Stylet-driven leads versus lumenless pacing leads in patients with left bundle branch area pacing: A systematic review and meta-analysis

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BACKGROUND Despite advancements in lead designs for optimum left bundle branch area pacing (LBBAP), limited data exist on the performance of stylet-driven leads (SDLs).

OBJECTIVE This meta-analysis sought to compare the performance and safety of SDLs in comparison with lumenless leads (LLLs) following LBBAP.

METHODS Systematic literature search was conducted using PubMed, Europe PMC, and ScienceDirect for studies that compared the outcomes of SDLs during LBBAP compared with LLLs. Study outcomes included periprocedural parameters, pacing metrics, and complications.

RESULTS A total of 6 studies involving 3991 participants were included. LBBAP procedural success was comparable between SDLs and LLLs (90.2% and 90.5%, respectively). Compared with LLLs, SDLs appeared to result in shortened procedural (−11.50 minutes) and fluoroscopy (−2.56 minutes) times, along with increased capture threshold and reduced lead impedance at implantation. However, paced QRS, R-wave amplitude, capture threshold, and lead impedance remained comparable between both groups during follow-up. The number of lead-implantation attempts was similar between SDLs and LLLs (2.6 ± 1.0 vs 2.2 ± 0.6). Lead dislodgement and lead-related complications (except septal perforation) occurred mostly in the SDL group. No statistical differences were found in life-threatening complications.

CONCLUSION SDLs demonstrated comparable effectiveness in achieving LBBAP, exhibiting similar success rates, mean attempts for lead placement, and pacing parameters, although they were associated with a higher overall incidence of lead-related complications. The reduced overall procedural and fluoroscopy time may be attributed to the ability of SDLs' different delivery sheath selections in identifying the optimal anatomical site, rather than being lead specific.

KEYWORDS Left bundle branch area pacing; Stylet-driven leads; Lumenless leads; Safety; Efficacy

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Introduction

Conduction system pacing, commonly referred to as His bundle pacing and left bundle branch area pacing (LBBAP), is an emerging method of pacing that has garnered significant attention in recent years for providing a more physiological alternative to conventional right ventricular pacing.[1,2] LBBAP has emerged as a preferred alternative to His bundle pacing implantation due to its broader zone, less reported ventricular undersensing, and lower, more stable threshold resulting from its pacing site in the myocardial septal tissue, which eventually enhances device longevity.[3] While this approach requires a deep penetration into the interventricular septum for subendocardial access to the left bundle branch, there are instances when the lead may not extend adequately into the septum due to a lack of LBBAP-specific leads and sheaths hitherto.[4,5]

The vast majority of LBBAP implantations have been performed using lumenless, bipolar pacing leads (lumenless leads [LLLs]) with a fixed helix.[2,6,7] The introduction of stylet-driven leads (SDLs) from various manufacturers into LBBAP brings several advantages, including enhanced stiffness that aids in septal penetration. Additionally, these leads allow for continuous pacing through the stylet, enabling precise monitoring of changes in pacing impedance and QRS morphology while securing the lead, unlike the interrupted approach applied in LLLs.[8,9] Nevertheless, the efficacy and safety of SDLs in comparison with LLLs are only discussed

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KEY FINDINGS

- Stylet-driven leads positioned in the left bundle branch area demonstrated comparable results concerning successful left bundle branch area pacing rates and pacing parameters stability during implantation and follow-up.
- Stylet-driven leads were associated with higher lead-related adverse events, although rates of complications were rare in both groups.
- The potential advantage of one type over the other based on lead performance remains contentious, as existing data are insufficient; additional long-term, randomized trials are necessary to corroborate these findings.

in a limited number of case series and cohorts, with a diverse range of data reported in each study.[8,10–12] We sought to provide a comprehensive comparison analysis of published literature and a detailed discussion in order to provide novel but credible insights into this issue.

Methods

Protocol and registration

This systematic review was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions and reported based on the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) statement.[13] The protocol was registered at PROSPERO, under identification number CRD42024543124.

Literature search strategy

Electronic databases, including PubMed, Europe PMC, and ScienceDirect, were searched by 2 independent investigators (W.K. and R.P.) from inception to September 9, 2024. The search query encompasses keywords and search phrases that involve ((lumenless) OR (lumen-less) OR (LLL)) AND ((stylet-driven) OR (stylet driven) OR (stylet) OR (SDL)) AND (left bundle branch area pacing OR conduction system pacing). We utilized the least number of keywords necessary to optimize the initial area of inquiry and maximize the number of articles recorded. To expand our search results, we additionally conducted hand searches through the references of the included articles. The PRISMA criteria were implemented in our search, and Figure 1 depicts the search and screening processes.

Study selection

This meta-analysis focused on studies that detailed particular characteristics of LBBAP delivered by SDLs, along with studies that assessed its efficacy, safety, and outcomes in comparison with LLLs. The detailed inclusion criteria were outlined as follows: (1) randomized controlled trials or observational studies (either prospective or retrospective); (2) patients 18 years of age and older who successfully underwent de novo LBBAP implantation for bradycardia indication, in accordance with the published recommendations available at the period of which the study was conducted, and had complete follow-up; and (3) studies that reported the outcomes of interest in a comparative manner among the approaches listed previously. Our investigation required the inclusion of studies that provided risk estimation data with 95% confidence intervals (CIs), or alternatively, studies that presented sufficient data to calculate the effect size.

Our meta-analysis excluded animal studies, review papers, editorials, comments, letters to editors, case reports/series, meta-analyses, and conference abstracts. Studies involving a heart failure population exceeding three-quarters of the population and patients who are indicated for cardiac resynchronization therapy were excluded from this research. In instances in which multiple articles derived from the same cohort, only studies that feature the most recent follow-up and the most comprehensive data were included in this meta-analysis.

