

Comparing Patient-Reported Quality of Life in Leadless Pacemakers versus Conventional Pacemakers: A Systematic Review

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Kontext: K implantaci permanentních kardiostimulátorů se doporučují klasické kardiostimulátory (conventional pacemaker, C-PM); díky technickému pokroku jsou dnes na trhu již bezdrátové kardiostimulátory (leadless pacemaker, L-PM). Neustále se aktualizující klinické doporučené postupy berou při výběru kardiostimulátoru v potaz i kvalitu života (quality of life, QoL), přičemž se předpokládá, že ta je v případě L-PM vyšší vzhledem k omezenému vzniku komplikací v souvislosti s elektrodami, variabilita v kritériích pro výběr pacientů však míru této přednosti snižuje. Cílem tohoto systematického přehledu je porovnat QoL hodnocenou samotnými pacienty s L-PM versus C-PM.

Metody: Při rešerši na dané téma se v databázích PubMed, EMBASE, Cochrane CENTRAL, Science Direct, Scopus, ProQuest, Google Scholar a Wiley Online Library vyhledávaly články publikované v letech 2015 až 2025. Vyhledané studie srovnávaly QoL, hodnocenou pomocí dotazníku SF-36, při implantaci L-PM nebo C-PM. Ke stanovení rizika byl použit nástroj ROBINS-I. Mezi analyzované položky dotazníku SF-36 patřily fyzické fungování (physical functioning, PF), fyzická omezení (role physical, RP), tělesná bolest (bodily pain, BP), všeobecné zdraví (general health, GH), vitalita (VT), sociální fungování (social functioning, SF), emoční problémy (role emotional, RE), duševní zdraví (mental health, MH), souhrn fyzických složek (physical component summary, PCS) a souhrn duševních složek (mental component summary, MCS).

Výsledky: Z celkového počtu 5 280 studií jich zařazovací kritéria splnily tři se 468 pacienty a s celkově středně vysokým rizikem. Ve vstupních hodnotách QoL nebyly nalezeny žádné statisticky významné rozdíly mezi L-PM versus C-PM ($p > 0,05$). V případě L-PM bylo zjištěno statisticky významně vyšší skóre PCS a MCS po 1 týdnu, lepší PF, RP, BP, VT, GH a MCS po 1 a 3 měsících, a setrvale lepší výsledky v PF, RP, MH, a PCS po 6 měsících ve srovnání s C-PM ($p < 0,05$).

Závěry: Kardiostimulátory L-PM si v doméně QoL fyzického zdraví vedly lépe než C-PM, pravděpodobně díky menšímu strachu z komplikací a menšímu omezení aktivit. Superiorita duševního zdraví nebyla ve studiích jednoznačná, což ukazuje na nutnost dalšího výzkumu.

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ABSTRACT

Background: Conventional pacemakers (C-PM) are recommended for permanent pacemaker implantation, but developments have led to leadless pacemakers (L-PM). Evolving clinical guidelines support quality of life (QoL) in pacemaker selection, with L-PM hypothesized to offer better QoL by minimizing lead-based complications, but variability in patient selection criteria complicates this. This systematic review aims to compare patient-reported QoL in L-PM versus C-PM.

Methods: A literature search was done on PubMed, EMBASE, Cochrane CENTRAL, Science Direct, Scopus, ProQuest, Google Scholar, and Wiley Online Library from 2015 to 2025. Included studies compared QoL between L-PM and C-PM using the SF-36 questionnaire. The ROBINS-I tool was used for assessing the risk of bias. Physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE), mental health (MH), physical component summary (PCS), and mental component summary (MCS) were the SF-36 questionnaire outcomes analysed.

