.

1. Introduction

Transcatheter aortic valve replacement (TAVR) has expanded from use solely in inoperable and high-risk patients to intermediate- and low-risk cohorts, becoming a reference therapy for severe aortic stenosis within multidisciplinary heart teams [1]. As indications broaden and survival improves, attention has shifted from periprocedural risk to long-term outcomes during follow-up. Post-procedural conduction disturbances, particularly new left bundle-branch block and high-grade atrioventricular block, remain frequent complications of TAVR and often lead to permanent pacemaker (PPM) implantation, with implications for remodeling, heart-failure admissions, and mortality [1,2].

Transvenous pacemakers (TVP) have long been the default strategy for bradyarrhythmias given their versatility (programmability and potential for dual-chamber pacing). However, the need for a subcutaneous pocket and intravascular leads confers device-specific risks, including pocket hematomas and infections, venous thrombosis/occlusion, lead displacement and fracture, and lead-related tricuspid regurgitation, events that may be especially consequential in typical TAVR recipients who are often elderly, frail, and have multiple comorbidities [2,3]. In contrast, leadless pacemakers (LPM) were designed to eliminate the pocket and the transvenous lead to reduce access- and device-related complications. Trade-offs remain including the predominance of single-chamber systems, challenges with extraction or upgrade, and cardiac perforation risk [3,4].

Decision-making after TAVR varies across centers because thresholds for monitoring, electrophysiology testing, and PPM implantation are not uniform. The ACC 2020 Expert Consensus Decision Pathway proposes practical algorithms for pre-, peri-, and post-procedural management of conduction disturbances (e.g., indications for extended telemetry, EP assessment, and PPM), while underscoring evidence gaps and institutional heterogeneity that can influence outcomes and resource use [5].

Against this background, we conducted a systematic review and meta-analysis comparing LPM versus TPM use after TAVR. We assess early and late safety and effectiveness, including mortality, heart-failure hospitalization, device-related complications (infection, hematoma, perforation/tamponade, vascular complications, lead malfunction/dislodgement), bleeding, stroke, procedure and fluoroscopy times, length of stay, pacemaker dependency and ventricular pacing burden, and the need for reintervention/upgrade/extraction.

2. Methods

This systematic review and meta-analysis followed the resolutions established by Cochrane Handbook [6] and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) 2020 statement [7]. This project is registered in Prospero (CRD420251183223).

2.1. Search strategy and data extraction

A comprehensive search was conducted in PubMed, Cochrane Library, Embase, Web of Science, and Scopus from inception to August 2025.

The search strategy combined the following terms: (“Leadless Pacemaker” OR “Leadless”) AND (“Transcatheter Aortic Valve Replacement” OR “Transcatheter Aortic Valve Implantation” OR “TAVR” OR “TAVI”). The selection process was carried out using Rayyan, with two independent reviewers (C-N and G.B) screening titles and abstracts. Disagreements were resolved by consensus or adjudication by a third reviewer. Data extraction for each included study was performed using a standardized form collecting the first author, publication year, the number of patients in the leadless and transvenous pacemaker groups, and the number of events for each predefined outcome, including vascular access complications, rehospitalization, all-cause mortality, and device-related complications.

2.2. Eligibility criteria

Studies were included if they met all of the following criteria: (1) randomized controlled trials or observational comparative studies evaluating patients who underwent transcatheter aortic valve replacement (TAVR) and subsequently required new PPM implantation; (2) direct comparison between LPM and TVP systems implanted after TAVR; and (3) reporting at least one predefined clinical outcome of interest. There were no restrictions on publication date, follow-up duration, or language. Studies were excluded if they lacked a direct comparison between leadless and transvenous devices, did not involve post-TAVR pacemaker implantation, or lacked outcome data.

2.3. Endpoints

The primary endpoints were the 30-day safety composite and all-cause mortality. The safety composite included device-related complications such as pocket hematoma or infection, lead dislodgement, pneumothorax, cardiac perforation or tamponade, major vascular or bleeding events, and device embolization. Secondary outcomes included rehospitalization, pacing dependency, device reintervention, pacemaker infection, electrical performance parameters, procedural or fluoroscopy time, and hospital length of stay when available.