Outcomes of interests

Our meta-analysis primarily focused on procedural implant success rates, total procedural and fluoroscopy time, composite pacing parameters, and a range of complications. Implant success is defined as the presence of LBBAP criteria, as stipulated by the operator at the end of the procedure, in accordance with the references cited in each study included.[5,14] The electrical parameters of the LBBAP lead, including the paced QRS, R-wave amplitude, capture threshold, and pacing impedance, were obtained both at the time of implantation and during the last follow-up. This research additionally gathered data concerning device lead-related adverse events and life-threatening complications throughout the period of observation. Septal perforation was described as either an overt perforation confirmed by fluoroscopy, or marked by a notable reduction in current of injury below 3 to 5 mV, or an alteration in current of injury morphology resulting in an RS or QS pattern. Other indicators of perforation consist of a reduction in pacing impedance below 450 Ω or a fall in impedance exceeding 200 Ω. Lead dislodgment was defined as the loss of LBBAP capture, which has been previously achieved, characterized by the disappearance or decrease in the terminal R-wave in V1. Septal hematoma was established by the observation of notable thickening of the interventricular septum (IVS) at the final LBBAP lead placement site during follow-up echocardiography examination.[5]

Data extraction and risk of bias assessment

Two independent reviewers (G.K. and W.K.) extracted the data from the eligible studies, consisting of (1) baseline characteristics, such as first author's name, the country in which the study was conducted, study design, total participants, age, male sex, and comorbidities; and (2) outcome-related data, including pacing indications, echocardiographic parameters, leads type and delivery sheaths, implantation

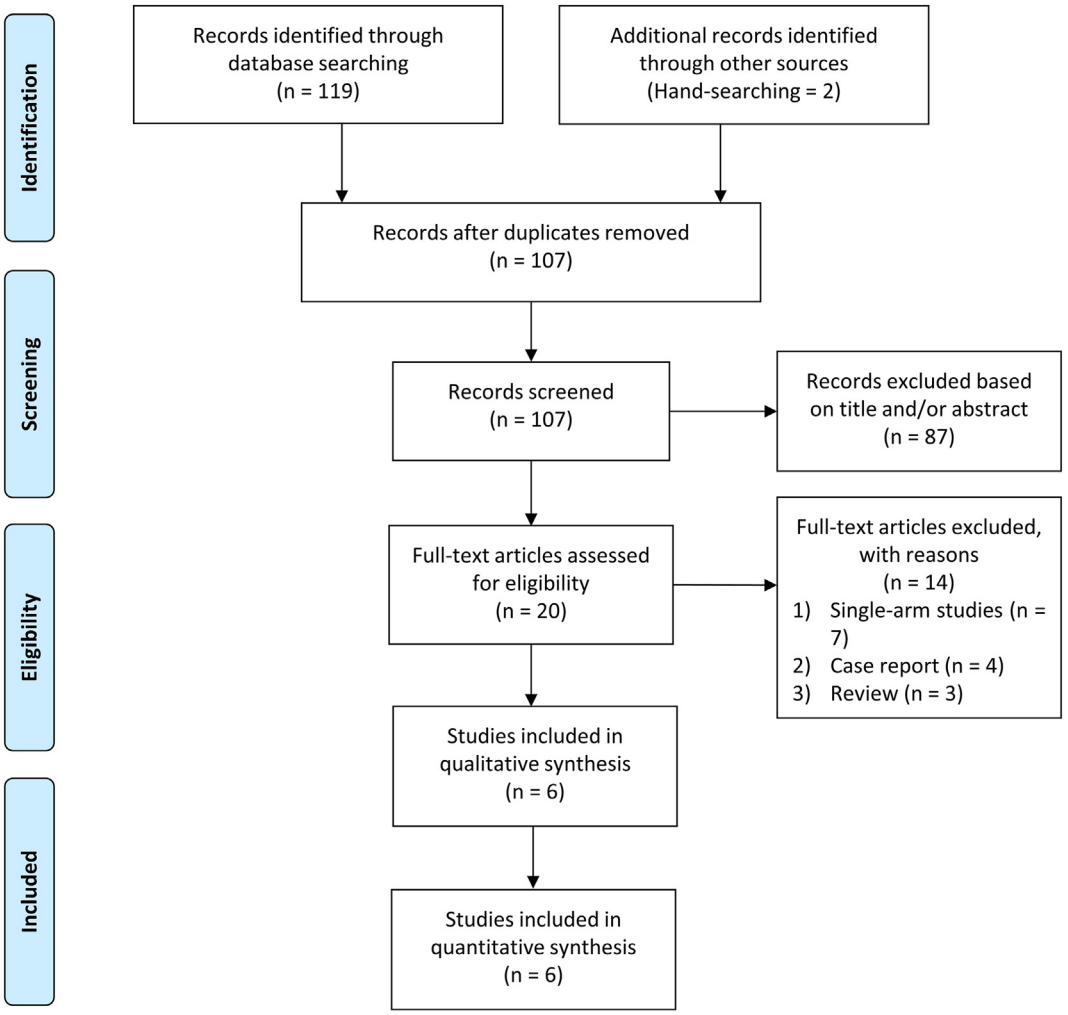

Figure 1 Flow chart of study selection.

procedure, and follow-up duration. Data extraction was conducted through mutual agreement, with any disputes resolved by a third researcher (M.I.).

The Newcastle-Ottawa scale was implemented to independently assess the possibility of bias in each study. A study with a total score of 7 or above was deemed bias-free. Research with a total score of 6 or less was deemed biased and thus excluded from the research. Author discussion was utilized to settle quality rating disagreements.[15]

Data analysis

In this meta-analysis, we employed Review Manager 5.4 (Cochrane Collaboration) to calculate the total effect size. The effect size in the current analysis was calculated as risk ratio (RR) with 95% CI, while mean difference (MD) was used to estimate the comparison of continuous variables as an effect unit. Values presented using the median (interquartile range) were transformed into mean ± SD for the purpose of statistical analysis.[16] We employed random-effects models along with the restricted maximum likelihood method to calculate the overall effect size, irrespective of the heterogeneity status.[17] The I^2 index was used to examine interstudy heterogeneity, with an I^2 statistic of more than 50% or a P value $<.10$ disclosing significant heterogeneity.[18] A sensitivity analysis was conducted using the leave-one-out method to identify the source of the observed interstudy heterogeneity.[19] Furthermore, the Egger test was utilized to quantify the publication bias. All statistical analyses were 2-sided, with statistical significance attained by a P value $<.05$.[17]

Results

Study selection and characteristics of the included studies

The primary search results yielded 121 articles. Following the evaluation of the titles and abstracts, 20 papers were identified for further assessment based on the specified inclusion criteria. Eventually, 6 prospective and retrospective observational studies with a total of 3991 (958 for SDLs and 3033 for LLLs) participants were included in our analysis.[7,20–24] Figure 1 depicts the results of the literature search, including the basis for excluding certain publications.