Keywords:

Artificial

Cardiac pacing

Pacemaker

Quality of life

Questionnaires

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Results: From 5280 studies, three met the inclusion criteria, encompassing 468 patients, with an overall moderate risk of bias. Baseline QoL showed no significant differences between L-PM versus C-PM ($p > 0.05$). L-PM had significantly higher PCS and MCS at 1 week, better PF, RP, BP, VT, GH, and MCS at 1 and 3 months, and sustained better PF, RP, MH, and PCS at the 6-months than C-PM ($p < 0.05$).

Conclusions: L-PM scored better physical health QoL than C-PM, likely due to less fear of complications and fewer activity restrictions. Mental health superiority is inconsistent across studies, highlighting the need for further research.

Introduction

Cardiac pacemakers are crucial to treat conduction problems such as bradycardia, atrial fibrillation, and ventricular arrhythmias.¹ Permanent pacemakers are implanted in patients with persistent conduction problems, such as sinus node dysfunction and atrioventricular block. Permanent pacemakers can be classified as leadless pacemakers (L-PM), such as the Micra™ by Medtronic PLC and Nanostim™ by St. Jude Medical, or conventional pacemakers (C-PM), such as single-chamber, dual-chamber, or biventricular pacemakers.^{2,3} Despite their known effectiveness, C-PMs have a number of unwanted complications, such as infection, lead dislodgement, tricuspid valve involvement, pneumothorax, hemothorax, and thrombosis. L-PM, which is a self-contained device that is implanted directly into the right ventricle via femoral access, is a cutting-edge substitute for C-PM because they do not require transvenous leads and subcutaneous pockets.^{2,3}

Quality of life (QoL) is an important deciding factor for the patient when deciding which type of pacemaker to implant. By improving restraints on physical activity post-procedure, aesthetic concerns, and psychological distress, L-PMs are hypothesized to provide better QoL outcomes.^{4,6} To our knowledge, this is the first systematic re-

Table 1 – Literature search keywords

First keyword	Second keyword	Third keyword
Leadless pacemaker	Conventional pacemaker	Quality of life
OR	OR	OR
Transcatheter pacemaker	Traditional pacemaker	Life quality
OR	OR	OR
Micra	Transvenous pacemaker	Patient-reported
OR	OR	OR
Nanostim	Single-chamber pacemaker	
	OR	
	Dual-chamber pacemaker	
	OR	
	Biventricular pacemaker	