2.4. Quality assessment

Given the observational nature of the identified studies, methodological quality was assessed using the ROBINS-I tool (Risk of Bias in Non-randomized Studies of Interventions) [8]. This instrument evaluates seven domains: (1) confounding, (2) selection of participants, (3) classification of interventions, (4) deviations from intended interventions, (5) missing data, (6) measurement of outcomes, and (7) selection of the reported result. Each domain is rated as low, moderate, serious, critical, or no information on risk of bias, and an overall classification is then assigned.

2.5. Statistical analysis

This systematic review and meta-analysis was performed according to PRISMA guidelines. Pooled risk ratios (RRs) with 95% confidence intervals

(CIs) were calculated using random-effects models to account for between-study variability. Heterogeneity was assessed using the I^2 statistic. Analyses were conducted for all-cause mortality, device-related complications, rehospitalization, and vascular access site complications. Subgroup and sensitivity analyses were conducted to explore heterogeneity across studies, according to study design, follow-up duration, and PPM type. All statistical analyses were performed using R software, version 4.2.3 [9]. A two-sided $p < 0.05$ was considered statistically significant.

3. Results

3.1. Study selection and characteristics

A total of 10,681 patients from six retrospective comparative studies were included in the final analysis [10–15]. Among them, 874 (8.19%) underwent implantation of a leadless pacemaker (LPM) and 9807 (91.81%) received a conventional pacemaker following transcatheter aortic valve replacement (TAVR). All included studies compared post-TAVR patients who required permanent pacing and evaluated clinical outcomes between leadless and transvenous systems. The study selection process is summarized in Fig. 1. A total of 359 records were initially identified across all

databases. After removal of duplicates and screening of titles and abstracts, six studies met the inclusion criteria and were included in the final synthesis.

Fig. 2 presents the ROBINS-I results, summarizing the domain-specific and overall risk of bias across studies. All six studies were judged to have an overall moderate risk of bias, with no study rated as serious or critical. The majority of studies presented low risk in the domains of selection of participants and measurement of outcomes, whereas moderate risk was consistently observed for confounding, classification of interventions, deviations from intended interventions, missing data, and selection of the reported result.

The baseline clinical characteristics of the study population are summarized in Table 1. A total of 10,681 patients were included across the 6 studies, with 874 (8.3%) receiving Leadless Pacemakers (LPM) and 9807 (91.7%) receiving Transvenous Pacemakers (TVP). The mean age was consistently high across both cohorts, reflecting the typical TAVR population. Regarding comorbidities, the prevalence of hypertension and diabetes mellitus was similar between groups. However, the LPM group presented a higher burden of certain conditions in specific cohorts; for instance, in the study by Ueyama et al. (2024), patients selected for LPM had a higher prevalence of prior history of heart failure and chronic kidney disease