Table 1 Baseline and clinical characteristics of the included studies (SDLs vs LLL).

No.	Author (year)	Country	Study design	Total participants	Age (y)	Male (%)	Pacing indications (%)	Comorbidities (%)	Echocardiographic parameters	Types of delivery system (sheath)	Pacemaker lead type	Implantation procedure	Follow-up length	NOS
1	Braunstein et al (2023)[20]	United States	Retrospective observational study	83 (53 vs 30)	74.5 ± 12.4 vs 73.4 ± 8.7	72 vs 60	SND: 36 vs 20 AVB: 60 vs 67 Others (unspecified): 4 vs 13	Hypertension: 66 vs 67 DM: 23 vs 20 CAD: 44 vs 47 HF: 11 vs 41 AF or AFl: 38 vs 33 CKD: 71 vs 57	LVEF: 59.6 ± 11.9% vs 59.1 ± 11.9% LVEDD: 48 ± 11 mm vs 51 ± 9 mm LA diameter: 42 ± 11 mm vs 47 ± 10 mm	SDL: Biotronik Selectra 3D or Boston Scientific SSPC LLL: Medtronic C315-HIS or C304-HIS	SDL: Biotronik Solia S60, Boston Scientific Ingevity LLL: Medtronic SelectSecure model 3830	Technique: Huang et al[14] Criteria used for confirmation of LBBAP: Huang et al[14]	12 mo	9
2	Cano et al (2023)[21]	Spain and United States	Retrospective observational study	925 (270 vs 655)	76 ± 10 vs 74 ± 14	NR	SND: 27 vs 15 AVB: 64 vs 58 Others: 9 vs 27	Hypertension: 76 vs 73 DM: 34 vs 37 CAD: 13 vs 24 HF: 40 vs 57 CKD: 34 vs 38	LVEF: 57 ± 12% vs 53 ± 15% LA diameter: 41 ± 8 mmvs 41 ± 7 mm	SDL: Biotronik Selectra 3D, Abbott Agilis HisPro LLL: Medtronic C315-HIS	SDL: Biotronik Solia S60, Boston Scientific Ingevity, Abbott Tendril 2088TC LLL: Medtronic SelectSecure model 3830	Technique: EHRA consensus recommendation[5], Huang et al[14] Criteria used for confirmation of LBBAP: EHRA consensus recommendation[5]	16.4 mo	9
3	Daniëls et al (2023)[22]	Netherlands	Prospective observational study	94 (63 vs 31)	74 ± 8.8 vs 75 ± 11.2	55.6 vs 38.7	SND: 6.3 vs 6.5 AVB: 20.6 vs 35.5 Pace and ablate due to refractory AF: 57.1 vs 51.6	NR	LVEF: 55.6 vs 54.8%	SDL: Biotronik Selectra 3D LLL: Medtronic C315-HIS	SDL: Abbott Tendril 2088TC LLL: Medtronic SelectSecure model 3830	Technique: Huang et al[14] Criteria used for confirmation of LBBAP: Huang et al[14]	30 wk	9
4	De Pooter et al (2021)[23]	Belgium	Prospective observational study	50 (23 vs 27)	72 ± 10.9 vs 68 ± 16.3	74 vs 41	SND: 22 vs 11 AVB: 52 vs 67 Others: 26 vs 22	Hypertension: 65 vs 52 CAD: 39 vs 11	LVEF: 53 ± 13.4% vs 53 ± 14.3%	SDL: Biotronik Selectra 3D LLL: Medtronic C315-HIS	SDL: Biotronik Solia S60 LLL: Medtronic SelectSecure model 3830	Technique: Huang et al[14] Criteria used for confirmation of LBBAP: Huang et al[14]	6 mo	9
5	Jastrzębski et al (2022)[7]	Multicentre European observational study	Prospective observational study	2533 (396 vs 2137)	73.9 ± 11.8	42.4	SND: 14.7 AVB: 48.1 AF: 3.7	Hypertension: 72.2 DM: 29.1 CAD: 30.5 HF: 39.6	NR	NR	NR	Technique: Huang et al[14] Criteria used for confirmation of LBBAP: Huang et al[14]	6.4 mo	8
6	Sritharan et al (2023)[24]	Switzerland	Prospective observational study	306 (153 vs 153)	80 ± 11 vs 74 ± 13	59 vs 60	AVB: 12 vs 16 Pace and ablate: 88 vs 84	Hypertension: 81 vs 73 DM: 32 vs 31 CAD: 41 vs 28 HF: 7 vs 8 CKD: 33 vs 29	LVEF (%): 54.8 ± 2.1 vs 53 ± 2.3	SDL: Biotronik Selectra 3D LLL: Medtronic C315-HIS	SDL: Biotronik Solia S60, Boston Scientific Ingevity, Abbott Tendril 2088TC, Microport VEGA LLL: Medtronic SelectSecure model 3830	Technique: EHRA consensus recommendation[5] Criteria used for confirmation of LBBAP: EHRA consensus recommendation[5]	7.7 mo	8

AF = atrial fibrillation; AFl = atrial flutter; AVB = atrioventricular block; CAD = coronary artery disease; CKD = chronic kidney disease; DM = diabetes mellitus; EHRA = European Heart Rhythm Association; HF = heart failure; LA = left atrium; LLL = lumenless lead; LVEDD = left ventricular end-diastolic diameter; LVEF = left ventricular ejection fraction; NOS = Newcastle-Ottawa scale; NR = not reported; SDL = stylet-driven lead; SND = sinus node dysfunction; SSPC = site-selective pacing catheter.