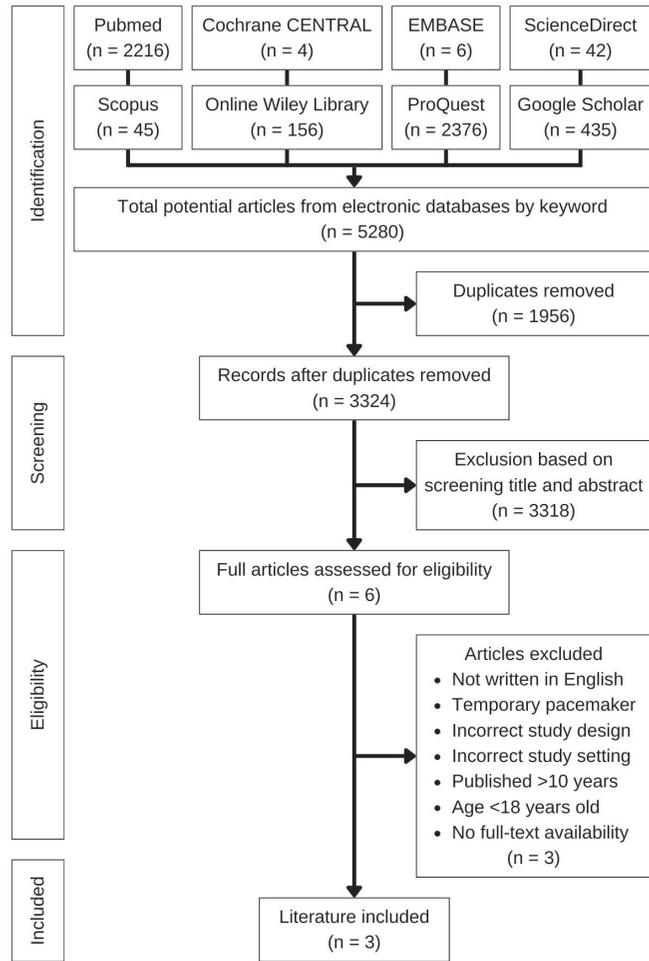


Fig. 1 – Study search flowchart for systematic review

view focusing exclusively on SF-36-based patient-reported QoL outcomes comparing L-PM and C-PM. This systematic review aims to compare the QoL outcomes of L-PM and C-PM patients to shed light on the possible advantages of L-PM and provide guidance for future decision-making by combining the existing literature that directly evaluates patient-reported QoL using the SF-36 questionnaire.

Methods

A literature search was conducted in PubMed, EMBASE, Cochrane CENTRAL, Science Direct, Scopus, ProQuest,

	D1	D2	D3	D4	D5	D6	D7	Overall
Study Cabanas-Grandío et al., 2019	-	-	+	-	-	+	+	-
Palmisano et al., 2021	-	+	-	-	-	-	-	-
Yu et al., 2023a	-	-	+	-	-	+	+	-

Domains:

- D1: Bias due to confounding.
 D2: Bias due to selection of participants.
 D3: Bias in classification of interventions.
 D4: Bias due to deviations from intended interventions.
 D5: Bias due to missing data.
 D6: Bias in measurement of outcomes.
 D7: Bias in selection of the reported result.

Judgement

- Moderate
 + Low

Fig. 2 – Risk of bias assessment for included studies

Google Scholar, and Online Wiley to compare the QoL of patients with L-PM and C-PM using various databases from 2015 to 2025, using Boolean operators and related terms (Table 1). We followed the PRISMA 2020 criteria to report

the study's results.⁷ The study assessed literature titles and abstracts based on eligibility criteria, including original research comparing QoL between L-PM and C-PM in adult patients over 18 years old, and articles written in English,

Table 2 – Systematic review study characteristics

Characteristics			
Author	Cabanas-Grandío, et al.	Palmisano, et al.	Yu, et al.
Year	2019	2021	2023a
Country	Spain	Italy	China
Study design	Prospective, multi-center, observational study	Prospective, single-center, propensity-scored matching, observational study	Prospective, single-center, observational study
Inclusion	(a) Patients with indications for single-chamber pacemaker implantation according to local clinic practice (b) Absence of cognitive impairment and ability to complete SF-36 questionnaire (c) Ability to provide written informed consent (d) Age ≥ 18 years old (e) Data from December 2016 to March 2018 from 4 tertiary hospitals in Spain (Hospital Álvaro Cunqueiro, Hospital Germans Trias i Pujol, Hospital Clínico Universitario, Hospital Virgen de la Salud)	(a) Patients that met class I or II ESC guideline recommendations on de novo ventricular pacing (b) Age ≥ 18 years old (c) Data from February 2016 to May 2020 from Cardinale Giovanni Panico General Hospital, Italy	(a) The patients had indications for pacemaker implantation (b) Absence of cognitive impairment and ability to complete SF-36 questionnaire (c) Ability to provide written informed consent (d) Age ≥ 18 years old (e) Data from January 2020 to March 2023a from Beijing Anzhen Hospital, China
Exclusion	(a) Surgical intervention or invasive treatment 3 months before the single-chamber pacemaker implant (b) Indication for any other surgical intervention at the moment of implantation	(a) Patients who underwent L-PM implantation after the extraction of a C-PM (b) Patients who underwent C-PM implantation after an unsuccessful attempt to implant an L-PM	(a) Patients that had surgical intervention or invasive treatment 3 months before the pacemaker implantation (b) Patients that had other indications for surgical intervention at the time of pacemaker implantation
Sample size	106 patients (64 C-PM, 42 L-PM)	243 patients (91 C-PM, 152 L-PM) After propensity-scored matching (77 C-PM, 77 L-PM)	119 patients (84 C-PM, 35 L-PM)
Follow-up duration	6 months and 2 out of 4 centres performed follow-up at 1 month	1 week, 3 months, 6 months	1 month, 3 months
QoL measures	SF-36 questionnaire and additional questionnaires	SF-36 questionnaire	SF-36 questionnaire and additional questionnaires

