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Initial experience of left bundle branch area pacing using stylet-driven pacing leads: A multicenter study

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Abstract

Background: Left bundle branch area pacing (LBBAP) has been performed exclusively using lumen-less pacing leads (LLL) with fixed helix design. This registry study explores the safety and feasibility of LBBAP using stylet-driven leads (SDL) with extendable helix design in a multicenter patient population.

Methods: This study prospectively enrolled consecutive patients who underwent LBBAP for bradycardia pacing or heart failure indications at eight Belgian hospitals. LBBAP was attempted using SDL (Solia S60; Biotronik) delivered through dedicated delivery sheath (Selectra3D). Implant success, complications, procedural, and pacing characteristics were recorded at implant and follow-up.

Results: The study enrolled 353 patients (mean age 76 ± 39 years, 43% female). The mean number of implants per center was 25 (range: 5–162). Overall, LBBAP with SDL was successful in 334/353 (94%), varying from 93% to 100% among centers. Pacing response was labeled as left bundle branch pacing in 73%, whereas 27% were labeled as myocardial capture. Mean paced QRS duration and stimulus to left

Abbreviations: EF, ejection fraction; HBP, his bundle pacing; LAO, left anterior oblique; LBBAP, left bundle branch area pacing; LBBP, left bundle branch pacing; LLL, Lumen-less pacing leads; LVSP, left ventricular septal pacing; RVP, right ventricular pacing; SCAF, septal coronary artery fistula; SDL, stylet-driven pacing leads.

ventricular activation time measured 126 ± 21 ms and 74 ± 17. SDL-LBBAP resulted in low pacing thresholds (0.6 ± 0.4 V at 0.4 ms), which remained stable at 12 months follow-up (0.7 ± 0.3, $p = .291$). Lead revisions for SDL-LBBAP occurred in 5 (1.4%) patients occurred during a mean follow up of 9 ± 5 months. Five (1.4%) septal coronary artery fistulas and 8 (2%) septal perforations occurred, none of them causing persistent ventricular septal defects.

Conclusion: The use of SDL to achieve LBBAP is safe and feasible, characterized by high implant success in low and high volume centers, low complication rates, and stable low pacing thresholds.

KEYWORDS

left bundle branch area pacing, left ventricular septal pacing, physiologic pacing, stylet-driven pacing leads

1 | INTRODUCTION

Right ventricular pacing (RVP) has been the standard pacing modality for ventricular pacing for many decades. However, RVP induces a dyssynchronous contraction pattern of the heart which might result in pacing induced cardiomyopathy, adverse hemodynamic effects and even increased mortality.[1–3] Conduction system pacing has emerged as an alternative pacing modality to achieve physiological pacing. His bundle pacing (HBP), which is deemed most physiological, is limited by high capture thresholds, low sensing amplitudes and low implant success in patients with infranodal conduction disease.[4,5]

Left bundle branch area pacing (LBBAP) has emerged as an attractive alternative to achieve physiological pacing as it results in comparable hemodynamic effects as HBP but with lower and more stable pacing thresholds, higher sensing amplitudes and higher implant success.[6–9] To date, the vast majority of published LBBAP reports have utilized a specialized lumen-less pacing lead (LLL), delivered through a preshaped delivery sheath.[6,8–10] Recently, LBBAP using standard stylet-driven pacing leads (SDL) has been proposed by our group as a feasible and safe approach to achieve capture of the left bundle branch area, paving the way to target the deep septum with different types of pacing leads.[11,12] This prospective multicenter registry aims to assess the feasibility, safety and pacing characteristics of LBBAP using SDL.

2 | METHODS

2.1 | Study population

This study prospectively enrolled consecutive adult patients who underwent LBBAP for anti-bradycardia pacing or heart failure indications at eight different Belgian hospitals. LBBAP was attempted as first choice pacing strategy or in case of failed HBP or conventional cardiac resynchronization therapy attempt. The study was approved by the local ethical committees of the participating centers and by the central ethical committee of Ghent University Hospital. Written informed consent was obtained upon participation in the registry.

2.2 | LBBAP via stylet-driven pacing leads

LBBAP was performed with a 5.6 Fr stylet-driven pacing lead with an extendable helix (Solia S60; Biotronik, SE & Co.) delivered through a preshaped sheath (Selectra3D; Biotronik). The Solia S lead was prepared as previously described.[11] First, the helix was extended using the white fixation-tool. Second, the Solia S lead was pretensioned by pushing the green stylet insertion tool onto the lead pin and by rotating clockwise 10–15 times to build up torque on the inner coil. Finally, without losing the build-up tension, the stylet insertion tool was pushed further over the first adjacent silicon seal to maintain the stored torque. These preparation steps ensure that the torque applied on the outer lead body during lead screwing are better transferred to the inner coil and helix, and decrease the risk of helix retraction. LBBAP was subsequently performed as described previously.[6,13] The delivery sheath was advanced to the right ventricle over the wire. Then the pacing lead was introduced and the sheath positioned perpendicular to the interventricular septum by counterclockwise rotation of the delivery sheath. The septum was targeted 1 cm inferior and distal to the His bundle region in the right anterior oblique view. The correct septal position was confirmed by delineating the right-sided septum with contrast injection in left anterior oblique (LAO) view. In this septal position, a "W" shaped QRS morphology in lead V1 was generally recorded using unipolar pacing from the extended helix. The SDL lead was then screwed in towards a deep septal position by clockwise rotating the outer lead body (Figure 1) and assessing lead advancement in LAO view 25–35°. While screwing, the stylet was kept advanced to the tip of the pacing lead and the stylet insertion tool remained connected to the pin of the pacing lead to maintain the torque on the inner coil (Figure 1). As the SDL pacing lead advanced into the septum, the