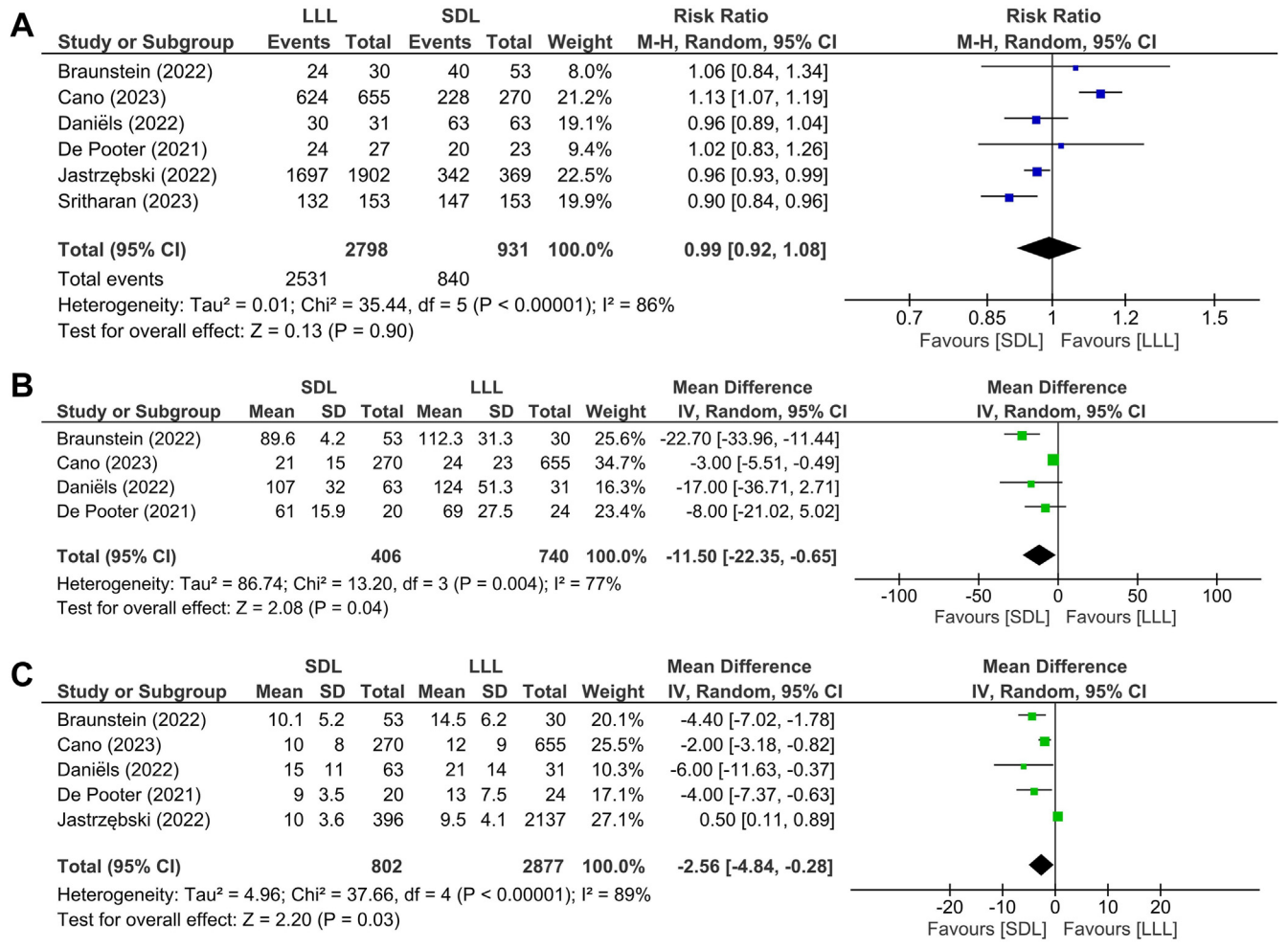

Figure 2 Comparison of procedural outcomes in stylet-driven leads (SDLs) and lumenless leads (LLLs). A: Successful rate; B: procedure time (minutes); C: fluoroscopy time (minutes). CI = confidence interval; IV = inverse-variance; M-H = Mantel-Haenszel.

Atrioventricular block was the primary indication for treatment in 58.3% of cases, while sinus node dysfunction accounted for 16.8% of cases in which LBBAP was employed, followed by atrial fibrillation–related cases at 12.6%, and unspecified cases at 12.3%. The mean age of participants in both groups was notably similar (75.1 ± 2.7 years of age vs 72.9 ± 2.8 years of age), with 54.5% being male. All patients had a left ventricular ejection fraction (LVEF) of over 50%. In the SDL group, a range of lead models were used, with the Biotronik Solia S60 being the predominant choice (4 studies), followed by Boston Scientific Ingevity and Abbott Tendril 2088TC (3 studies). The Medtronic SelectSecure model 3830 was utilized uniformly in all investigations within the LLL group. The mean duration of follow-up was 9.3 months. Table 1 presents the baseline and clinical characteristics of the studies included in the final review.