C-PM – conventional pacemaker; ESC – European Society of Cardiology; L-PM – leadless pacemaker; QoL – quality of life; SF-36 – short-form health survey questionnaire.

while exclusion criteria included non-English, temporary pacemaker studies, review articles, and no full-text availability (Fig. 1). Two reviewers independently assessed the risk of bias using the ROBINS-I tool, which is appropriate for observational studies.⁸ The reported ROBINS-I tool is visually shown using the *Robvis* traffic light plot figure (Fig. 2).⁹ A meta-analysis was not conducted due to heterogeneity in follow-up durations, outcome reporting, and patient populations.

This review compares the QoL of patients with L-PM versus C-PM. The primary QoL measure used for data extraction and analysis is the SF-36 questionnaire, with additional comparisons including patient characteristics, comorbidities, and pacing indications. Two independent reviewers conducted data extraction to ensure accuracy and consistency. Any discrepancies were resolved through discussion and consultation.

Results

A comprehensive literature search across 8 databases found 5280 articles, with 1956 duplicates excluded and 3324 screened (Fig. 1). Six articles were examined in full text, two for lack of full text, and one for not being written in English.¹⁰⁻¹² Three studies were selected for critical appraisal, showing an overall moderate risk of bias, accor-

ding to the ROBINS-I tool (Fig. 2). This systematic review of three studies involving 468 patients evaluated the QoL of patients with L-PM compared to C-PM.^{2,13,14} Although the studies shared a prospective observational design, differed in follow-up time points, and used the same QoL measure, these minor variations did not affect the overall comparability of the findings (Table 2).

The SF-36 questionnaire was used in studies to measure baseline QoL (Table 3). There were no significant differences in QoL between L-PM and C-PM in any of the SF-36 domains at baseline in all three studies ($p > 0.05$).^{2,13,14}

Table 3 presents the results of studies comparing L-PM and C-PM at different follow-up intervals. All three studies used the SF-36 questionnaire to measure QoL in various domains, including physical functioning (PF), social function (SF), role physical (RP), role emotional (RE), mental health (MH), bodily pain (BP), vitality (VT), general health (GH), physical component summary (PCS), and mental component summary (MCS).^{2,13,14} Palmisano et al.'s study found that at a one-week follow-up, patients with L-PM showed significantly higher scores for PF, SF, RP, RE, BP, VT, GH, PCS, and MCS compared to those with C-PM, indicating quicker short-term improvements in their QoL ($p < 0.05$).¹³ Studies by Cabanas-Grandio et al. and Yu et al. found higher scores for PF, RP, and PCS in L-PM compared to C-PM at the 1-month follow-up ($p < 0.05$).^{2,14} Yu et al. also reported higher scores for RE, BP,

Table 3 – SF-36 questionnaire results comparing L-PM and C-PM at baseline and follow-ups

