# Left bundle branch area pacing using stylet-driven pacing leads as compared to lumen-less leads

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## Abstract

Introduction Left bundle branch area pacing (LBBAP) aims to achieve physiological pacing by capturing the conduction system in the area of the left bundle branch. LBBAP has exclusively been performed using lumen-less pacing leads (LLL) with fixed helix design. This study explores the feasibility, safety and pacing characteristics of LBBAP using stylet-driven leads (SDL) with an extendable helix design. Methods Patients, in which LBBAP was attempted for bradycardia or heart failure pacing indications, were prospectively enrolled at the Ghent University Hospital. LBBAP was attempted with two different systems: 1/ LLL with fixed helix (SelectSecure 3830, Medtronic, Inc) delivered through a preshaped sheath (C315His Medtronic) and 2/ SDL with extendable helix (SoliaS60, Biotronik, SE & CO) delivered through a new delivery sheath (Selectra 3D, Biotronik). Results The study enrolled 50 patients (mean age 70?14 years, 44% female). LBBAP with SDL was successful in 20/23 (87%) patients compared to 24/27 (89%) of patients in the LLL group (p=0.834). Screw attempts, screw implant depth, procedural and fluoroscopy times were comparable among both groups. Acute LBBAP thresholds were low and comparable between SDL and LLL (0.5?0.15V versus 0.4?0.17V, p=0.251). Pacing thresholds remained low at 3?2.1 months of follow up in both groups and no lead revisions were necessary. Post procedural echocardiography revealed a septal coronary artery fistula in one patient with SDL LBBAP. Conclusion LBBAP using stylet-driven pacing leads is feasible and yields comparable implant success to LBBAP with lumen-less pacing leads. LBBAP thresholds are low and comparable with both types of leads.


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**Short title: Left bundle branch area pacing using stylet-driven leads**

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**Structured Abstract**

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**Methods**

Patients, in which LBBAP was attempted for bradycardia or heart failure pacing indications, were prospectively enrolled at the Ghent University Hospital. LBBAP was attempted with two different systems: 1/ LLL with fixed helix (SelectSecure 3830, Medtronic, Inc) delivered through a preshaped sheath (C315His Medtronic) and 2/ SDL with extendable helix (SoliaS60, Biotronik, SE & CO) delivered through a new delivery sheath (Selectra 3D, Biotronik).

**Results**

The study enrolled 50 patients (mean age 70±14 years, 44% female). LBBAP with SDL was successful in 20/23 (87%) patients compared to 24/27 (89%) of patients in the LLL group (p=0.834). Screw attempts, screw implant depth, procedural and fluoroscopy times were comparable among both groups. Acute LBBAP thresholds were low and comparable between SDL and LLL (0.5±0.15V versus 0.4±0.17V, p=0.251). Pacing thresholds remained low at 3±2.1 months of follow up in both groups and no lead revisions were necessary. Post procedural echocardiography revealed a septal coronary artery fistula in one patient with SDL LBBAP.

**Conclusion**

LBBAP using stylet-driven pacing leads is feasible and yields comparable implant success to LBBAP with lumen-less pacing leads. LBBAP thresholds are low and comparable with both types of leads.

**Keywords:** Left bundle branch area pacing, physiologic pacing, stylet-driven pacing leads, lumen-less pacing leads

## Introduction

Right ventricular pacing (RVP) has been the standard approach to obtain ventricular pacing for many decades, but is associated with an increased risk for pacing-induced cardiomyopathy and mortality.[1, 2] Both His bundle pacing (HBP) and left bundle branch area pacing (LBBAP) aim to directly capture the His Purkinje system and are therefore deemed to be more physiologic pacing alternatives.[3-6] LBBAP captures the His Purkinje system more distally compared to HBP and requires the lead to be screwed transseptally towards the left side of the interventricular septum. Compared to HBP, LBBAP is associated with lower pacing thresholds and better sensing values, overcoming two important limitations of HBP.[6-9] Most experience with LBBAP has been performed using a lumen-less pacing lead (LLL) with fixed helix design (SelectSecure 3830 pacing lead, Medtronic Inc, Minnaepolis, MN, USA), delivered through a preshaped sheath dedicated for HBP (C315His, Medtronic).[4, 6, 7, 10-13] This implant technique yields high succes rates, both in patients with bradycardia and heart failure indications. Although data on HBP with standard stylet-driven leads (SDL) delivered through preshaped sheaths have been published[14], experience with LBBAP using SDL with extendable helix design is limited to two recent case reports.[15] This study aims to compare implant success and short-term pacing characteristics of LBBAP using either LLL or SDL.

## Methods

### Study population

The study prospectively enrolled consecutive adult patients who underwent LBBAP for bradycardia or heart failure indications at the Ghent University Hospital since November 2019. In bradycardia patients, LBBAP was attempted as first choice pacing strategy or in case of failed HBP attempt. In heart failure patients, LBBAP was attempted in case of failed coronary sinus lead placement. The study was approved by the local ethics committee of Ghent University Hospital and all patients gave written informed consent.

