



The Zwolle experience with left bundle branch area pacing using stylet-driven active fixation leads

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Abstract

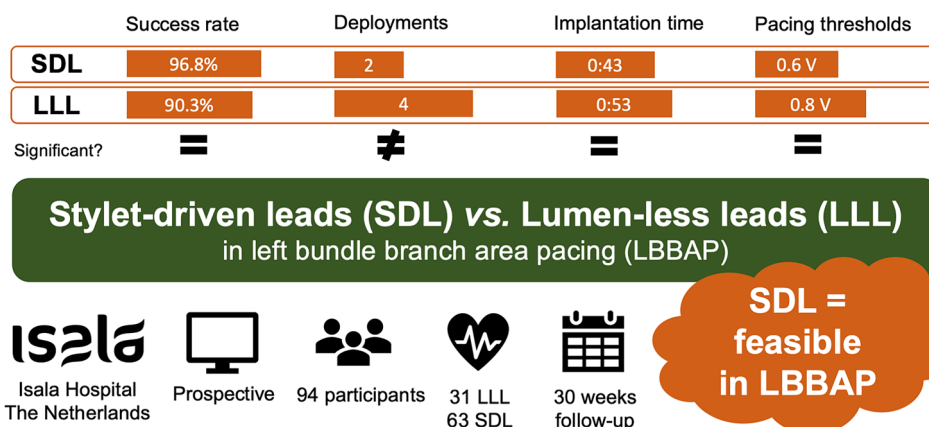
Aims Left bundle branch area pacing (LBBAP) is a novel physiological pacing modality and is regarded as a viable alternative to His bundle pacing. LBBAP has mostly been performed with the lumen-less permanent pacing lead (SelectSecure™ Model 3830, Medtronic, Inc.) with a fixed helix. The aim of this study was to compare the non-stylet driven lumen-less lead (LLL) (Medtronic 3830) with a standard stylet-driven active fixation lead (SDL) (Tendril™ STS Model 2088TC-38, Abbott Laboratories) in terms of lead parameters, procedural success and complication rates.

Methods Patients receiving a LBBA pacemaker in the Isala Hospital, The Netherlands, were prospectively enrolled. The majority received a standard right ventricular (RV) lead as backup, the implantor chose between LLL and SDL for the LBBAP lead.

Results The study included 94 patients with a mean follow-up of 30 weeks. 30/31 LLL procedures were successful, compared with 62/63 in the SDL group. Including the participants that lost LBBAP during follow-up resulted in success rates of 90.3% for LLL versus 96.8% for SDL, $P=0.199$. Mean number of deployments was significantly lower in the SDL group compared with the LLL group (2 ± 2.3 versus 4 ± 3.4 , $P=0.005$), implantation and procedural times were comparable. Pacing thresholds were low and remained low in both groups (at last follow-up 0.8 ± 0.30 V for LLL versus 0.6 ± 0.20 V for SDL). Complication rates did not differ significantly between both groups, $P=0.805$.

Conclusion LBBAP using SDL is feasible and has comparable success rates with lower number of deployments of the active fixation screw.

Graphical abstract



Keywords Left bundle branch area pacing · Stylet-driven pacing leads · Lumen-less pacing leads

Extended author information available on the last page of the article

Introduction

Multiple studies have shown that right ventricular apical pacing (RVAP) results in mitral and tricuspid regurgitation, systolic dysfunction and a higher incidence of atrial fibrillation (AF). This latter is caused by dyssynchronous electromechanical activation by not utilizing the physiological pathway of the His–Purkinje system [1]. Especially patients with higher percentages of RVAP and reduced LVEF are at risk to develop these pacemaker-related complications [2, 3].

Searching for alternative pacing sites, His bundle pacing (HBP) was first described in humans by Deshmukh et al. as a physiological alternative to RVAP with synchronous ventricular activation utilizing the His–Purkinje system [4]. HBP is associated with a significant reduction in all-cause mortality, heart failure hospitalization and upgrade to biventricular pacing compared to RVAP [5]. However, identifying the His bundle is difficult, pacing management is complicated by low R-wave amplitude or large atrial signals, implantation can damage the His bundle and 5–10% of patients have a high and unstable pacing threshold [6, 7].

Compared to HBP, left bundle branch area pacing (LBBAP) is associated with easier lead positioning, a lower and more stable capture threshold and easier pacing management due to a higher amplitude of sensed R-wave [7]. The vast majority of LBBAP implantations have been performed with the lumen-less, bipolar, permanent pacing lead (SelectSecure™ lead model 3830, Medtronic, Inc.), with a fixed helix [8–11]. Although HBP using stylet-driven active fixation leads is shown to be feasible, only two case reports and one prospective study described the use of a stylet-driven active fixation lead in LBBAP (Solia S60, Biotronik, SE & Co, KG) [12–15]. This study aims to compare a lumen-less, non-stylet-driven lead (LLL) with a standard stylet-driven active fixation lead (SDL) in terms of pacing parameters, success and complication rates.