SF-36	Cabanas-Grandío, 2019			Palmisano, 2021			Yu, 2023a		
	L-PM	C-PM	<i>p</i>	L-PM	C-PM	<i>p</i>	L-PM	C-PM	<i>p</i>
Baseline									
PF	44 ± 29	41 ± 25	0.508	57 ± 11	59 ± 14	0.191	41 ± 10	41 ± 5	0.752
SF	75 ± 29	73 ± 28	0.757	66 ± 11	64 ± 14	0.419	61 ± 15	65 ± 11	0.195
RP	23 ± 35	22 ± 38	0.962	40 ± 16	38 ± 14	0.657	27 ± 10	30 ± 12	0.194
RE	61 ± 48	62 ± 47	0.882	59 ± 8	61 ± 8	0.245	57 ± 8	59 ± 7	0.174
MH	61 ± 22	61 ± 23	0.984	68 ± 9	70 ± 14	0.275	55 ± 12	59 ± 8	0.128
BP	51 ± 26	52 ± 30	0.894	58 ± 6	59 ± 7	0.337	48 ± 9	48 ± 8	0.746
VT	40 ± 20	39 ± 22	0.856	36 ± 4	35 ± 9	0.623	39 ± 9	41 ± 8	0.386
GH	43 ± 18	44 ± 16	0.723	43 ± 5	42 ± 6	0.276	44 ± 10	44 ± 6	0.874
PCS	33 ± 10	33 ± 11	0.793	36 ± 9	36 ± 11	0.855	40 ± 7	41 ± 6	0.583
MCS	46 ± 14	46 ± 15	0.936	45 ± 14	46 ± 15	0.868	53 ± 8	56 ± 5	0.100
1 week follow up									
PF				63 ± 7	57 ± 10	<0.001			
SF				64 ± 14	54 ± 14	<0.001			
RP				55 ± 10	38 ± 12	<0.001			
RE				59 ± 5	48 ± 8	<0.001			
MH				73 ± 12	70 ± 14	0.096			
BP				47 ± 7	42 ± 6	<0.001			
VT				42 ± 8	34 ± 9	<0.001			
GH				48 ± 7	43 ± 7	<0.001			
PCS				39 ± 7	33 ± 8	<0.001			
MCS				46 ± 11	41 ± 12	<0.009			

Pokračování na další straně

Table 3 – SF-36 questionnaire results comparing L-PM and C-PM at baseline and follow-ups

SF-36	Cabanas-Grandío, 2019			Palmisano, 2021			Yu, 2023a		
	L-PM	C-PM	<i>p</i>	L-PM	C-PM	<i>p</i>	L-PM	C-PM	<i>p</i>
1 month follow up									
PF	61 ± 30	45 ± 27	0.035				56 ± 13	42 ± 8	<0.001
SF	88 ± 22	79 ± 30	0.165				74 ± 14	69 ± 11	0.055
RP	59 ± 44	18 ± 32	<0.001				52 ± 14	24 ± 8	<0.001
RE	74 ± 42	61 ± 44	0.243				71 ± 11	62 ± 9	<0.001
MH	73 ± 20	70 ± 21	0.670				70 ± 10	67 ± 9	0.092
BP	66 ± 30	64 ± 27	0.760				59 ± 12	54 ± 13	0.042
VT	55 ± 27	47 ± 22	0.188				54 ± 13	45 ± 8	<0.001
GH	53 ± 18	48 ± 19	0.236				55 ± 10	45 ± 7	<0.001
PCS	41 ± 9	34 ± 9	0.004				56 ± 10	41 ± 5	<0.001
MCS	50 ± 13	49 ± 13	0.792				67 ± 9	61 ± 6	<0.001
3 months follow up									
PF				63 ± 9	59 ± 9	0.026	63 ± 9	47 ± 7	<0.001
SF				65 ± 11	58 ± 12	0.001	80 ± 10	74 ± 8	0.004
RP				58 ± 9	50 ± 10	<0.001	60 ± 10	40 ± 9	<0.001
RE				64 ± 9	55 ± 9	<0.001	76 ± 10	71 ± 6	0.015
MH				75 ± 9	71 ± 9	0.002	75 ± 10	68 ± 9	<0.001
BP				55 ± 7	55 ± 8	0.939	65 ± 9	61 ± 9	0.042
VT				47 ± 12	45 ± 11	0.200	56 ± 10	49 ± 9	0.001
GH				55 ± 8	46 ± 8	<0.001	55 ± 12	52 ± 9	0.175
PCS				42 ± 3	38 ± 5	<0.001	61 ± 8	50 ± 5	<0.001
MCS				47 ± 11	42 ± 12	0.008	72 ± 6	65 ± 5	<0.001
6 months follow up									
PF	63 ± 27	42 ± 26	<0.001	62 ± 9	59 ± 10	0.035			
SF	85 ± 21	78 ± 29	0.149	73 ± 11	60 ± 10	<0.001			
RP	64 ± 43	36 ± 45	0.004	57 ± 9	52 ± 12	<0.001			
RE	75 ± 40	68 ± 44	0.428	64 ± 10	58 ± 9	<0.001			
MH	75 ± 16	65 ± 21	0.017	75 ± 10	71 ± 9	0.005			
BP	69 ± 25	60 ± 30	0.167	54 ± 7	53 ± 9	0.402			
VT	52 ± 21	44 ± 23	0.091	49 ± 7	46 ± 9	0.013			
GH	48 ± 18	48 ± 20	0.945	56 ± 8	48 ± 7	<0.001			
PCS	41 ± 11	35 ± 10	0.007	42 ± 3	38 ± 4	<0.001			
MCS	50 ± 11	48 ± 12	0.393	49 ± 12	43 ± 13	0.006			