Periprocedural characteristics

The pooled results of 6 comparative studies suggest that the success rates of LBBAP implantation were comparable between the SDL (90.2%) and LLL (90.5%) groups (RR 0.99, 95% CI 0.92–1.08, $P = .90$, $I^2 = 86\%$) (Figure 2A). A leave-one-out sensitivity analysis indicated that the heterogeneity decreased to ($I^2 = 8\%$) in the success rate outcome while maintaining a comparable success rate between both groups upon removal of the Cano and colleagues[21] study. The SDL group experienced a significantly reduced procedure and fluoroscopy duration in contrast to the LLL group (MD –11.50 minutes, 95% CI –22.35 to –0.65 minutes, $P = .04$, $I^2 = 77\%$; and MD –2.56 minutes, 95% CI –4.84 to –0.28 minutes, $P = .03$, $I^2 = 89\%$, respectively) (Figures 2B and 2C). The exclusion of the Braunstein and colleagues[20] study reduced the heterogeneity of procedural and fluoroscopy time to 17% and 38%, respectively, while preserving $P < .05$ for both outcomes following a leave-one-out sensitivity analysis. Nevertheless, the number of attempts to implant the lead was similar between the 2 lead variants (2.6 ± 1.0 vs 2.2 ± 0.6).

Electrical and pacing parameters

Regarding acute pacing parameters, the paced QRS and R-wave amplitude were comparable between 2 groups (MD 4.42 ms, 95% CI –2.54 to 11.38 ms, $P = .21$, $I^2 = 87\%$; and MD –0.30 mV, 95% CI –1.09 to 0.49 mV, $P = .46$,

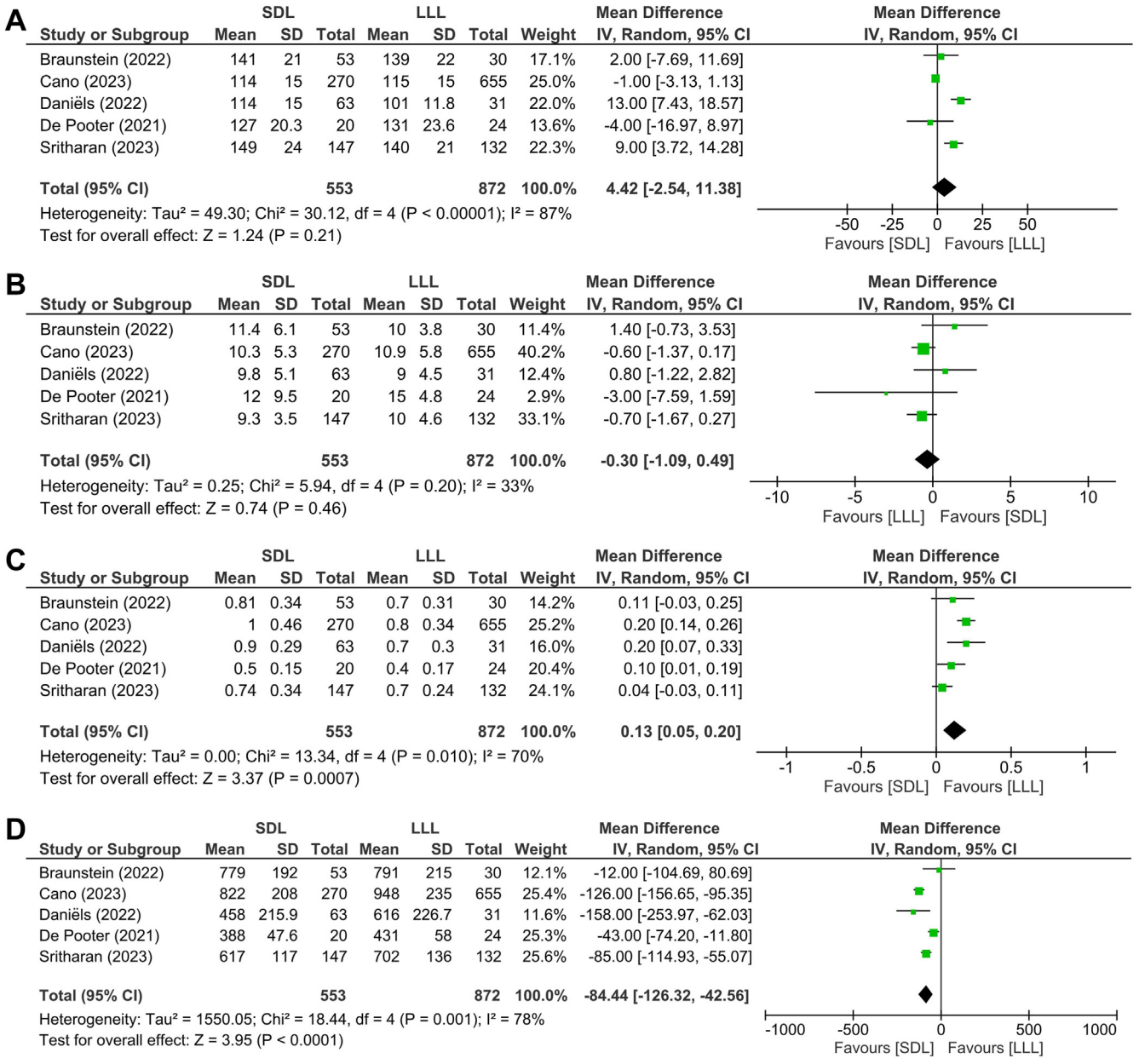

Figure 3 Comparison of ventricular pacing lead parameters during implantation in stylet-driven leads (SDLs) and lumenless leads (LLLs). A: Paced QRS (ms); B: R-wave amplitude (mV); C: pacing threshold (V); D: pacing impedance. CI = confidence interval; IV = inverse-variance.

I^2 = 33%, respectively) (Figures 3A and 3B). Nonetheless, the overall findings indicate that participants in the SDL group demonstrated significantly higher capture threshold (MD 0.13 V, 95% CI 0.05–0.20 V, $P < .001$, $I^2 = 70\%$) (Figure 3C) and reduced pacing impedance (MD –84.44 Ω, 95% CI –126.32 to –42.56 Ω, $P < .001$, $I^2 = 78\%$) (Figure 3D) in comparison with those in the LLL group at the time of implantation. The R-wave amplitude, capture threshold, and lead impedance were similar in both groups during the most recent follow-up (mean 9.3 months) (Figures 4A–C).