Materials and methods

Study population

In this ongoing prospective observational study, patients who received a pacemaker with left bundle branch area pacing lead in the Isala Hospital, Zwolle, The Netherlands, in the period of December 2019 until June 2021 were included. The study was approved by the local ethics committee of the Isala Hospital. Patients with an implantable cardioverter defibrillator and patients who did not

have their first follow-up visit before August 1st 2021 were excluded from the study. For safety reasons, considering the novelty of the technology and the use in a pacing-dependent population, the majority received a standard right ventricular (RV) lead as backup. The referring cardiologist and electrophysiology team decided whether the patient was eligible for LBBAP. Patients were informed of the potential complications and benefits of LBBAP and gave their consent for the procedure. The use of a stylet-driven or non-stylet driven lead was based on availability and the implanters' preference. The procedures were performed by two primary electrophysiologists and less experienced implanters supervised by these two electrophysiologists. For all implanters, this was their first experience with LBBAP.

LBBAP leads

Two different combinations of pacing leads and delivery sheaths were used for LBBAP. One group received the non-stylet driven 4.1 Fr thin lead with a fixed helix design (SelectSecure™ lead model 3830, Medtronic, Inc.), introduced through a fixed curve sheath (C315 HIS, Medtronic, Inc.). In the other group, a stylet-driven active fixation 6 Fr lead (Tendril™ STS Model 2088TC-38, Abbott Laboratories) was used, delivered through a custom-made sheath (Selectra 3D, Biotronik, SE & Co, KG). The SDL has flexible handling characteristics and is, therefore, able to adapt to anatomic variations. On the other hand, the smaller diameter of the LLL could limit septal damage.

LBBAP implantation procedure

Transvenous access was obtained via the vena cephalica sinistra (VCS) or the vena subclavia sinistra (VSS). Before LBBAP placement, three-dimensional (3D) electro-anatomical mapping (EAM) was performed using a LBBAP bipolar pacing lead (SDL or LLL) connected to the Ensite NavX system (Abbott, Des Plaines, IL) to identify and tag the His bundle and right bundle region (Fig. 1). Lead placement was guided by EAM to generate a 3D map of the region of the His bundle and right bundle branch, ostium of the coronary sinus and surrounding areas; optimal LBBAP location was defined as an area 1–1.5 cm distal to the His bundle cloud towards the right ventricular apex in the right anterior oblique (30°) fluoroscopic view, with a slight counterclockwise rotation to orient the pacing lead in the proper septal direction. Detailed 3D electro-anatomical mapping with the Medtronic 3830 lead was not possible due to the presence of a non-retractable bare screw which might cause collateral damage during passage

Fig. 1 3-Dimensional electro-anatomical mapping to identify and tag the His-bundle, right bundle region and ostium of coronary sinus. The green dot represents the right bundle branch, the two yellow dots the His bundle and the blue dots the coronary sinus catheter. The divided white dots represent the locations where left bundle branch area pacing was attempted



of the tricuspid valve and during mapping of the His and right bundle region and localization of the ostium of the CS. Standard steerable EP catheters were used for mapping in patients who received a Medtronic 3830 lead. On the other hand, detailed mapping was possible with the standard stylet-driven active fixation lead. In addition to 3D electro-anatomical mapping, pace mapping was used routinely to identify the target areas for lead placement. In the appropriate target area, the paced QRS morphology before fixation demonstrated a ‘W’ pattern with a notch at the nadir of the QRS in lead V1. Once the site for LBBAP was determined, the fixation started. For deep fixation, rapid rotation of the lead, 3–4 turns at a time by one or both hands, was performed to achieve penetration of the lead body behind the screw, into the septum. In SDL, pacing during screwing is possible. With advancement of the screw in the interventricular septum, the ‘W’ shaped QRS morphology in lead V1 changed to incomplete right bundle branch block pattern, unipolar pacing impedance decreased and the lead’s position changed along with the fulcrum sign on fluoroscopy. The exact lead implantation depth was aimed at 6–8 mm inside the septum, confirmed by contrast injection through the delivery catheter. Confirmation of LBB capture with acceptable parameters was done using the following four criteria: paced morphology of right bundle branch block pattern in leads V1 and V2, identification of the LBB potential at the local EGM recorded with the septal pacing lead, pacing stimulus to LV activation time (LVAT) in leads V4–V6 shortening abruptly with increasing output or remaining short and constant at low and high outputs, and maneuvers used for the determination of selective or nonselective left bundle branch pacing [16].