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only

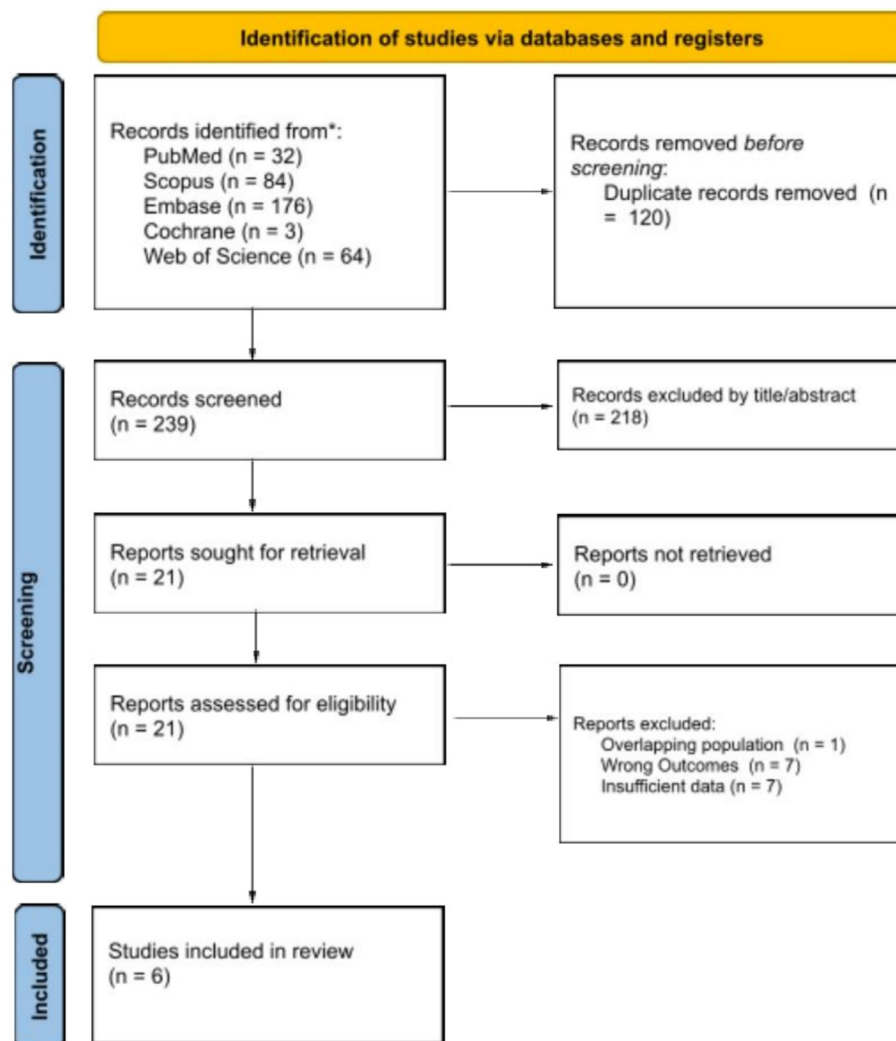


Fig. 1. PRISMA flow diagram.