Procedure- and lead-related complications

Septal perforation rates in all studies documenting the event at implantation were 7.1% in the SDL group and 4.6% in the LLL group. No statistically significant difference was observed between both groups (RR 1.34, 95% CI 0.99–1.81, $P = .06$, $I^2 = 0\%$) (Figure 5A). The risk of other lead-related complications (eg, septal hematoma, lead damage during implantation) (RR 2.61, 95% CI 1.27–5.37, $P = .009$, $I^2 = 63\%$) (Figure 5B) and lead dislodgement (RR 3.06, 95% CI 1.90–4.94, $P < .001$, $I^2 = 0\%$) (Figure 5C) in the SDL group was notably greater than

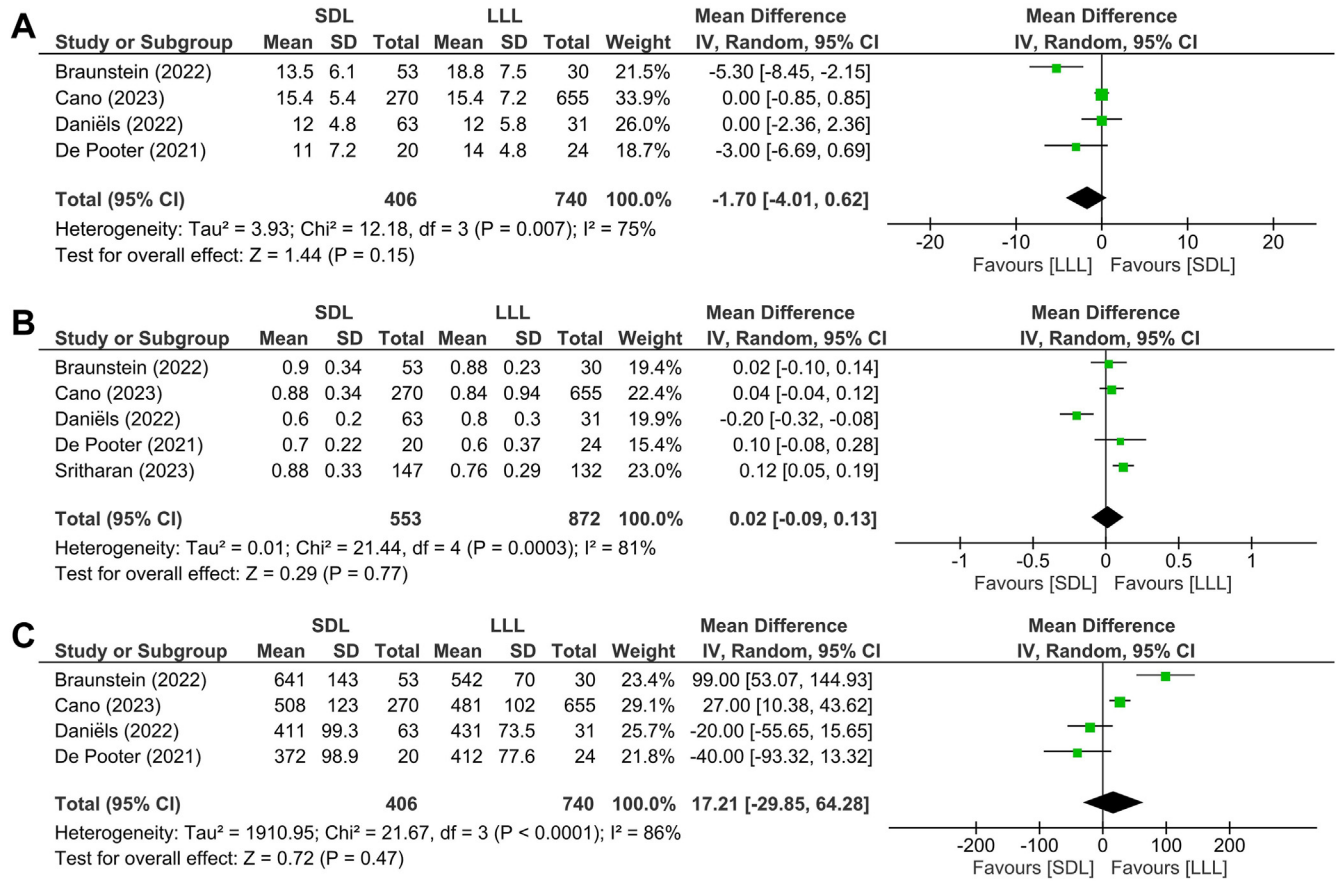

Figure 4 Comparison of ventricular pacing lead parameters during last follow-up in stylet-driven leads (SDLs) and lumenless leads (LLLs). A: R-wave amplitude; B: pacing threshold; C: pacing impedance. CI = confidence interval; IV = inverse-variance.

that in the LLL group. A leave-one-out sensitivity analysis reduced the heterogeneity of other lead-related complications to 0%; however, the aforementioned adverse events persisted to be higher in the SDL group ($P < .05$) following the removal of the Cano and colleagues[21] study. Life-threatening complication rates were similar in both groups (RR 0.90, 95% CI 0.30–2.71, $P = .85$, $I^2 = 0\%$) (Figure 5D). No incidents of helix retraction were reported within the SDL group.

Publication bias

We were unable to conduct a qualitative analysis of funnel plots to identify publication bias due to a paucity of research in our analysis. Hence, the Egger test was used to quantitatively detect publication bias, and our findings revealed the absence of a small study effect.

Discussion

The most notable findings in this study indicate that the SDL group demonstrated a similarly high success rate of implants when compared with the LLL group. The expedited lead implantation duration of around 11 minutes, along with a reduction of approximately 3 minutes in fluoroscopy time, may be attributed to the efficacy of various SDL delivery sheath selections in pinpointing the optimal anatomical site, rather than being lead specific. Current evidence attained from this meta-analysis also suggests that acute pacing parameters exhibited higher capture threshold and lower lead impedance, although these parameters became comparable between both groups during follow-up. Lead dislodgement and other lead-related complications, excluding septal perforation, were predominantly observed in the SDL group. Life-threatening complications were uncommon in pacemaker placements within this population with preserved LVEF; hence, no statistical differences were observed in this outcome. To our knowledge, this is the first meta-analysis comparing SDLs and LLLs regarding the efficacy and safety for the LBBAP implantation, which will be discussed in detail in the remainder of this article.