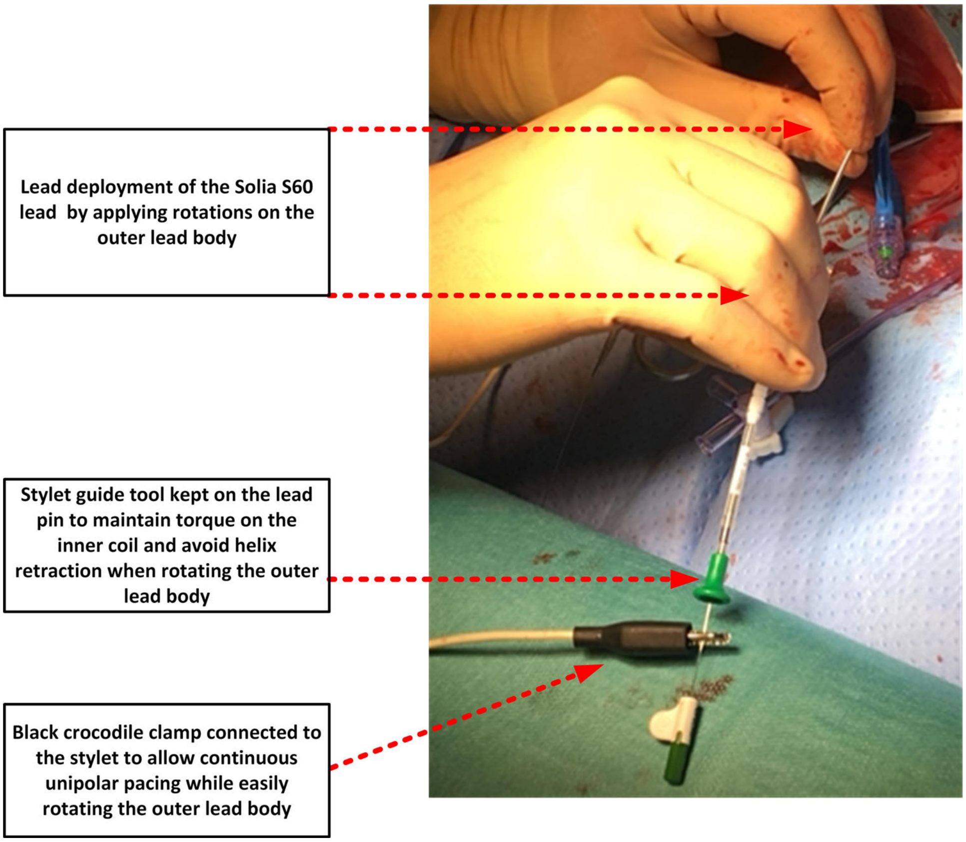

FIGURE 1 Practical considerations when screwing the Solia S60 lead in a deep septal position. The lead is deployed into the septum by rotating the outer lead body clockwise The green stylet insertion tool is kept connected to the pin of the pacing lead to maintain the torque. The crocodile clamp can be connected to the stylet of the lead, for easy lead deployment while allowing continuous pacing

"W" shaped QRS morphology in lead V1 gradually narrowed and evolved to a Qr, qR, or rSR pattern (so-called incomplete right bundle branch block [RBBB] pattern). Screwing of the SDL towards a deep septal position was further guided by contrast injections, unipolar paced QRS morphology and monitoring of unipolar pacing impedance to achieve LBBAP. While deploying the lead in the septum, unipolar pacing was applied either intermittent at different steps during lead progression while other operators preferred continuous unipolar pacing while screwing the lead in the septum.[14] Unipolar pacing impedances were measured either on the lead pin or the stylet to allow for continuous pacing while screwing (Figure 1).[14]

Upon each new screw attempt, the lead was removed out of the delivery sheath and inspected for any remaining tissue at the helix. In case any remaining tissue at the helix was observed, the helix was cleaned before a new screw attempt was started.

2.3 | Defining successful LBBAP

Successful LBBAP was defined as either left bundle branch pacing (LBBP, left sided conduction system capture) or left ventricular septal pacing (LVSP, pure myocardial capture). Following criteria were used to define the pacing response[9,13,15,16]: (1) appearance of a Qr, qR, rSr pattern in lead V1, (2) observed transition in pacing responses (nonselective, selective LBBP or myocardial capture) with changes in unipolar pacing output, (3) stimulus to peak left ventricular activation time (LVAT, measured as interval between stimulus and R wave peak time in lead V6) remaining shortest and constant at both low and high pacing output or shortening abruptly by >10 ms with increasing output, (4) stimulus to LVAT <80 ms in patients with baseline narrow QRS or RBBB or <100 ms in patients with left bundle branch block (LBBB) or interventricular conduction delay (IVCD). Patients who fulfilled the first criterium with at least one other criterium were deemed as LBBP. If despite a deep septal lead position, a narrow Qr or qR pattern in lead V1 was observed without fulfilling other criteria, the pacing response was defined as LVSP. In patients without r′ in lead V1 despite confirmed deep septal position, narrow paced QRS and significant QRS narrowing (compared to right sided septal pacing), the pacing response was also labeled as LVSP. Acceptance of final lead position was left to the discretion of the implanting physician. In case LBBAP was not successful, the Solia S60 lead was left in the right ventricular apex (antibradycardia pacing indication) or a switch to biventricular pacing was performed using the Solia S60 for right ventricular apical pacing with an additional left ventricular lead in a tributary of the coronary sinus (heart failure indications).