Data collection and follow-up

Baseline characteristics, pacing indication, QRS duration and QRS morphology were collected pre-operatively. Left ventricular systolic function was divided in four groups: normal function (left ventricular ejection fraction (LVEF) $\geq 50\%$), mild dysfunction (LVEF 40–49%), moderate dysfunction (LVEF 30–39%) and severe dysfunction (LVEF $< 30\%$). Perioperatively, lead implantation time, procedural time, fluoroscopy duration, procedural complications, paced QRS duration, presence of LBB potential, LVAT in lateral precordial leads, latency, pacing threshold, lead impedance and sensed R-wave amplitude were recorded. LVAT and latency were measured from the pacing stimulus and paced QRS duration from rapid onset of the R-wave. According to standard care, all patients were reviewed at the outpatient departments approximately 6–8 weeks after pacemaker implantation for pacemaker interrogation and assessment of complications. Due to the COVID-19 pandemic, this visit was postponed in several patients with home-monitoring in the meantime. Next follow-up visits varied between the patients.

Statistical analysis

Statistical analysis was performed using SPSS Statistics Version 27.0 (Chicago, IL, USA). Continuous variables were described as mean \pm standard deviation and means were compared using Student’s *t* test for normally distributed data or Mann–Whitney *U* test for not normally distributed data. Paired data were assessed with paired *t* test or Wilcoxon signed rank test when the normality assumption was not met. Categorical values were described as frequency and

percentages, with differences in frequency assessed using Fisher's exact or Pearson's Chi-squared test. A *P* value of <0.05 was considered statistically significant.

Results

A total of 94 participants were included in this study. The majority of the procedures, 55.3%, was performed as part of a pace-and-ablate strategy due to refractory atrial fibrillation. The LLL group included 31 participants (33.0%), compared with 63 participants (67.0%) in the SDL group. There were no significant differences in baseline characteristics between both groups. Baseline left ventricular systolic function did not differ significantly between both groups, *P*=0.577. The majority (55.3%) had a normal systolic function, with only few participants (6.4%) with severe left ventricular dysfunction. All baseline patient characteristics and pacing indications are summarized in Table 1.

Mean first follow-up was 10 ± 7 weeks with no significant differences between both groups, *P*=0.950. Mean last follow-up was significantly longer in the LLL group, *P*<0.001, with 45 ± 18 weeks versus 22 ± 12 weeks for SDL.

Procedural characteristics

Twenty-five LLL participants (80.6%) received a RV lead in the same procedure, compared to 58 (92.1%) in the SDL group, with no significant differences, *P*=0.344. Considering previously implanted transvenous systems, all participants in the SDL group had a functional RV lead as backup lead, where 26/31 (83.9%) in the LLL group had a backup RV lead. Procedural success, defined as adequate positioning of the LBBA lead and reliable pacing parameters < 24 h post-implantation, did not differ significantly between both groups, *P*=0.553. Of all the procedures, one LLL procedure was not successful, due to inability to screw the lead in the right position with

Table 1 Baseline characteristics

	All patients (n=94)	LLL (n=31)	SDL (n=63)	<i>P</i> value*
Age, years	74 ± 9.6	75 ± 11.2	74 ± 8.8	0.290
Male gender	47 (50.0%)	12 (38.7%)	35 (55.6%)	0.125
Body Mass Index, kg/m ²	26 ± 6.9	27 ± 4.2	25 ± 7.9	0.797
Pacing indication				
High degree AV block	18 (19.1%)	9 (29.0%)	9 (14.3%)	0.088
First-degree AV block	6 (6.4%)	2 (6.5%)	4 (6.3%)	1.000
Sick sinus syndrome	6 (6.4%)	2 (6.5%)	4 (6.3%)	1.000
Pace and ablate due to refractory AF	52 (55.3%)	16 (51.6%)	36 (57.1%)	0.612
Upgrade in pacing induced cardiomyopathy	6 (6.4%)	0	6 (9.5%)	0.076
Correction LBBB	5 (5.3%)	2 (6.5%)	3 (4.8%)	1.000
Atrial fibrillation	72 (76.6%)	21 (67.7%)	51 (81.0%)	0.155
Left ventricular systolic function				0.577
Normal systolic function	52 (55.3%)	17 (54.8%)	35 (55.6%)	
Mild dysfunction	23 (24.5%)	11 (35.5%)	12 (19.0%)	
Moderate dysfunction	13 (13.8%)	2 (6.5%)	11 (17.5%)	
Severe dysfunction	6 (6.4%)	1 (3.2%)	5 (7.9%)	
Previous transvenous system	12 (12.8%)	3 (9.7%)	9 (14.3%)	0.745
QRS morphology pre-implantation				0.350
Narrow (< 110 ms)	51 (54.3%)	22 (71.0%)	29 (46.0%)	
LAH	2 (2.1%)	1 (3.2%)	1 (1.6%)	
RBBB	7 (7.4%)	1 (3.2%)	6 (9.5%)	
RBBB + LAH	1 (1.1%)	0	1 (1.6%)	
LBBB	14 (14.9%)	3 (9.7%)	11 (17.5%)	
NVICD	8 (8.5%)	1 (3.2%)	7 (11.1%)	
Escape/asystole/paced	11 (11.7%)	3 (9.7%)	8 (12.7%)	
QRS duration pre-implantation	117 ± 34.0	108 ± 26.4	122 ± 36.5	0.112