To fully comprehend the principles behind the previously mentioned findings, it is crucial to have a thorough understanding of the anatomy and functioning of each lead design, as the findings of this meta-analysis directly correlate with these fundamental characteristics following LBBAP implantation. Currently, LBBAP is commonly accomplished using LLLs, specifically the Medtronic SelectSecure model 3830 with a diameter of 4.1-F. This model is equipped with a fixed, nonretractable electrically active helix with a surface area of 3.6 mm^2 and is typically delivered with Medtronic

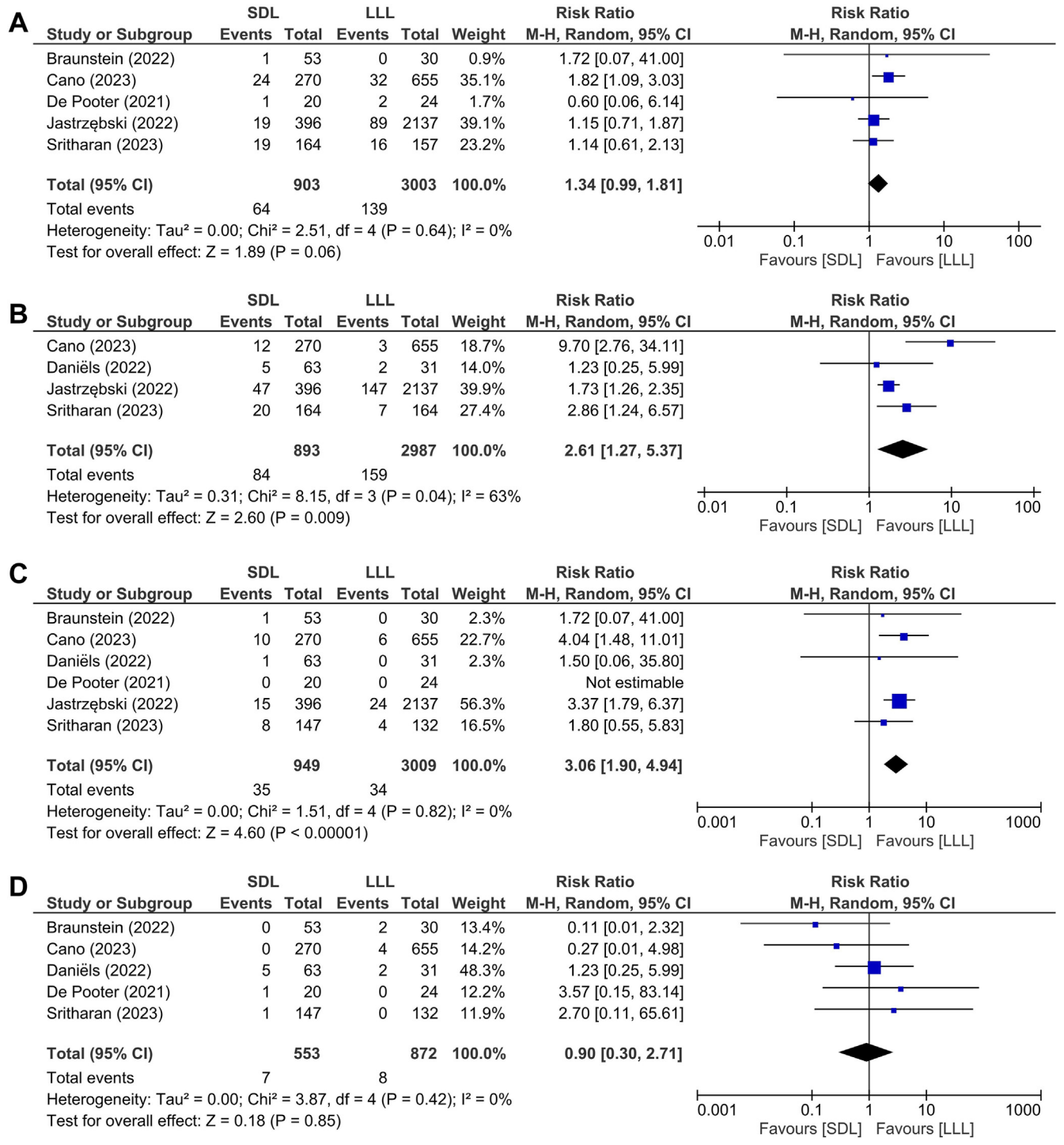

Figure 5 Comparison of procedural complications in stylet-driven leads (SDLs) and lumenless leads (LLLs). A Septal perforation; B: other lead-related complications (septal hematoma, lead damage during implant); C: lead dislodgement; D: life-threatening complications. CI = confidence interval; IV = inverse-variance; M-H = Mantel-Haenszel.