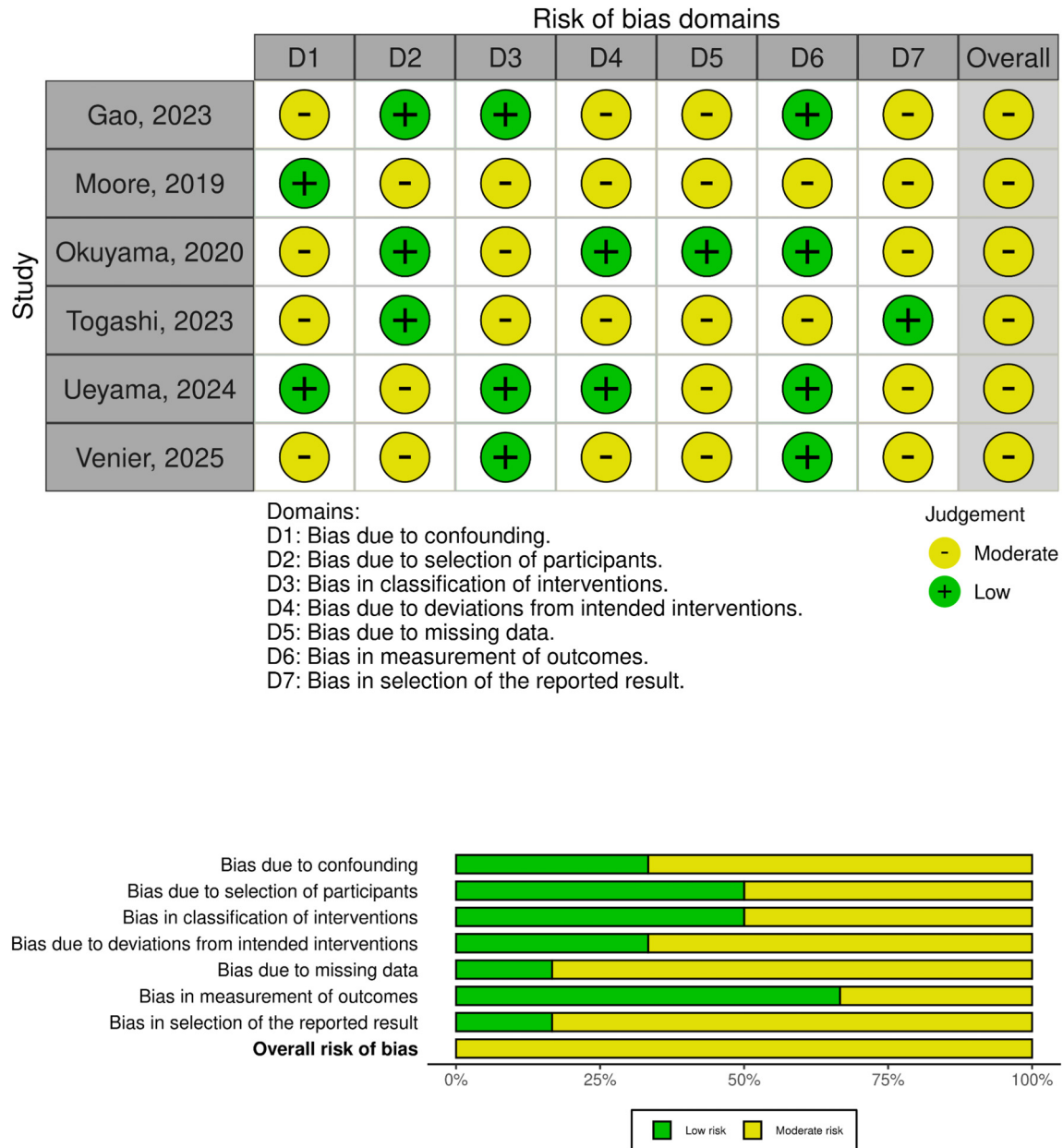


Fig. 2. Risk of bias among the included studies

Top panel: Each individual study by domain (ROBINS-1 tool), and overall summary

Bottom panel: Proportion of all studies meeting each bias criterion.

compared to the TVP group. The choice of TAVR valve type also varied, with self-expanding valves being frequently associated with a higher need for subsequent pacing, although this distribution was balanced between the LPM and TVP arms in most included studies (Tables 1 and 2).

3.2. Meta-analysis results

Among 10,492 patients in five studies reporting data, patients who received LPM after TAVR had a higher risk of all-cause mortality compared

Table 1

Baseline characteristics of the studies.

Study	Country	Design	Sample size (LPM/TVP)	Sex, male (LPM/TVP)	Mean age (LPM/TVP)	Follow-up - months (LPM/TVP)
Gao, 2023	USA	Retrospective single center	27/33	15 (55.6%) / 10 (30.3%)	78 /79	6/1
Moore, 2019	USA	Retrospective single center	10/23	6 (60.0%) / 12 (52.0%)	82.8/84	2.8/6.6
Okuyama, 2020	Japan	Retrospective single center	10/14	2 (20.0%) / 3 (21.4%)	86.5/83	6/6
Togashi, 2023	Japan	Retrospective single center	17/22	4 (23.5%) / 5 (22.7%)	85/85	24
Ueyama, 2024	USA	Retrospective multicenter	730/9608	434 (59.5%) / 5398 (56.2%)	82/82	17.3/17.3
Venier, 2025	France	Retrospective Two-Center Study	80/107	37 (46.3%) / 72 (67.3%)	83.1/83.6	12

Abbreviations: LPM = leadless pacemaker; TVP = transvenous pacemaker.

Table 2

Baseline patient and procedural characteristics.

Study	Previous MI (LPM/TVP)	Diabetes (LPM/TVP)	Mean LVEF (%) (LPM/TVP)	Atrial fibrillation (LPM/TVP)	AV Block (LPM/TVP)	RBBB (LPM/TVP)	LBBB (LPM/TVP)	TAVR Access Site	Type of TAVR
Gao, 2023	3 (11.1%) / 1 (3.0%)	9 (33.3%) / 16 (48.5%)	57.5/60	7 (25.9%) / 12 (36.4%)	1 (3.7%) / 8 (24.2%)	6 (22.2%) / 9 (27.3%)	0 (0.00%) / 1 (3.0%)	Transfemoral (all)	Predominantly self-expanding: LPM: Evolut Pro (81.5%), Evolut R (14.8%), Sapien 3 (3.7%) TVP: Evolut Pro (42.4%), Evolut R (51.5%), Sapien 3 (0.0%)
Moore, 2019	NR	NR	53/52	5 (62.5%) / 10 (43.0%)	3 (37.5%) / 12 (52.0%)	4 (40.0%) / 7 (32.0%)	2 (20.0%) / 6 (27.0%)	LPM: Transfemoral 9, transapical 1 TVM: Transfemoral 20, transaortic 2, transapical 1	LPM: Sapien 3 (90%); Evolut R (10%) TVP: CoreValve (30%); Sapien (22%); Sapien XT (9%)
Okuyama, 2020	NR	3 (30.0%) / 4 (28.6%)	59/68	0 (0.0%) / 0 (0.0%)	10 (100%) / 13 (92.9%)	NR	NR	Transfemoral (all)	LPM: Self-expanding (30%); balloon-expandable (70%) TVP: Self-expanding (14.3%); balloon-expandable (85.7%)
Togashi, 2023	NR	3 (16.0%) / 5 (22.0%)	66/66	2 (12.0%) / 1 (5.0%)	17 (100%) / 22 (100%)	8 (47.0%) / 14 (64.0%)	0 (0%) / 0 (0%)	Transfemoral (all)	LPM: Self-expanding (35%); balloon-expandable (65%) TVP: Self-expanding (32%); balloon-expandable (68%)
Ueyama, 2024	46 (6.3%) / 572 (6.0%)	374 (51.2%) / 4547 (47.3%)	NR	403 (55.2%) / 3142 (32.7%)	433 (59.3%) / 7443 (77.5%)	NR	NR	NR	NR
Venier, 2025	NR	20 (25.0%) / 27 (25.2%)	60/60	23 (28.8%) / 20 (18.7%)	NR	NR	NR	NR	NR