TABLE 1 Baseline patient and ECG characteristics of all patients

	All patients (*n* = 353)
Baseline patient characteristics	
Age, years	76 ± 39
Female gender, *n* (%)	150 (43)
Weight, kg	79 ± 17
Length, cm	169 ± 12
Medical history	
History of coronary artery disease, *n* (%)	111 (31)
History of acute coronary syndrome, *n* (%)	36 (10)
History of atrial fibrillation, *n* (%)	150 (43)
Heart failure, *n* (%)	67 (19)
ICMP, *n* (%)	30 (8)
NICM, *n* (%)	37 (11)
Baseline ECG	
Sinus, *n* (%)	251 (71)
PR-interval, ms	208 ± 59
QRS, ms	122 ± 33
Bundle branch block, *n* (%)	146 (41)
LBBB, *n* (%)	74 (21)
RBBB, *n* (%)	56 (16)
IVCD, *n* (%)	16 (4)
Pacing indication	
Sinus node disease, *n* (%)	95 (27)
Atrioventricular block, *n* (%)	224 (63)
Heart failure, *n* (%)	34 (10)
Baseline echocardiographic characteristics	
Left atrial diameter, mm	43 ± 8
End diastolic diameter, mm	50 ± 8
End systolic diameter, mm	35 ± 9
Left ventricular ejection fraction, %	53 ± 11

Note: Continuous variables are expressed as mean ± standard deviation. Categorical variables are expressed as number of patients (percentage).
Abbreviations: ECG, electrocardiogram; ICMP, ischemic cardiomyopathy; IVCD, intraventricular conduction delay; LBBB: left bundle branch block; NICMP, nonischemic cardiomyopathy; RBBB, right bundle branch block.

2.4 | Data collection and follow-up

Patient characteristics, baseline electrocardiographic data and pacing indications were collected in a standardized case report form (CRF) at implant. Procedural characteristics, number of screw attempts, procedural and fluoroscopy times were recorded in the CRF. Lead implant depth was estimated by contrast injections and based on the fluoroscopic landmarks of the Solia S lead to obtain a uniform estimation of the lead implant depth in the septum.[11]

Electrophysiological characteristics were obtained on the paced electrocardiogram and the intracardiac signal at the lead tip. Paced QRS duration and stimulus to peak LVAT were measured from pacing stimulus to peak of the R wave in leads V4, V5, or V6 during unipolar pacing.

Pacing thresholds, sensing amplitudes and impedance were measured at implant and during each follow-up. For purposes of homogeneity of the data, pacing characteristics at follow-up were collected as unipolar pacing threshold voltage at 0.4 ms, bipolar R wave amplitude sensing and unipolar pacing impedance. Clinical, echocardiographic and device follow-up were scheduled at 1, 6, and 12 months according to local institutional protocols.

2.5 | Safety endpoints and complications

Procedural complications were defined as tamponade, pneumothorax, iatrogenic atrioventricular block, permanent right bundle branch injury, vascular access complications or pocket hematoma. Lead related complications were defined as helix fracture, helix elongation resulting in lead disuse, helix entrapment resulting in an abandoned lead, septal coronary artery fistulas (SCAF) and periprocedural lead perforation through the septum. During implant, perforation of the lead through the interventricular septum was suspected if one of the following events occurred: sudden decrease in pacing impedance of >200 Ω, high unipolar pacing thresholds >3 V or leakage of contrast into the left ventricle. The integrity of the septum was further evaluated on echocardiography by screening for SCAF (diastolic timed color Doppler jets originating from the septum)[17] septal hematoma and ventricular septal defects pre hospital discharge.

2.6 | Statistical analysis

Categorical variables are expressed as absolute numbers (percentage). Continuous variables are expressed as mean (±standard deviation) in case of Gaussian distribution or median [1st and 3rd quartile] or median [range] if data are non-Gaussian distributed. Normality was tested using the Shapiro–Wilk test. To compare means and medians of continuous variables among groups, the Student *t* test, Mann–Whitney *U* test and Kruskall Wallis were used. Paired analysis among groups was performed using Wilcoxon signed rank test and Friedman test. Comparison of categorical variables among groups was performed by Fisher's exact test and Chi Square test. Statistical significance was set at a two-tailed probability level of <.05. All statistical analyses were performed using SPSS software (Version 28.0; IBM).