Values are mean ± standard deviation or numbers with percentages. * = comparison between the LLL and SDL group

LLL Lumen-less lead, SDL stylet-driven lead, AV atrioventricular, AF atrial fibrillation, LBBB left bundle branch block, LAH left anterior hemiblock, RBBB right bundle branch block, NVICD nonspecific intraventricular conduction delay

adequate capture, despite successful His mapping. One SDL procedure did not show LBB pacing on post-implantation ECG and no LBB potential during implantation and was, therefore, considered as unsuccessful. 33.0% of the participants showed LBB potential during implantation, with no significant differences between LLL and SDL ($P=0.576$). Mean number of deployments was significantly lower in the SDL group compared with the LLL group (2 ± 2.3 versus 4 ± 3.4 , $P=0.003$). There was no correlation between number of deployments and paced QRS duration ($P=0.250$) and number of deployments and lead impedance ($P=0.476$). LBBA lead implantation time and procedural times were comparable between both the groups, although fluoroscopy duration was shorter in the SDL group (21 ± 14 min for LLL versus 15 ± 11 min for SDL, $P=0.025$). All the procedural characteristics are shown in Table 2. Figure 2 shows examples of paced ECG and fluoroscopy images during implantation with both LLL and SDL.

Paced ECG characteristics

As shown in Table 3, left ventricular activation time (LVAT) and latency were comparable between both groups, respectively, 80 ± 10.6 ms (ms) and 33 ± 9.6 for LLL versus 81 ± 13.4 and 32 ± 8.2 for SDL ($P=0.587$, $P=0.271$). The mean paced QRS duration was significantly shorter in the LLL group versus SDL group, respectively, 101 ± 11.8 ms and 114 ± 15.0 ms, $P=0.001$. 87.2% of the post-implant ECGs showed a dominant R-wave in V1, with no significant differences between LLL and SDL ($P=0.576$). The majority of the LLL procedures, 64.5%, showed an inferior axis on the ECG, whereas the majority of SDL procedures showed a superior axis ($P<0.001$).

Lead parameters

At implantation, the LLL group had a significantly higher impedance of the LBBA lead: 616 ± 227 Ohm versus 458 ± 216 Ohm in the SDL group, $P=0.001$. At first and last follow-ups, there was no significant difference in lead impedance, caused by a significant decrease of lead impedance in

Table 2 Procedural characteristics and complications

	All patients ($n=94$)	LLL ($n=31$)	SDL ($n=63$)	P value*
Procedural characteristics				
Number of deployments	3 ± 3	4 ± 3.4	2 ± 2.3	0.003
LBBA lead implantation time, min	46 ± 32.6	53 ± 47.2	43 ± 24.0	0.696
Procedural time, min	112 ± 40.0	124 ± 51.3	107 ± 32.0	0.189
Right atrial lead implantation	49 (52.1%)	18 (58.1%)	33 (52.4%)	0.419
Right ventricular lead implantation	81 (86.2%)	25 (80.6%)	58 (92.1%)	0.344
LBBA lead implantation successful	93 (98.9%)	30 (96.8%)	63 (100%)	0.330
LBB potential (8 missing, 1 LLL, 7 SDL)	31 (33.0%)	12 (38.7%)	19 (30.2%)	0.576
Dose area product, Gy·cm ²	11 ± 24.1	16 ± 39.6	9 ± 9.1	0.405
Fluoroscopy time, minutes	17 ± 12	21 ± 14	15 ± 11	0.025
Location LBBA lead (3 unknown)				
High septal	20 (21.3%)	10 (32.3%)	10 (15.9%)	0.068
Mid septal	69 (73.4%)	19 (61.3%)	52 (82.5%)	0.062
Low septal	2 (2.1%)	1 (3.2%)	1 (1.6%)	0.605
Complications				
Major complications	7 (7.4%)	2 (6.5%)	5 (7.9%)	1.000
Minor complications	7 (7.4%)	2 (6.5%)	5 (7.9%)	1.000
Pneumothorax	6 (6.4%)	2 (6.5%)	4 (6.3%)	1.000
Pocket hematoma/infection	3 (3.2%)	0	3 (4.8%)	0.548
LBBAP failure during follow-up	3 (3.2%)	2 (6.5%)	1 (1.6%)	0.252
RV lead dislocation during follow-up	2 (2.1%)	0	2 (3.2%)	1.000