Binary data re numbers of patients in each group. Abbreviations: LPM = leadless pacemaker; TVP = transvenous pacemaker; MI = myocardial infarction; LVEF = left ventricular ejection fraction; AV = atrioventricular; RBBB = right bundle branch block; LBBB = left bundle branch block.

with those implanted with TVP (RR 1.61; 95% CI 1.01–2.57; $p = 0.047$; $I^2 = 0.0\%$; Fig. 3). In contrast, among 10,646 patients in five studies, LPM were associated with significantly fewer device-related complications (RR 0.46; 95% CI 0.25–0.84; $p = 0.011$; $I^2 = 0.0\%$; Fig. 4) and a lower incidence of vascular access site complications (RR 0.15; 95% CI 0.03–0.68; $p = 0.01$; $I^2 = 0.0\%$; Fig. 5) compared with TVP. Finally, among 309 patients in four studies, no significant difference was observed between the two groups in rehospitalization rates (RR 0.82; 95% CI 0.21–3.12; $p = 0.76$; $I^2 = 59.8\%$; Fig. 6).

4. Discussion

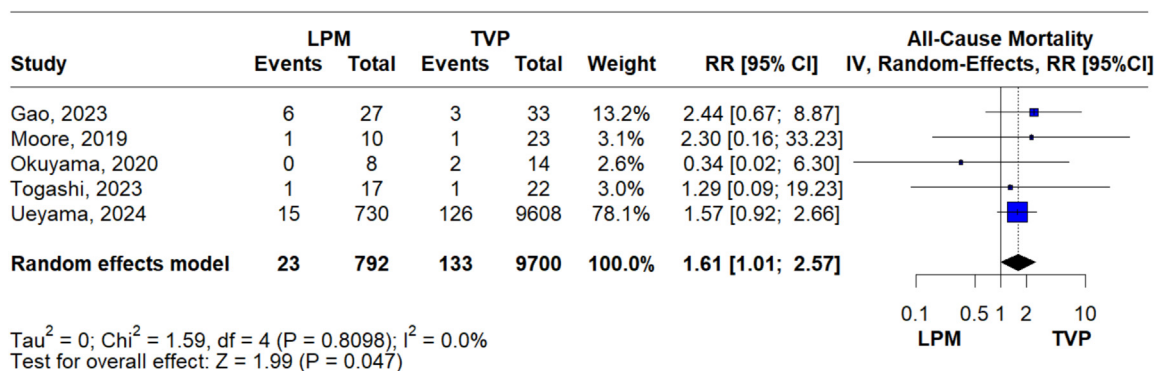
TAVR has become an established treatment for many patients with severe aortic stenosis ranging from low to high or prohibitive surgical risk. However, complete heart block requiring a permanent pacemaker (PPM) occurs in approximately 15% of patients within 30 days after TAVR, varying with patient risk and device type (lower with balloon expandable systems, higher with self-expanding systems) [3]. Nonetheless, the optimal type of PPM remains uncertain.

In the present systematic review and meta-analysis of leadless and transvenous systems, LMP implantation was associated with fewer device-related vascular access complications. This finding supports existing

literature and likely explained by the design attributes of LPM, as the PPM pockets and transvenous leads required in TVPs may cause complications such as pneumothorax, pocket hematoma, lead fracture or dislodgement, vascular occlusion, valvular injury, and infection [10,11,13,15]. However, despite these benefits, the risk of mortality was increased with LPM compared with TVP in 2y follow up. There were no significant differences in rehospitalization rates between the two device types in 2y.