3 | RESULTS

3.1 | Patient characteristics

The study included 353 patients (43% female, 76 ± 39 years). Baseline patient characteristics are summarized in Table 1. Pacing

TABLE 2 Procedural and pacing characteristics in patients with SDL-LBBAP

	SDL-LBBAP *n* = 353
Implant success	334 (95)
Procedural characteristics	
Screw attempts, *n*	2.2 ± 1.9
Implant depth, mm	13 ± 2
Procedural time, min	60 [60–80]
Total fluoroscopy time, min	7 [4–11]
Electrophysiological characteristics	
Paced QRS duration, ms	126 ± 21
Stimulus to LVAT, ms	74 ± 17
LBB potential, *n* (%)	48 (14)
LBBAP capture type	
NS-LBBP, *n* (%)	192 (57)
S-LBBP, *n* (%)	52 (16)
LVSP, *n* (%)	90 (27)
Pacing characteristics at implant	
Unipolar pacing threshold at 0.4 ms, V	0.6 ± 0.4
Bipolar pacing threshold at 0.4 ms, V	0.9 ± 1.7
Unipolar R wave amplitude, mV	10 ± 5
Bipolar R wave amplitude, mV	11 ± 5
Unipolar impedance, ohms	441 ± 106
Bipolar impedance, ohms	607 ± 94

Abbreviations: LBB, left bundle branch; LBBAP, left bundle branch area pacing; LVAT, left ventricular activation time; LVSP, left ventricular septal pacing; NS-LBBP, nonselective left bundle branch pacing; SDL, stylet-driven pacing leads; S-LBBP, selective left bundle branch pacing.

indication was sinus node disease or brady-tachy syndrome in 27%, atrioventricular block in 63% and heart failure in 10% of patients. Baseline QRS duration measured 122 ± 33 ms, with 21% of patients having LBBB, 16% RBBB and 4% IVCD. Mean follow-up duration of the overall cohort was 9 ± 5 months.

3.2 | Procedural success and characteristics of LBBAP using SDL

Overall LBBAP with SDL was successful in 334 (94.6%) out of 353 patients. Implant success was comparable among different pacing indications: 95.7% in patients with sinus node disease or brady-tachy indication, 95.2% in patients with atrioventricular block and 91.1% in patients with heart failure indication (p = .131). LBBAP implant failure with SDL occurred in 19 (5.3%) patients. Reasons for LBBAP failure were: inability to reach deep septal position in 6 (1.7%) patients, high pacing thresholds in 2 (0.6%) patients, electrocardiographic criteria for LBBAP were not met in 8 (2.2%) patients and dislocation after slitting in 3 (0.8%) patients. The mean number of screw attempts was 2 ± 2, with a mean lead depth in the septum of 13 ± 2 mm. Mean procedure and fluoroscopy time were 71 ± 26 and 9 ± 8 min, respectively (Table 2).

3.3 | Electrophysiological and pacing characterization of LBBAP using SDL

A representative example of LBBAP with SDL lead is shown in Figure 2 and electrophysiological and pacing characteristics are summarized in Table 2. Pacing response was labeled as LBBP in 244 (73%) of the patients (16% of patients revealed s-LBBP, whereas 57% ns-LBBP) and as LVSP in 90 (27%) of patients. Mean paced QRS duration measured 126 ± 21 ms and LVAT measured 74 ± 17 ms. With LBBAP, QRS duration shortened from 152 ± 20 ms to 130 ± 20 ms in patients with LBBB, from 143 ± 19 ms to 130 ± 23 ms in RBBB and from 128 ± 20 ms to 125 ± 21 ms in patients with IVCD. In patients with baseline narrow QRS (<120 ms), QRS duration increased from 95 ± 16 ms to 125 ± 18 ms with LBBAP. LBB potentials were recorded in 48 (14%) patients.

At implant, mean unipolar LBBAP pacing threshold was 0.6 ± 0.4 V at 0.4 ms pulse width, whereas mean bipolar pacing threshold was 0.9 ± 1.7 V at 0.4 ms. The number of patients with implant pacing thresholds >1 and >3 V were 23 (6.5%) and 3 (0.8%), respectively. Unipolar pacing impedance measured 441 ± 106 Ω, whereas bipolar impedance measured 607 ± 94 Ω. The mean sensed R wave amplitude was measured at 10 ± 4.8 mV in unipolar sensing configuration and 11 ± 4.8 mV in bipolar sensing configuration. LBBAP pacing thresholds and sensing amplitudes remained stable during follow-up, as shown in Table 3.

3.4 | Procedural and long-term lead related complications of LBBAP using SDL

All procedural and lead related complications are listed in Table 4. Periprocedural lead perforation through the septum occurred in 8 (2%) patients, all perforations remained asymptomatic (Figure 3). In all these patients the lead was retracted and successfully re-implanted in a different deep septal position. No tamponades occurred related to the LBBAP lead placement. With lead repositioning, severe helix damage occurred in three patients resulting in lead disuse. One helix fracture occurred in a deep septal position and could not be retrieved. SCAF were detected in 5 (1.4%) patients. Two SCAF were detected upon contrast injection whereas 3 SCAF were detected on echocardiographic follow-up the day after implant. All 5 SCAF patients remained asymptomatic without signs of cardiac ischemia or heart failure. All SCAF disappeared at 3 months echocardiographic evaluation. No ventricular septal defects or septal hematomas were documented on echocardiographic follow-up. This was also the case in patients with periprocedural perforation and with multiple screwing attempts.