Major complications consist of possible life-threatening complications or complications requiring intervention or prolonged hospital admission. Complications that were conservatively treated and did not result in prolonged hospital admission were considered as minor complications

Values are mean \pm standard deviation or numbers with percentages. * = comparison between the LLL and SDL group

LLL Lumen-less lead, SDL stylet-driven lead, LBBA left bundle branch area, Min minutes, LBBAP left bundle branch area pacing, RV right ventricular

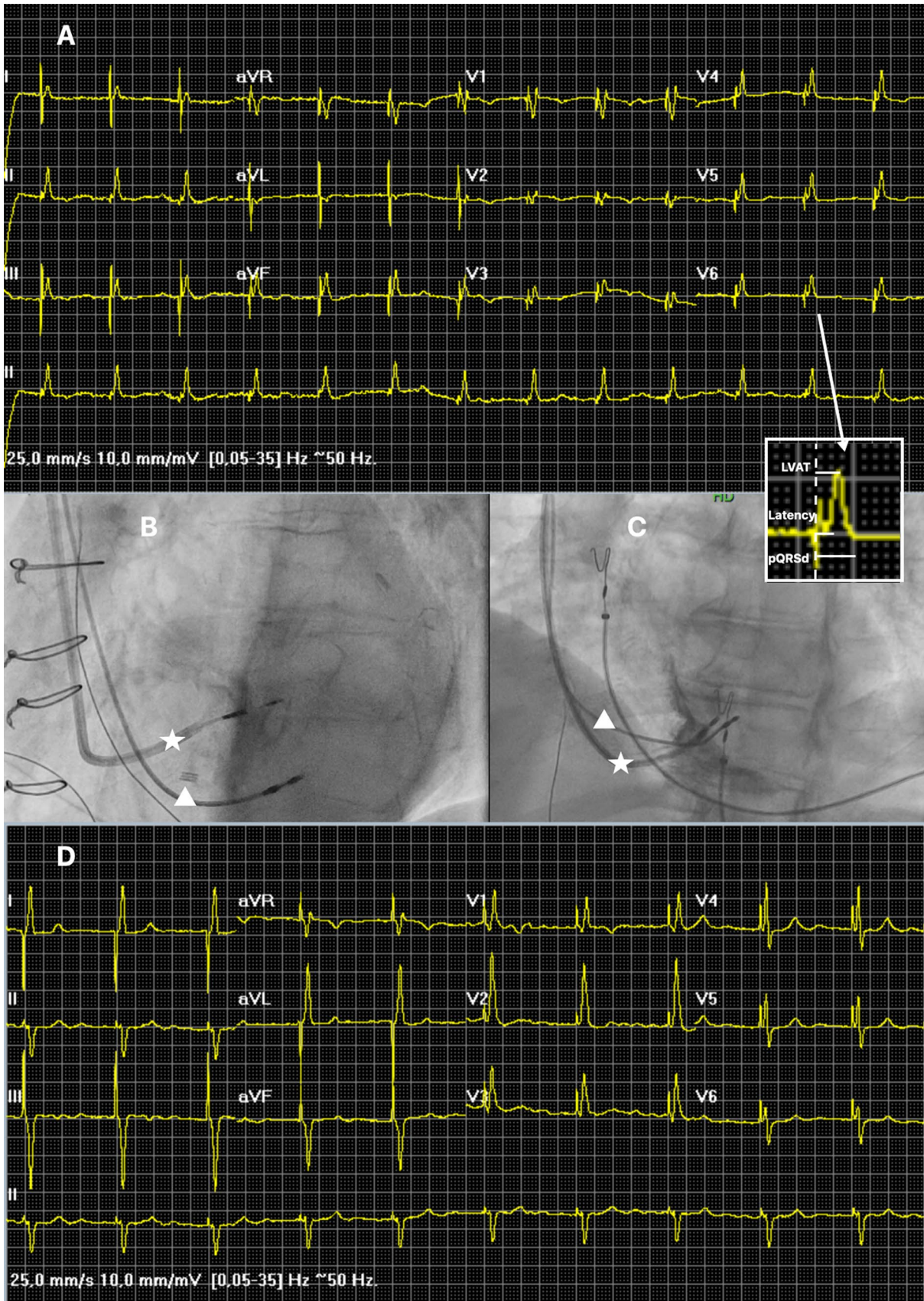


Fig. 2 Electrocardiogram during bipolar pacing and fluoroscopic localization of the two different leads. **A** Left anterior fascicular pacing using a lumen-less lead. Unipolar pacing yielded a paced QRS duration (pQRSd) of 77 ms (ms). The electrocardiogram (ECG) showed a typical Qr pattern in V1, latency of 37 ms, and left ventricular activation time (LVAT) of 79 ms. **B** The position of the pacemaker leads resulting in paced ECG A. The star marks the position of the lumen-less left bundle branch lead, the triangle marks the stylet-driven right ventricular lead. **C** The position of the pacemaker leads resulting in paced ECG D, with the star marking the position of the stylet-driven left bundle branch lead and the triangle the stylet-driven right ventricular lead. **D** Left posterior fascicular pacing using a stylet-driven lead. Bipolar pacing yielded a pQRSd of 92 ms. The ECG showed a typical Qr pattern in V1, latency of 33 ms and LVAT of 70 ms