C-PM – conventional pacemaker; BP – bodily pain; GH – general health; L-PM – leadless pacemaker; MCS – Mental Component Summary; MH – mental health; *p* – *p*-value of L-PM versus C-PM; PCS – Physical Component Summary; PF – physical functioning; RE – role emotional; RP – role physical; SF – social function; VT – vitality.

VT, GH, and MCS at the 1-month follow-up, suggesting L-PM may have broader benefits for emotional well-being and vitality early on ($p < 0.05$).¹⁴ L-PM has shown medium-term advantages over C-PM in patient-reported physical and mental health outcomes at a 3-month follow-up, with L-PM scoring significantly higher in PF, SF, RP, RE, MH, PCS, and MCS ($p < 0.05$).^{13,14} However, Yu et al. found significantly higher BP and VT scores for L-PM compared to C-PM ($p < 0.05$), while Palmisano et al. found significantly higher GH ratings for L-PM ($p < 0.05$).^{13,14} Cabanas-Grandio et al.

and Palmisano et al. found that L-PM had significantly higher scores in PF, RP, MH, and PCS compared to C-PM at the 6-month follow-up ($p < 0.05$).^{2,13} Palmisano et al. also found higher scores in SF, RE, VT, GH, and MCS at the 6-month follow-up, indicating the long-lasting benefits of L-PM ($p < 0.05$).¹³

The distribution of sexes and mean patient age were among the patient characteristics (Table 4). Two studies found that patients in the L-PM and C-PM groups were generally younger, with a mean age significantly higher

Table 4 – Baseline patient variables

Variables n (%)	Cabanas-Grandío, 2019			Palmisano, 2021			Yu, 2023a		
	L-PM	C-PM	<i>p</i>	L-PM	C-PM	<i>p</i>	L-PM	C-PM	<i>p</i>
Patient characteristics									
Age**	77 ± 10	81 ± 7	0.012	77 ± 8	78 ± 5	0.488	76 ± 7	67 ± 9	0.000
Male sex	32 (78)	42 (64)	0.129	55 (71)	49 (63)	0.302	23 (65)	51 (60)	0.608
Comorbidities									
DM	7 (17)	24 (38)	0.021	19 (24)	20 (26)	0.853	13 (37)	34 (40)	0.735
HT	34 (81)	54 (84)	0.646	58 (75)	64 (83)	0.233	21 (60)	58 (69)	0.341
HF	1 (3)	5 (8)	0.401	7 (9)	12 (15)	0.221	4 (11)	7 (8)	0.595
Renal disorder	4 (10)	10 (17)	0.347	21 (27)	13 (16)	0.120	7 (20)	10 (11)	0.250
Pacing indications									
AF	36 (88)	49 (78)	0.196	60 (77)	58 (75)	0.703	20 (57)	34 (40)	0.096
Others	6 (12)	15 (22)	0.196	–	–	–	15 (42)	50 (59)	0.096
SR AVB	–	–	–	9 (11)	11 (14)	0.632	–	–	–
Syncope*	–	–	–	4 (5)	5 (6)	0.731	–	–	–