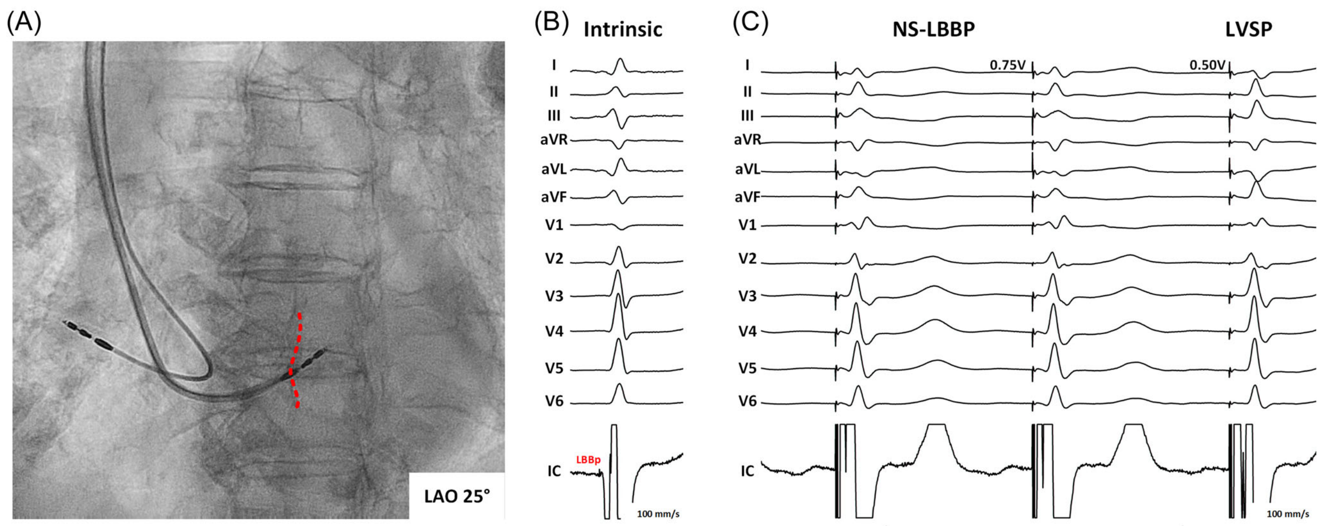

FIGURE 2 Left bundle branch area pacing using stylet-driven pacing leads. (A) Representative example of LBBAP using SDL. The SDL was screwed approximately 13 mm deep into the septum to achieve LBBAP. (B) A small left bundle branch potential (LBBp) was observed during intrinsic rhythm at this final position. (C) During threshold testing a transition from nonselective (NS-LBBP) to left ventricular septal pacing (LVSP) was observed. LBBAP, left bundle branch area pacing; SDL, stylet-driven leads

TABLE 3 Pacing characteristics of LBBAP using SDL at follow-up

Pacing characteristic	Implant	1 Month	6 Months	12 Months	*p* value
Number of patients, *n*	353	349	259	67	
Pacing threshold at 0.4 ms, V	0.6 ± 0.4	0.6 ± 0.2	0.7 ± 0.2	0.7 ± 0.3	.291
R-wave sensing, mV	11 ± 5	12 ± 5	12 ± 5	13 ± 6	.061
Unipolar impedance, Ohms	441 ± 106	399 ± 90	384 ± 74	397 ± 75	.115

Abbreviations: LBBAP, left bundle branch area pacing; SDL, stylet-driven leads.

Overall LBBAP lead revision rate was low (5 patients, 1.4%). Lead dislocation at day 1 occurred in 2 patients. In both patients, the leads dislocated to the right ventricle. One late septal perforation with dislocation to the left ventricle occurred 3 weeks after implant, which resulted in loss of capture with unipolar pacing configuration. There were no thrombo-embolic events related to this perforation. The lead was successfully reimplanted in a new deep septal position. One patient presented with dislocation of both the atrial and the LBBAP leads, due to Twiddler's syndrome. One patient experienced LBBAP lead fracture at 7 months, which was characterized by a sudden increase in both unipolar and bipolar impedances (>2000 Ω), noise oversensing and intermittent loss-of-capture.

3.5 | Echocardiographic outcome

In patients with normal ejection fraction (EF) at implant, EF remained preserved (56 ± 3% at baseline, vs. 56 ± 6% with LBBAP, $p = .384$). In patients with heart failure indication and reduced EF, EF increased from 28 ± 6% to 40 ± 3%, $p < .01$. None of the patients developed de novo heart failure or experienced worsening heart failure.

3.6 | LBBAP implant success using SDL in low and high-volume centers

The median number of patients implanted per center was 25 (range: 5–162 patients). The caseload among the 8 different centers is shown in Figure 4A. Implant success for LBBAP using SDL was comparable among different centers (97 ± 3%, range: 93%–100%, $p = .75$) and independent of the caseload (Figure 4B). Mean procedural time varied from 52 to 95 min and was not related to center volume (Figure 4C). Mean fluoroscopy time varied from 5 to 15 min and was also not related to center volume (Figure 4D).

4 | DISCUSSION

4.1 | Main findings

This study demonstrates the feasibility and safety of LBBAP using SDL and represents the first and largest multicenter experience of LBBAP using SDL to date. The main findings are:

(1) LBBAP via SDL is associated with a high implant success rate (95%).
(2) Pacing thresholds are low and remain stable at midterm follow-up, with low rates of lead complications.
(3) LBBAP using SDL yields similar high implant success rates in both high and low volume centers.