the LLL group, $P=0.001$, which remained stable at last follow-up. Pacing thresholds were low in both groups, although the LLL group had significantly lower pacing thresholds at implantation: 0.7 ± 0.30 V for LLL versus 0.9 ± 0.29 V for SDL, $P=0.026$. At first follow-up, pacing thresholds were comparable and remained low (0.7 ± 0.39 V for LLL versus 0.7 ± 0.50 V for SDL, $P=0.220$). The pacing threshold in the SDL group was significantly decreased at first follow-up, $P<0.001$. Last follow-up showed stable pacing thresholds in the SDL group compared with first follow-up, $P=0.589$, with thresholds of 0.6 ± 0.20 V, although it was significantly lower compared with implantation, $P<0.001$. Compared with SDL, the LLL group had significantly higher pacing thresholds at last follow-up: 0.8 ± 0.30 V, $P=0.017$. There were no significant differences in LLL pacing thresholds during follow-up, $P=0.352$. Lead parameters and differences between groups are shown in Table 3.

For both leads, threshold pulse width was significantly lower at first follow-up compared with acute values at implantation. Sensing values did not differ significantly between both groups at implantation and follow-up, with a R-wave sense of 12 ± 5.4 for LLL and 13 ± 4.9 for SDL at last follow-up, $P=0.284$. The percentage of ventricular pacing did not differ between both groups at implantation, first follow-up and last follow-up, with mean ventricular pacing percentages of, respectively, 63, 69 and 92% ($P=0.762$, 0.153, 0.479).

Complications

All complications, including the follow-up period, were registered and are specified in Table 2. The total amount of complications was four in the LLL group (12.9%) and ten in the SDL group (15.9%), with no significant differences, $P=1.000$. In both groups, half of the complications were considered as major, the other half as minor. Major complications consist of possible life-threatening complications or complications requiring intervention or prolonged hospital admission. Complications that were conservatively

treated and did not result in prolonged hospital admission were considered as minor complications. The complications that required intervention were a severe pocket infection in the SDL group, resulting in successful extraction of the complete transvenous system, two dislocated RV leads in the SDL group of which one was revised, and one pneumothorax in the SDL group requiring pleural drain insertion. One of the participants with the dislocated RV lead lost capture before the first follow-up. Although no specific problems were reported during the implantation, the procedure consisted of removing an old, dislocated RV lead as well. The other participant showed a decrease in RV sense the first day of follow-up (23.6–3.5 mV), without any problems reported during the implantation. Since the participant also experienced pain complaints of the pacemaker generator, lead and pocket revision were performed. Two of the patients in the LLL group lost capture of the LBBA pacing lead during His bundle ablation, both with a backup RV lead. One LBBA lead was successfully revised. Since the other patient had a normal left ventricular ejection fraction, a conservative approach was adopted. In the SDL group, one participant lost LBBA pacing due to dislocation of the LBBA lead, presumably due to a trauma 2 weeks after implantation. Lead explantation has been performed safely.

Success rate

Considering the participants with LBBA lead dislocation and LBBA lead damage during follow-up, success rates at mean follow-up of 30 weeks were 96.8% in the SDL group and 90.3% in the LLL group, $P=0.199$. This resulted in an overall success rate of 94.7%. Procedural success rate was higher: 98.4% in the SDL group compared with 96.8% in the LLL group, with an overall procedural success rate of 97.9%.

Discussion

Our study demonstrates that LBBAP using a stylet-driven active fixation lead is feasible, successful at implantation and does not result in higher complication rates or longer procedural times compared with a lumen-less lead with a non-retractable fixed helix.