The choice of LPM is fundamentally supported by the mitigation of risks inherent to transvenous systems, such as pocket infection and lead-related endocarditis, while avoiding mechanical interference with the tricuspid valve, which can lead to progressive valvular regurgitation. Conversely, the safety profile of leadless devices warrants caution due to a documented higher risk of cardiac perforation during implantation and persistent concerns regarding atrioventricular (AV) dyssynchrony. The maturation of this technology, marked by the development of dual-chamber leadless pacing systems, emerges as a promising solution to overcome these hemodynamic limitations by providing physiological pacing without the mechanical risks associated with traditional leads [10–15].

Regarding the higher risk of all-cause mortality observed in the LPM cohort, selection bias must be strongly considered as a primary driver, as most included studies were not fully adjusted for baseline clinical disparities. This potential benefit of fewer lead-related complications may have

**Fig. 3.** Meta-analysis of all-cause mortality.

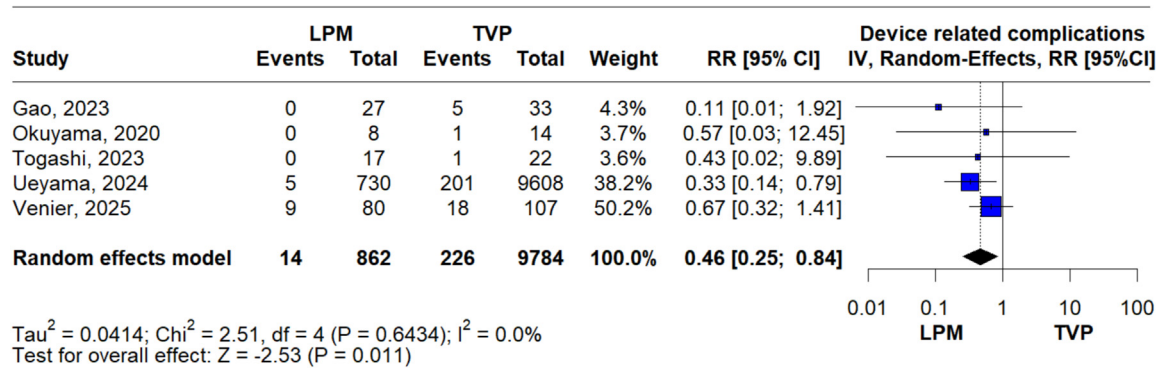


Fig. 4. Meta-analysis of device-related complications.

Vascular access site complications

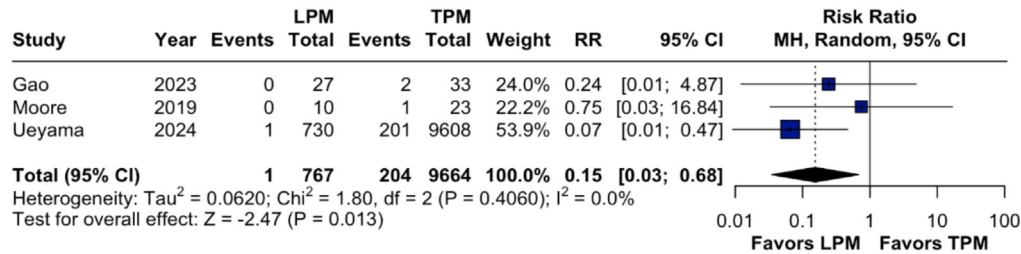


Fig. 5. Meta-analysis of vascular access site complications.

been offset by other factors inherent to the study periods. Specifically, the steep learning curve associated with LPM implantation and the limited options for device retrieval or system upgrade may have influenced procedural or post-procedural mortality during early adoption phases. Furthermore, In the absence of detailed knowledge regarding the specific timing and circumstances of death, firm conclusions regarding a direct causal link between the device type and mortality cannot be reached [5,10–12].