C315-HIS or C304-HIS sheaths.[25,26] In contrast, the diameter of SDLs is greater than that of LLLs (5.6-F for Biotronik Solia S60, 5.7-F for Boston Scientific Ingevity, 5.8-F for Abbott Tendril 2088TC). It features an extendable or retractable electrically active helix that is roughly the same length as that of LLLs but with a wider surface area ranging from 4.5 to 6.9 mm^2, equipped with stylet support.[26]

With this fundamental design difference, SDLs may provide several benefits compared with LLLs for LBBAP. These advantages include a larger and thicker lead body, supported by a stylet for easier handling, superior torque transmission and stiffness, and higher penetration power due to the incorporation of an inner lumen with a stylet for targeting deep septal locations when aiming to access the left bundle branch

area. SDLs are further enhanced through the use of delivery sheaths, with each company offering its own proprietary sheath designs featuring specific curves to target the mid septal LBBAP region.[7,12,23] In addition, the existence of the stylet enables uninterrupted pacing and continuous monitoring of lead parameters, unlike in LLLs when this process is interrupted.[27] These characteristics may account for the decrease in overall procedure and fluoroscopy time, despite the similar number of attempts in positioning the lead in both groups. The significant heterogeneity arising from the research conducted by Braunstein and colleagues, attributed to the greater prevalence of heart failure in the LLL group, was expected to render the procedure more challenging and time-consuming compared with the SDL group, leading to the most prominent difference in the aforementioned outcomes among the other studies included.[20]

The increased surface area of SDLs will result in more significant local trauma or edema, leading to a higher acute pacing threshold compared with LLLs,[28] with values reverting to no statistically significant difference during follow-up. Moreover, the pacing impedance will be affected by the lead design, as impedance is inversely proportional to surface area,[29] a relationship that is corroborated by our findings. This finding holds significance as the elevated value influences the approach to estimating helix retraction or the occurrence of septal perforation, given the distinct impedance cutoff values compared with LLLs. Despite the statistically significant differences observed, the variations in capture threshold and pacing impedance in this acute setting seem to remain within clinically insignificant differences.

Our meta-analysis demonstrated similar success rates for LBBAP implantation between the 2 groups (90.2% vs 90.4% for SDLs and LLLs, respectively), with three-quarters of cases being referred for atrioventricular block or sinus node dysfunction pacing indications. This result was achieved despite the stringent LBBAP criteria requiring QRS transition (nonselective to selective left bundle branch pacing) endorsed by the European Heart Rhythm Association[5] applied in the Cano and colleagues[21] and Sritharan and colleagues[24] studies. The disparity might be attributed to the commencement of data collecting in 2019 in the research conducted by Cano and colleagues.[21] The influence on the learning curve is apparent in this research's relatively low success rate, in contrast to Sritharan and colleagues,[24] who began the data-collecting phase at the end of 2021. Still, the notion of this learning curve is reinforced by the subgroup analysis conducted by Cano and colleagues[21] on the last 100 patients in their registry, which revealed similar rates of success between the 2 groups.

Nevertheless, a higher incidence of lead-related complications was observed in the SDL group, reflected by the amount of lead dislodgment and other lead-related adverse events. The rates of septal perforation in the SDL group were higher than in the LLL group (7.1% vs 4.6%) due to the stiffer and bigger lead design of SDLs, though this difference did not reach statistical significance. This may be attributed to the substantial injury current delivered by the SDL, which complicates the interpretation of subtle changes in sensing and impedance. The observed phenomenon might once again be attributed to a learning curve that arises from the operator's efforts to attain conduction system capture in the context of LBBAP, which results in overshooting the target.[30] The minor difference in septal perforations observed in this study could also be attributed to the comparable rates of lead implantation attempts between the 2 groups. It is noteworthy that none of the studies included in our meta-analysis reported septal perforation in the 2 groups that necessitated additional intervention, nor were there any clinically significant events such as the formation of a shunt or fistula.[7,20,21,23,24] Moreover, the increased incidence of lead dislodgement with SDLs may be attributed to the larger lead tip size, the more abrupt transition between lead tip and helix diameters, and the overall higher lead stiffness. The occurrence of septal hematoma and lead damage during implantation is also more frequent in SDLs, attributed to the greater driving force and the extendable-retractable nature of the helix, which is more susceptible to lead damage.[26] However, there is currently a lack of clinical data on myocardial injury and troponin release following SDL implantation. No incidents of helix retraction were documented in the SDL group across all studies included, as the routine practice involved providing additional pretension on the inner coil of the lead using a standard clip-on tool or the lead end cap.[7,20–22,24,26]

Anatomical considerations must also be taken into account during the LBBAP implantation procedure. Although the LLL subgroup may seem to have a higher prevalence of heart failure compared with SDLs, the currently available echocardiography data only include LVEF, which indicates values within the normal range for both groups.[7,20–22,24,26] Unfortunately, there is a lack of data regarding ventricular or atrial dimensions, owing to the inherent limitations of data reported in the studies. Structural heart diseases, including thickening or fibrosis of the IVS resulting from coronary artery disease, the aging process, and other factors, should be evaluated and contrasted between the 2 groups. This comparison can offer valuable insights and further highlight the benefits and drawbacks of opting leads in various specific populations.

Study limitations

Several limitations still warrant consideration in this meta-analysis. First, significant heterogeneity was discovered in the analysis as a result of various SDLs utilized across the studies as well as the preponderance of distinctive characteristics in several previously described studies. Second, we were unable to conduct subgroup analysis or meta-regression on several confounding factors (eg, age, sex, structural heart disease, echocardiographic parameters [eg, IVS], different SDL types, specific site of LBBAP) due to a paucity of research. Third, data on lead extraction related to lead-related complications, particularly in SDLs, are limited. Fourth, the data presented here were sourced from centers that specialize in the conduction system pacing field. Additionally, the lead types used were only from the manufacturers listed in the Results, and the outcomes might

significantly be influenced by the operator's familiarity with a particular brand's product. Therefore, the results of this meta-analysis should be extrapolated with caution. Other limitations also include a small number of studies, a relatively short follow-up duration, and the lack of randomized controlled trial available, hence increasing the potential of selection bias.

Conclusion

SDLs are equally effective in achieving LBBAP with similar success rates, mean number of attempts at LBBAP lead placement, and overall pacing parameters. The increased rate of lead complication may be associated with the operator learning curve or the characteristics of the lead. Shorter overall procedural and fluoroscopy times lack clinical significance and may be indicative of the SDLs' delivery sheath design or the ability to interpret electrograms continuously during deployment. Further prospective, randomized controlled trials with extended follow-up periods are required in order to validate and compare the performance of these 2 different kinds of leads.

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Authorship: All authors attest they meet the current ICMJE criteria for authorship.

Ethics Statement: This systematic review was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions and reported on the basis of the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA).

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