LBBAP is an upcoming pacing technique as a physiological alternative to right ventricle area pacing with normal synchronous ventricular activation. In comparison to HBP, LBBAP has a lower and more stable capture threshold and easier pacing management due to a higher amplitude of sensed R-wave. Although HBP was first described in humans 2 decades ago by Deshmukh et al., technical developments have drastically improved procedural success and long-term outcomes over the past years. These developments

Table 3 Paced electrocardiogram characteristics and lead parameters

	All patients (<i>n</i> =94)	LLL (<i>n</i> =31)	SDL (<i>n</i> =63)	<i>P</i> value*
Paced ECG characteristics				
Paced QRS duration, <i>ms</i>	110 ± 15.1	101 ± 11.8	114 ± 15.0	0.001
Pace to QRS (latency), unipolar, <i>ms</i>	38 ± 20.7	41 ± 23.8	36 ± 19.6	0.690
Pace to QRS (latency), bipolar, <i>ms</i>	32 ± 8.6	33 ± 9.6	32 ± 8.2	0.271
Pace to peak (LVAT), unipolar, <i>ms</i>	80 ± 11.8	78 ± 8.9	81 ± 12.7	0.198
Pace to peak (LVAT), bipolar, <i>ms</i>	80 ± 12.5	80 ± 10.6	81 ± 13.4	0.587
R in V1 (4 missing, 2 LLL, 2 SDL)	82 (87.2%)	27 (87.1%)	55 (87.3%)	1.000
Paced QRS axis (4 missing (2 LLL, 2 SDL))				<0.001
Inferior	31 (33.0%)	20 (64.5%)	11 (17.5%)	
Superior	41 (43.6%)	4 (12.9%)	37 (58.7%)	
Intermediate	18 (19.1%)	5 (16.1%)	13 (20.6%)	
Lead parameters at implantation				
Impedance, Ohm	509 ± 230.4	616 ± 226.7	458 ± 215.9	0.001
Threshold, volt	0.8 ± 0.30	0.7 ± 0.30	0.9 ± 0.29	0.026
Threshold pulse width, <i>ms</i>	0.5 ± 0.10	0.5 ± 0.16	0.5 ± 0.03	0.081
R-wave sense, mV	10 ± 4.9	9 ± 4.5	9.8 ± 5.1	0.898
Percentage ventricular pacing	63.4 ± 41.5	67.2 ± 40.9	61.6 ± 42.0	0.762
Lead parameters at first follow-up				
Impedance, Ohm	447 ± 114.7	463 ± 115.8	440 ± 114.2	0.183
Threshold, volt	0.7 ± 0.47	0.7 ± 0.39	0.7 ± 0.50	0.220
Threshold pulse width, <i>ms</i>	0.4 ± 0.08	0.4 ± 0.12	0.4 ± 0.03	0.724
R-wave sense, mV	12 ± 5.1	12 ± 5.8	12 ± 4.8	0.912
Percentage ventricular pacing	69.3 ± 38.3	78.7 ± 32.6	64.3 ± 40.4	0.153
Lead parameters at last follow-up				
Impedance, Ohm	417 ± 92.1	431 ± 73.5	411 ± 99.3	0.112
Threshold, volt	0.7 ± 0.24	0.8 ± 0.30	0.6 ± 0.20	0.017
Threshold pulse width, <i>ms</i>	0.4 ± 0.12	0.4 ± 0.20	0.4 ± 0.02	0.358
R-wave sense, mV	13 ± 5.1	12 ± 5.4	13 ± 4.9	0.284
Percentage ventricular pacing	91.5 ± 21.7	91.6 ± 23.5	91.4 ± 21.0	0.479

Values are mean ± standard deviation or numbers with percentages. *Comparison between the LLL and SDL group

LLL Lumen-less lead, SDL stylet-driven lead, ECG electrocardiogram, LVAT left ventricular activation time, *Ms* milliseconds, *mV* millivolt

include the use of specific delivery sheaths and studies with stylet-driven leads. Although the first implantations were performed with lumen-less His bundle pacing leads, standard stylet-driven leads have also been shown to be successful over the past years, with 88–89% implantation success rates, achieving stable pacing thresholds and similar sensed R-wave amplitudes compared with previous studies with lumen-less leads [4, 12, 13].

The lessons learned in HBP raise the question whether the developments could also apply to LBBAP, as described and confirmed in this report by the use of stylet-driven leads, with even higher success rates. Currently, most LBBAP implantations have been performed with the Medtronic 3830 lumen-less lead in combination with Medtronic's C304 or C315 delivery sheaths. The main advantage of this combination is that the relatively small diameter and floppy design of the exposed screw lead ease screwing of the lead in the

interventricular septum, even when the sheath is not perpendicular to the target site. However, the delivery sheath's ability to adapt to anatomic variations is limited. Moreover, lack of a lead lumen does not allow for use of a (locking) stylet, which could increase difficulty of extraction with possible greater risk of myocardial perforation or myocardial tissues adhering to the lead tip. Especially in terms of future lead extractions, SDL might provide a safer alternative.

Only two case reports and one prospective study described the successful use of a SDL in LBBAP. The prospective study by De Pooter et al. compared Biotronik stylet-driven Solia lead in combination with Biotronik Selectra 3D sheath, with Medtronic 3830 lumen-less lead delivered through the fixed curve C315 sheath. They showed that LBBAP yielded comparable implant success, procedural time, pacing characteristics and short-term follow-up with SDL and LLL. The overall implant success rate was 88%,

which is lower than the 97.9% in the present report. On the other hand, they showed no LBBAP lead dislocation during follow-up [14].