4.2 | Current experience with LBBAP using LLL and SDL

LBBAP is emerging as a new promising pacing modality as it preserves normal ventricular activation during ventricular pacing as opposed to conventional RVP.[7,18] Moreover, pacing thresholds have been reported to be low and stable over time, overcoming two important limitations of HBP.[6,8] To date, experience with LBBAP has been mostly gained with one single type of LLL (SelectSecure 3830; Medtronic) delivered through a preshaped delivery sheath (C315His or C304; Medtronic).[6,8,9] Due to the absences of inner lumen for stylet insertion and retractable helix mechanism, LLL design benefits of a thin iso-diametric lead body (4.1 Fr). Different groups reported high implant success and excellent pacing characteristics in single and multicenter studies when performing LBBAP with this type of LLL.[8,10]

SDL are frequently used for standard atrial and RVP and differ from LLL in two important features. First, the lead body of SDL contains an inner lumen for stylet insertion resulting in a thicker lead body of SDL (5.5–6 French) as compared to LLL. Second, SDL often have an extendable helix design, which needs to be exposed preimplant and require some measures to remain extended while rotating the lead body in the targeted septal position. The experience with SDL in the field of CSP is limited. A few studies reported on HBP with SDL, but the experience on LBBAP using SDL remains scarce. Zanon et al.[12] reported two cases of LBBAP using SDL (Solia S; Biotronik) with a dedicated delivery sheath (Selectra3D; Biotronik). Recently, our group reported the first comparison of LBBAP using SDL (Solia S; Biotronik) and LLL (SelectSecure 3830; Medtronic) in a small series of patients, showing comparable implant success and acute pacing characteristics with both types of leads.[11] The current large multicenter study confirms that LBBAP with SDL yields high implant success in a multicentric setting with excellent pacing thresholds and high safety profile up until 1 year after implant. Pacing thresholds, paced QRS duration, LBBAP capture response and procedural characteristics of LBBAP with SDL are comparable with previous single and multicenter reports on LBBAP using LLL.[8,10]

4.3 | Safety profile of SDL used for LBBAP

Depending on the septal thickness and the obliqueness of the lead course, LBBAP requires the lead to be screwed 10–15 mm deep into the septum, to reach the area of the left bundle branch.[9,11] As the helices of current SDL and LLL are only 1.8–2.0 mm long, LBBAP requires a significant part of the distal lead body to be implanted into the septal myocardium. As SDL have a larger lead body and a non-isodiametric lead design (at the point where the helix extends the helix cage), one might assume that deep septal positions might be more difficult to achieve with SDL leads. However, the high implant success with an overall implant depth of 13 mm, shows that the lead design and diameter of SDL is not a limitation to perform LBBAP.

With the stylet inserted, SDL become stiffer compared to LLL and might be more prone to perforate through the septum when targeting the left-sided subendocardial septal area. In this registry, septal perforations with SDL occurred in 2% of the patients, but did not result in adverse outcome, major complications or persistent

TABLE 4 Procedural and lead-related complications of LBBAP using SDL

Type of complication	Patients (*n*)
Complications at implant	
Pneumothorax	4
Hemothorax	1
Tamponade related to atrial lead	2
Tamponade related to LBBAP lead	0
Takotsubo cardiomyopathy	1
Permanent RBB injury	1
New persistent iatrogenic AV block	0
Septal perforation	8
Septal coronary artery fistula	5
Helix fracture or elongation resulting in lead disuse	3
Complications during FU	
Revision for pocket hematoma	1
Atrial lead revision	3
LBBAP lead revision at day 1	2
Reason for LBBAP revision at day 1	
Septal perforation	0
Lead dislodgement to right ventricle	2
LBBAP lead revision beyond day 1	3
Reason for LBBAP revision beyond day 1	
Late septal perforation	1
Lead dislodgement to right ventricle	1
Lead fracture (impedance >2000 Ω)	1
Echocardiographic follow-up	
Septal coronary artery fistula persisting >3 months	0
Septal hematoma	0
Ventricular septal defect	0

Abbreviations: AV block, atrioventricular block; LBBAP, left bundle branch area pacing; SDL, stylet driven pacing leads.