AF – atrial fibrillation; C-PM – conventional pacemaker; DM – diabetes mellitus; HF – heart failure; HT – hypertension; L-PM – leadless pacemaker; *p* – *p*-value; SD – standard deviation; SR AVB – sinus rhythm with paroxysmal atrioventricular block. age** – mean ± SD; syncope* – unexplained syncope with chronic bifascicular block.

than those in the C-PM group ($p < 0.05$).^{2,14} The male predominance in the L-PM and C-PM groups did not significantly differ in terms of sex distribution ($p > 0.05$).^{2,13,14}

The study included diabetes mellitus (DM), hypertension (HT), heart failure (HF), and renal disorders as comorbidities in all three studies (Table 4). Results showed a lower prevalence of DM in L-PM patients compared to C-PM patients. According to Cabanas-Grandío et al., DM was significantly lower in L-PM than C-PM at baseline ($p < 0.05$), while the other two didn't find it significant ($p > 0.05$).^{2,13,14} Furthermore, no significant differences were found in HT, HF, and renal disorders prevalence at baseline ($p > 0.05$).^{2,13,14}

Pacing indications in L-PM implantations were categorized into four groups: atrial fibrillation (AF), others, sinus rhythm with paroxysmal atrioventricular block, and unexplained syncope with persistent bifascicular block (Table 4). Yu et al. and Cabanas-Grandío et al. did not identify pacing indications other than AF, resulting in a non-standard grouping of pacing indications.^{2,14} AF was the predominant pacing indication in all investigations, accounting for the majority of L-PM implantations. However, there was no significant difference in AF prevalence between L-PM and C-PM groups across studies ($p > 0.05$).^{2,13,14} Other pacing indications, such as sinus rhythm with paroxysmal atrioventricular block and unexplained syncope with chronic bifascicular block, were less common and showed no significant differences between groups ($p > 0.05$).^{2,13,14}

Discussion

This systematic review compares the QoL of L-PM and C-PM using the SF-36 questionnaire. The SF-36 question-

naire is a well-validated, general tool for measuring health-related QoL in a variety of patient groups.^{15,16} The multidimensional structure includes eight subscales that measure both physical and mental health. It also gives composite scores for the physical and mental components, which makes it useful for comparing studies.^{15,17} The self-administered format improves patient-centered assessment and facilitates efficient administration in clinical and research environments.¹⁸ But the SF-36 is not disease-specific, so it may not be able to pick up on small, condition-specific changes, especially in people with heart problems.¹⁹ As a result, subtle differences in psychological burden or procedural discomfort between L-PM and C-PM may not be fully captured by the SF-36. It also has ceiling and floor effects, which means it doesn't work as well for people who are very sick or very healthy.²⁰ Also, because it relies on patient memory over four weeks, it could be biased, and it might not work well in groups of people who have cognitive problems or low literacy.²¹ Even with these flaws, the SF-36 is still a useful tool for measuring QoL, especially when comparing treatments like L-PM vs C-PM that affect both physical and mental health.