The two case reports where LBBAP was successfully performed used the Biotronik stylet-driven Solia lead. Both patients were scheduled to receive HBP with the SDL, but since this resulted in high pacing thresholds, the same leads were used for an attempt of LBBAP. This was achieved successfully with adequate pacing thresholds. However, no follow-up was reported. These case reports do support our experience that a SDL is associated with good stability and provides better support for screwing the lead into the inter-ventricular septum [15].

Besides demonstrating that LBBAP using a stylet-driven lead does not result in longer procedural times compared with a lumen-less lead with a non-retractable fixed helix and even resulted in shorter fluoroscopy duration, our study demonstrates that the mean number of deployments was significantly lower in the SDL group compared with the LLL group, respectively, 2 versus 4 times, possibly resulting in less septal damage. This could be addressed to a learning effect, since the SDL group consisted of more than twice the number of procedures than the LLL group, and implanters were already more experienced with SDLs. On the other hand, the lower number of deployments could also be caused by accepting suboptimal paced QRS duration when LVAT and latency are low. Although both leads have remarkably short paced QRS durations, the mean paced QRS duration was significantly shorter in the LLL group. Both the differences in number of deployments as differences in paced QRS durations are not supported by the previously conducted prospective study [14].

Most complications could not be addressed to the specific lead that was used and the majority does not seem to be related to left bundle branch area pacing specifically. Pacing thresholds were low in both groups at implantation and at first follow-up, although pacing thresholds significantly decreased at first follow-up in the SDL group, from 0.9 ± 0.29 V to 0.7 ± 0.50 V. This might be caused by the larger diameter of the lead, resulting in more edematous tissue and is not clinically relevant, since the last follow-up period showed no further significant decrease of pacing thresholds. Moreover, the low pacing thresholds in both groups once again demonstrate the advantages of LBBAP compared with HBP. The LLL group had a significantly higher impedance of the lead at implantation compared with the SDL group, including a significant decrease of lead impedance at follow-up. No specific explanation could be found in the literature.

In addition to equal LBBAP lead implantation times between both leads, our implanters experience that both leads are well implantable and implantation eases as their experience increases. The LLLs were initially implanted by experienced

electrophysiologists, whereas the SDLs were implanted by a group of implanters with different levels of experience, including implanters in the learning phase supervised by electrophysiologists. These aspects should be taken into consideration when comparing procedure times and complication rates of the LLL and SDL. Nevertheless, the success rates were comparable between LLL and SDL. Moreover, there was a tendency to shorter procedure times in experienced hands.

Two patients in the LLL group lost capture of the LBBAP pacing lead during His bundle ablation, with unknown cause. One explanation could be that the lead was damaged during ablation, possibly due to a relatively proximal positioned lead. Since this occurred in 2 procedures in the first 13 procedures, the level of experience could also have contributed to this. On the other hand, the loss of capture could also have been caused by ablation of the tissue being paced by the leads.

Both SDLs that unfortunately had to be extracted due to infection and dislocation, respectively, were extracted without complications. The difference in extraction between SDL and LLL could be supported by one unsuccessful LLL procedure. During fixation, LBB capture was lost. However, repositioning or explantation was not possible due to severe fixation of the lead and eventually the lead was left in the ventricular septum. Since SDL implantation required a lower number of deployments and does not lead to longer procedural times compared with LLL, SDLs should be considered in LBBAP, taking into account future lead extractions.

Limitations

This single-center study is not randomized and does not include sufficient data on the feasibility of extraction procedures with the different pacing leads. The procedures were performed by two primary electrophysiologists and less experienced implanters supervised by these two electrophysiologists. Furthermore, we used electro-anatomical mapping in all patients. Although this is not a requirement for implantation, our implanters are experienced with electro-anatomical mapping and, therefore, specifically chose to use mapping to ease lead positioning. Therefore, our results cannot be extrapolated to LBBAP procedures that are performed without the use of electro-anatomical mapping. Future studies should include the feasibility of extraction procedures and our findings need to be confirmed by multicenter, randomized studies with a larger number of participants.

Conclusion

LBBAP using stylet-driven leads is feasible and has comparable success rates, procedural times and complication rates with lumen-less leads, with a lower number of deployments.

During a mean 30-week follow-up period, pacing thresholds remained low and did not differ significantly between stylet-driven and lumen-less leads.

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Declarations

Conflict of interest The authors have no conflict of interest to declare.

Ethics approval This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the local Ethics Committee of the Isala hospital.

Consent to participate All the participants gave their consent for the procedure and to collect data from the electronic patient file for research purposes.

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