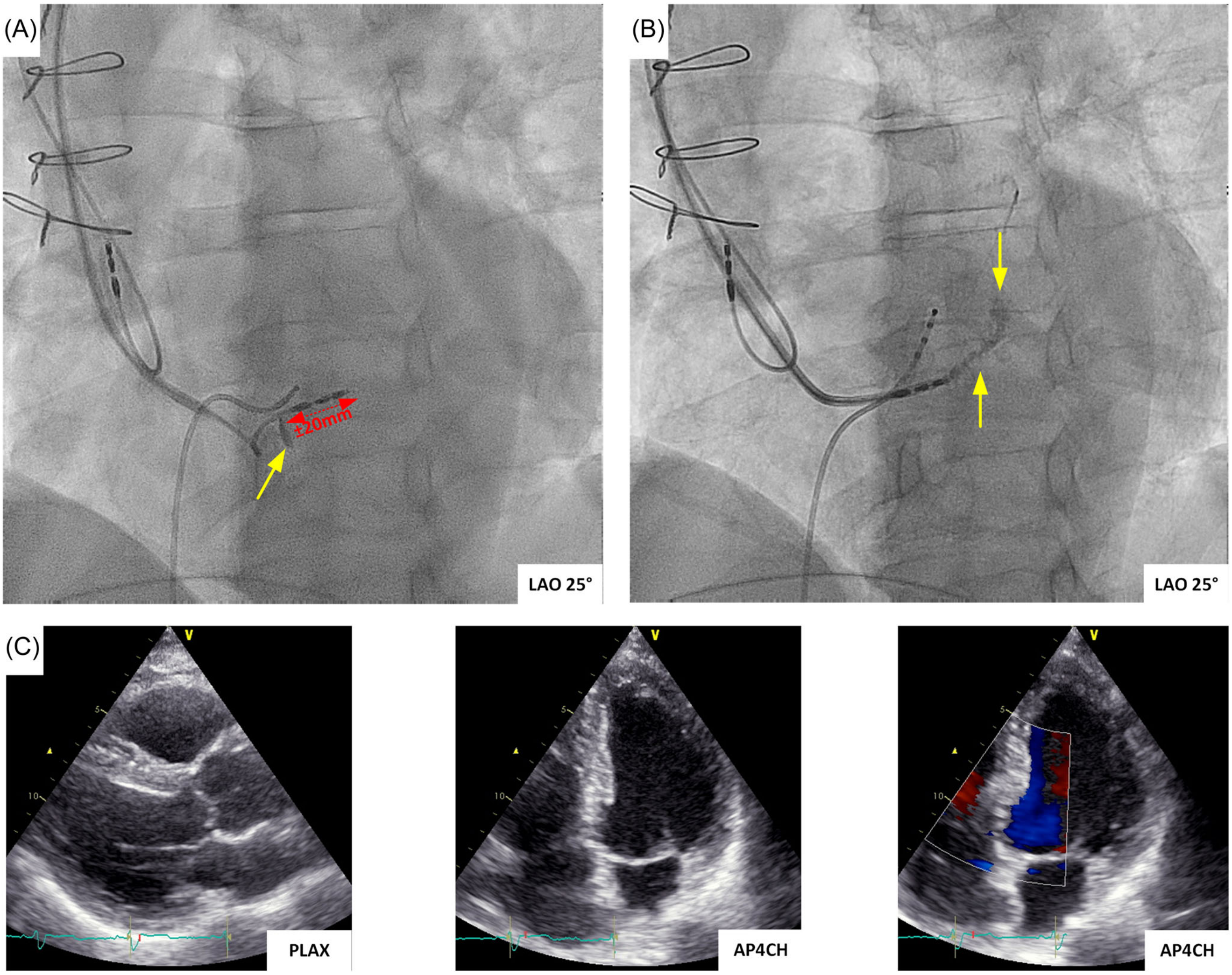

FIGURE 3 Lead perforation through the septum of a stylet driven pacing lead. (A) Contrast injection delineated the right septal border (yellow arrow) with the lead approximately 20 mm deep trough the septum. Drop in unipolar impedance and loss of unipolar pacing capture were observed at this position. (B) The lead was easily retracted with the delivery sheath kept in position. Contrast injection confirmed the perforation though the septum with contrast leaking into the left ventricular cavity (yellow arrow). (C) Echocardiography the day after implant did not show any ventricular septal defects. AP4CH, apical four chamber view; LAO, left anterior oblique. PLAX, parasternal long axis view

damage to the septum as assessed on echocardiographic evaluation. The incidence of septal perforations in this study is slightly higher than previously reported in a single center study of LBBAP using LLL.[8] This might be explained by the learning curve associated with the use of SDL, which requires as any new technique a training period. In our registry, it is important to highlight that the first implanted patients were not excluded as this was the case in some other studies on LBBAP using LLL.[8] Moreover, with continuous unipolar pacing and impedance monitoring on the stylet when screwing SDL in the septum, perforation will be avoided more easily.[19] In our registry no ventricular septal defects were documented on echocardiography, not even in patients with multiple screw attempts or perforation of the SDL through the septum during implant. This indicates that SDL, despite the larger lead body up to 5.6 Fr, do not cause persistent septal damage and might be equally suitable for LBBAP as LLL.

Theoretically, a larger lead body and helix might also have a higher chance to damage septal structures such as the septal coronary arteries causing SCAF. However, SCAF following LBBAP is rarely reported. This is explained by the fact that SCAF are rare, usually asymptomatic, and easily missed if no contrast injection is used or if no targeted echocardiography is performed early after LBBAP implant.[8,17] The low number of SCAF in our registry, despite contrast injections and dedicated echo follow-up in the majority of patients, confirms the safety of LBBAP using SDL leads.

One previous report mentioned that the helix of SDL might get tangled up into the right-sided septal tissue when performing LBBAP.[19] This so-called entanglement effect occurs when the