Our findings extend previous reports comparing leadless and transvenous pacemakers after TAVR. In the largest single study, Ueyama et al. reported that after TAVR, atrioventricular synchronous LPM resulted in a lower rate of procedural complications than with TVPs, although a 13% dyssynchronous pacing rate occurred, along with a numerical increase in early mortality [6]. Togashi et al. concluded that in post-TAVR high-grade AV block TVP use was not associated with better prognosis than LPM, despite their hemodynamic superiority from maintaining AV

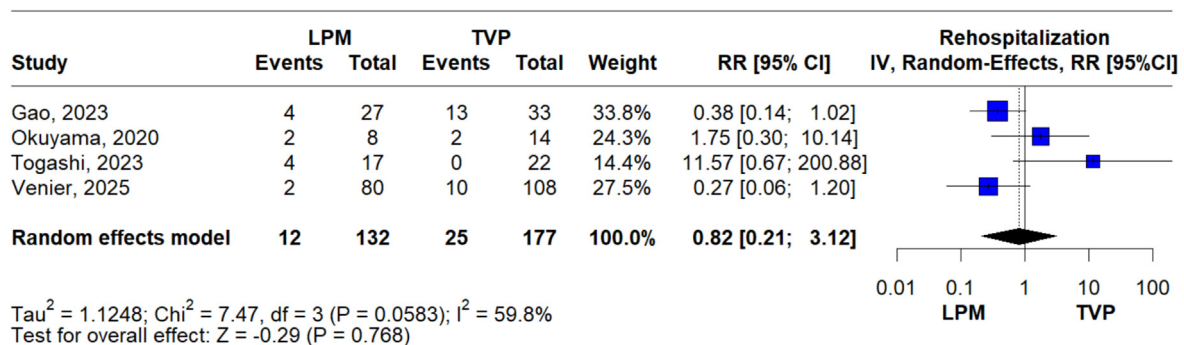


Fig. 6. Meta-analysis of re-hospitalizations.

synchrony. They also reported favorable two-year outcomes with ventricular-demand LPMs but emphasized the importance of patient selection based on conduction system recovery and the need for atrioventricular synchrony [10,16,17]. Taken together, these data suggest that while LPMs lower device-related morbidity compared with TVPs, the ideal candidate profile remains unclear, and additional prospective studies are required to determine whether there is a long-term benefit from LPM (particularly with AV synchrony capabilities) vs. TVP stratified according to RV pacing need, which could potentially influence in long-term survival.

4.1. Limitations

Importantly, all included studies were retrospective, potentially introducing selection bias, incomplete data, and imprecise estimates. Patient characteristics, device use and follow-up times varied between the studies. There are intrinsic differences between the groups, as patients undergoing LPM implantation were generally more fragile or had specific contraindications to transvenous access (e.g., high risk of pocket infection or permanent atrial fibrillation). Although some included studies, such as those by Ueyama (2024) and Venier (2025), utilized propensity score matching to mitigate these differences, the potential for unmeasured confounding factors remains, which may influence the comparison of clinical outcomes between the two pacing strategies. Additionally, technical disparities inherent in the procedures may have influenced outcomes, such as time to PPM implantation, implant depth, and specific device generation. These limitations require careful consideration and highlight avenues for future research.

5. Conclusions

The present systematic review and meta-analysis demonstrated that LPM use to treat conduction system disease following TAVR procedure is associated with significantly fewer device-related and vascular complications but possibly higher all-cause mortality when compared with TVP use, likely driven by intrinsic patient characteristics which were not available for further adjustment. Given the risk of confounding in these non-randomized studies, larger prospective trials (ideally with randomization) are required to substantiate these results and assess the long-term impact of LPMs in post-TAVR patients in whom conduction disease develops.

CRedit authorship contribution statement

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Disclosures

Dr. Stone has received speaker honoraria from Medtronic, Amgen, Boehringer Ingelheim; has served as a consultant to Robocath, Daiichi Sankyo, Vectorious, Miracor, Millennia Biopharma, Apollo Therapeutics, Cardiac Success, Occlutech, Ablative Solutions, Oxitope, Elixir, Impulse Dynamics, Asceneuron, Myochron, Vesalio, Remote Cardiac Enablement, Valfix, Zoll, HeartFlow, Shockwave, Adona Medical, Abbott, HighLife, Elucid Bio, Aria, Alleviant, FBR Medical, Colibri, Bioventrix, MedHub; and has equity/options from Cardiac Success, Ancora, Cagent, Applied Therapeutics, Biostar family of funds, SpectraWave, Orchestra Biomed, Aria, Valfix, Xenter. Dr. Stone's employer, Mount Sinai Hospital, receives research grants from Shockwave, Biosense-Webster, Bioventrix, Abbott, Abiomed, Cardiovascular Systems Inc., Phillips, Pulnovo, V-wave and PCORI (via Weill Cornell Medical Center). The other authors report no conflicts of interest.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. There was no external funding source for this systematic review and meta-analysis.

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