This systematic review found that L-PM patients consistently reported better physical health than C-PM, as seen in the higher PF, RP, and PCS in all three studies and every follow-up period (1 week, 1 month, 3 months, and 6 months).^{2,13,14} This consistency across studies could be attributed to L-PM not being at any risk of lead dislodgement and pocket injury due to its absence of transvenous leads and subcutaneous pockets, which are frequent causes of complications in C-PM.²² Furthermore, both Cabanas-Grandío et al. and Yu et al. each did an additional specific questionnaire, which found that C-PM patients reported persistent procedural discomfort and concern

regarding complications post-implantation, which led to a reduction of physical activities of the patients' own accord.^{2,14} Moreover, L-PM patients only face short activity restrictions, such as relative rest for 3 to 7 days before returning to daily activities after hospital discharge, while C-PM patients are recommended by current guidelines to refrain from raising the arm nearest to the device above shoulder height, to minimize lead dislodgement and pocket injury for 4–6 weeks following implantation.²³

However, this systematic review revealed mixed outcomes concerning the mental health-related QoL advantages of L-PM in comparison to C-PM. Some studies indicated significant enhancements in mental health domains among L-PM recipients, whereas others did not, even at the same follow-up period.^{2,13,14} This highlights a gap in previous research, where mental health outcomes were reported in isolation in each primary study, without being compared across multiple studies. While each included study concluded that L-PM had significantly better mental health than C-PM when comparing baseline to follow-up, a side-by-side comparison shows that these benefits vary across different mental health domains and follow-up periods in different studies.^{2,13,14} These discrepancies may arise from variations in patient characteristics that may influence mental health outcomes across studies, as well as from the SF-36 questionnaire's lack of condition-specific sensitivity, which makes it difficult to determine whether observed mental health changes are due to the type of pacemaker or other unrelated factors.

Specific patient characteristics may affect QoL post-implantation. L-PM recipients are significantly younger than C-PM recipients ($p < 0.05$), suggesting younger patients may prefer L-PM due to its minimally invasive nature, quicker recovery, and reduced risk of complications.^{2,13,14} Additionally, the male gender is the majority of L-PM recipients in two studies, which may affect QoL outcomes.^{2,13} Further research is needed to understand how these gender differences could affect QoL variations between L-PM and C-PM. Underlying comorbidities may impact QoL outcomes after pacemaker implantation, but the studies included found them not statistically significant. L-PM patients at baseline had a lower prevalence of DM, HT, HF, and renal disorder compared to C-PM.^{2,13,14} However, only DM is statistically significant in one study, while the others aren't.² Patients with higher cardiovascular risk load are more likely to receive C-PM, as it preserves AV synchronization with dual-chamber pacing.²⁴ In one study, renal insufficiency is more common in L-PM than C-PM, suggesting different patient selection standards in different institutions.¹⁴ Further studies using multivariate analysis are needed to understand how comorbidities impact QoL variations between L-PM and C-PM recipients.

This systematic review offers a comprehensive analysis of QoL outcomes in patients receiving L-PM versus C-PM. One of its primary strengths lies in its strict inclusion criteria, ensuring that only high-quality studies directly comparing L-PM and C-PM using the SF-36 questionnaire were included. However, this systematic review has several limitations. The small number of included studies restricts the generalizability of the findings, and the relatively short follow-up durations (up to six months) limit the ability to assess long-term QoL trends. Differences in

study populations and methodological approaches may have also influenced the results.

Conclusion

This systematic review concluded that L-PM is linked to consistently better physical health-related QoL outcomes than C-PM, as determined by PF, RP, and PCS subscales from the SF-36 questionnaire. The lesser fear of complications and shorter post-implantation physical restrictions in L-PM are the probable cause of these advantages. Although the superiority of L-PM for mental health is supported by each included study separately, cross-study comparisons show that these superiorities aren't consistently seen across all mental health domains and follow-up times. The SF-36 questionnaire's limited condition-specific sensitivity and variations in patient demographics may be the reason for this. To fully grasp the complex effects of pacemaker type on physical and mental health outcomes, more research is required using multivariate analyses, longer-term follow-up, and condition-specific QoL tools.

Conflict of interest

The authors declare no conflict of interest for this article.

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