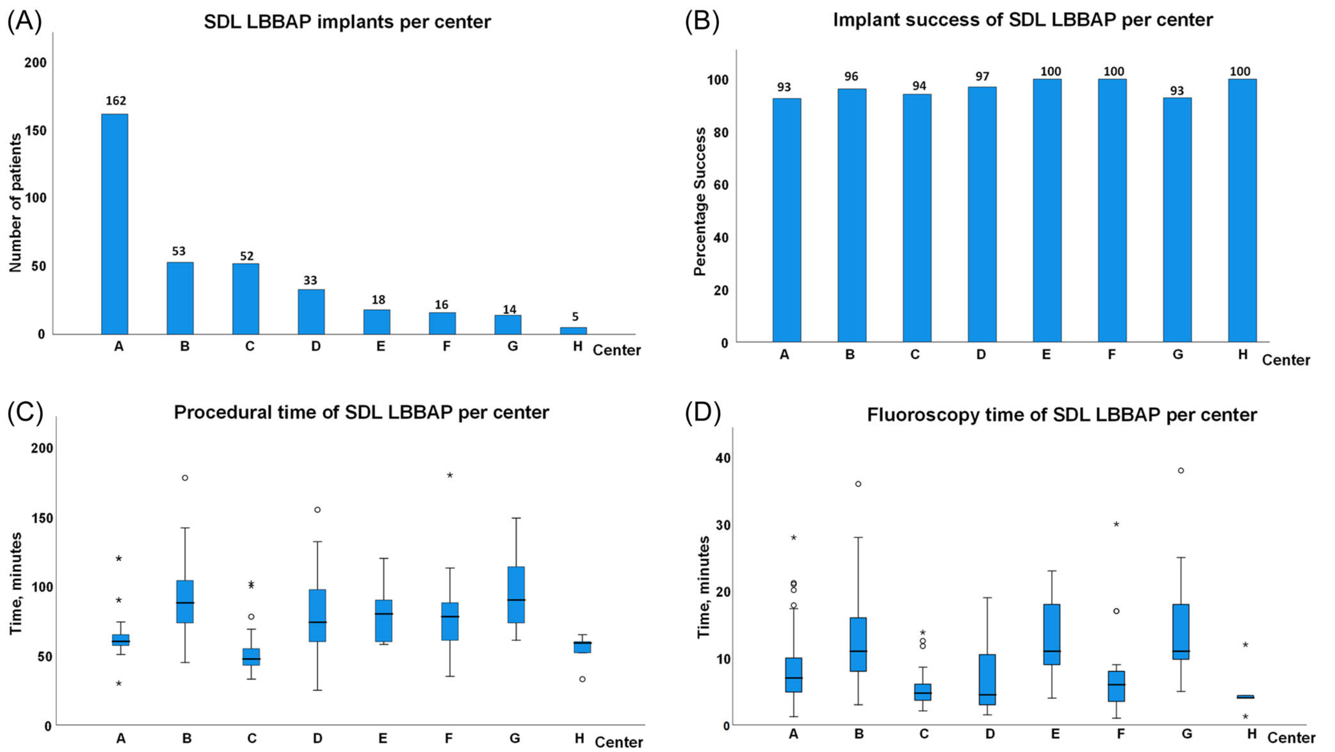

FIGURE 4 Procedural characteristics of left bundle branch area pacing using stylet driven pacing leads in individual centers procedural characteristics of left bundle branch area pacing (LBBAP) using stylet driven pacing leads (SDL). (A) Caseload of the different centers. (B) Implant success. (C) Procedure times. (D) Fluoroscopy times

helix gets entrapped in the subendocardial tissue, rather than advances into the septum.[20] In such situation, excessive traction on the lead and helix can result in helix elongation, helix fracture and need to abandon the lead or broken helix. In our study, only one helix fracture occurred, unfortunately without possible retrieval. This complication happened in the very early learning curve of one center. In the overall registry, the mean number of screw attempts was 2 per patient. Given the very low number of damaged helices, it indicates thus that repositioning of SDL generally do not lead to helix damage. Gentle alternating clockwise and counterclockwise rotations of the lead body (without actively retracting the helix and without releasing the build-up torque) allow for easy removal of the entangled lead in the vast majority of cases.

4.4 | Advantages and disadvantages of SDL leads used for LBBAP

LBBAP using SDL is characterized by high implant success, in both high and low volume centers. Considering the novelty of the technique and learning curve for each center, this high implant success along with the low complication rate consistent among centers, confirm that SDL are easy to use and promising for LBBAP. Different properties of SDL contribute to the excellent performance of this type of lead when targeting a deep septal position. First, the larger lead caliber allows for excellent grip when applying rotations on the outer lead body. Second, with the stylet inserted, the overall maneuverability (torque and push) of the SDL is exemplary, and seriously facilitates lead progression into the septum without excessive risk of septal perforation. Thirdly, the stylet adds stability on the septum when mapping and screwing. Fourthly, impedance monitoring is easily achieved by connecting the pacing clamp to the stylet, allowing for continuous pacing and impedance monitoring when screwing.[14] Finally, the delivery sheaths, used to target SDL towards deep septal positions, have a larger diameter and are more supportive compared to the delivery sheaths currently used with LLL.

The disadvantage of SDL with extendable helices is that helix unwinding might occur when rotating the outer lead body. However, with appropriate lead preparation, helix retraction can easily be avoided. In addition, the low number of lead dislocations in this study confirms the stability of SDL implanted in deep septal position. From a future perspective, a lead design combining the lead properties of current SDL with a fixed helix design might further improve LBBAP success.

4.5 | Limitations

Successful LBBAP was defined as both LBBP and LVSP which is different compared to other reports on LBBAP, where only proven capture of the conduction system was accepted as successful final position. Most operators in this multicenter registry are certified electrophysiologist with a large (>5 years) experience in implanting cardiac implantable electronic devices. Care should be taken to extrapolate the results of this registry to starting implanters without experience in electrophysiology. LBBAP implants in this study were executed with one type of SDL (Solia S60; Biotronik) and with one type of delivery sheath (Selectra3D; Biotronik), which was developed for conduction system pacing. Other types of SDL with different delivery sheaths might behave differently during LBBAP implant. Currently, no long-term data (>1 year) are available regarding pacing performance and extractability of LBBAP leads.

5 | CONCLUSION

LBBAP with SDL is associated with high implant success, stable pacing characteristics, and low complication rates in this large multicenter registry. The observations of this study suggest that LBBAP can be performed safely with a variety of standard pacing leads, which might contribute to a wider implementation of LBBAP as a new pacing modality.

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