### LBBAP implant procedure

LBBAP was attempted with two different combinations of pacing leads and delivery sheaths. In the first group, LBBAP was performed with a 4.1 Fr thin lumen-less pacing lead (LLL group) with a fixed helix design (SelectSecure 3830 pacing lead, Medtronic Inc, Minnaepolis, MN, USA) delivered through a long preshaped sheath (C315His, Medtronic) (Figure 1, panel A). In the comparator group, LBBAP was performed with a 5.6 Fr stylet-driven pacing lead with an extendable helix (Solia S60, Biotronik, SE & Co, KG, Berlin, Germany) delivered through a preshaped sheath (Selectra 3D, Biotronik) (Figure 1, panel B). This sheath became available in a prelimited market release with three different curves depending on the width of the primary curve (40, 55 or 65mm).

The SelectSecure 3830 lead requires no additional lead preparation and the lead was directly advanced through the C315His delivery sheath. The Solia S lead was prepared by exposing the extendable screw by turning the outer pin 5-10 times clockwise. After complete exposure of the 1,8 mm extendable helix, tension on the inner coil was applied by clockwise turning the outer pin an additional 8 times using the standard stylet guide tool delivered with the lead (Figure1 panel B).[15] This manoeuver helps to avoid partial unwinding of the extendable helix, as manual rotations applied on the outer body of the lead could cause the inner coil not to follow the outer lead body rotations[15].

LBBAP was subsequently performed as described previously by Huang et al.[4, 7] In brief, the His bundle region was mapped with the pacing lead in unipolar configuration and used as fluoroscopic reference. The pacing lead and sheath were than advanced 1-2cm towards the apex in the right anterior oblique view with a slight counterclockwise rotation to guide the pacing lead towards the septum. Perpendicular position to the septum was assessed in the left anterior oblique view by injecting a small amount of contrast through the delivery sheath to delineate the septum. At this point, pace mapping with unipolar pacing at the tip of the lead was performed to assess the presence of a wide "W" shaped QRS morphology in lead V1 of the 12-lead surface electrocardiogram (ECG). Both LLL and SDL were advanced with manual rotations applied on the outer lead body. For the SDL, the stylet was fully advanced to the tip of the pacing lead during screwing in of the lead. Manual rotations were applied with the use of a third hand, while the first operator fixated the sheath against the septum. As the pacing lead advanced into the septum, the "W" shaped QRS morphology in lead V1 gradually changed to incomplete right bundle branch block morphology with continuous monitoring of the unipolar lead impedance and fluoroscopic advancement of the lead into the septum. Successful LBBAP was defined by the appearance of an incomplete right bundle branch block morphology in lead V1 and a shortened stimulus to peak left ventricular activation time (LVAT) among leads V5-V6, which remained constant and short at both low and high output pacing.[6, 7, 16]intracardiac recordings on the tip of the pacing lead were assessed for a discrete left bundle branch potential (LBBp) with the use of an electrophysiology recording system (BARD Labsystem, C.R Bard Inc, Lowell, MA, USA). Final lead implant depth and confirmation of the lead position towards the left side of the septum were assessed by injecting a small amount of contrast though the delivery catheter (Figure 2). Perforation of the septum during implant was defined as sudden decrease in pacing impedance of $>$ 200 ohms, high unipolar pacing thresholds $>$ 3V and leakage of contrast into the left ventricle.

### Data collection

Baseline patient characteristics, ECG features and pacing indications were collected. Pacing thresholds, R-wave sensing amplitudes and lead impedances were measured both during uni- and bipolar pacing at implant and follow-up. Paced QRS morphology and duration were measured from stimulus to end-QRS. The stimulus to peak LVAT was measured from pacing stimulus to peak of the R wave in leads V5-V6 during LBBAP. Number of screw-in attempts, procedural and fluoroscopy times and acute procedure-related complications were recorded. All patients underwent post-procedural transthoracic echocardiographic evaluation to assess potential LBBAP implant-related complications.

### Statistical analysis

Continuous variables are presented as mean ± standard deviation (SD) and were compared with Student t or Mann–Whitney test. For paired data, paired Student t and Wilcoxon signed rank test were used. Categorical variables are expressed as numbers and percentages and were compared by use of Pearson's $\chi 2$ or Fisher's exact test. Statistical significance was set at a 2-tailed probability level of $<$0.05. Statistical analyses were performed using IBM SPSS Statistics (version 24.0; IBM Corp, Armonk, NY).

## Results

### Baseline patient characteristics

The study included 50 patients (mean age 70±14.1 years, 44% female). Pacing indications were sinus node disease in 8 (16%) patients, atrioventricular block in 30 (60%) and 12 (24 %) patients had a heart failure indication. The SDL group included 23 (46%) patients compared to 27 (54%) patients in the LLL-group. Baseline patient and ECG characteristics and pacing indications are summarized in Table 1.

### LBBAP pacing implant success

Overall implant success was 88%. Implant success in the SDL and LLL group was comparable: 20/23 (87%) versus 24/27 (89%) respectively, p=0.834. Detailed procedural characteristics for both LBBAP groups are summarized in Table 2. Screw-in attempts, lead implant depth, and total procedure and fluoroscopy times to achieve LBBAP were comparable for both groups (Table 2).

In 6 patients, LBBAP failed because of different reasons. In the LLL group LBBAP failed due to: high pacing thresholds in the left ventricular septal region related to extensive anteroseptal myocardial infarction (n=1) and previous surgical correction of a ventricular septal defect (n=1), and failed lead engagement into the septum due to right atrial enlargement (n=1). In the SDL group, LBBAP failed due to repetitive lead dislodgment after slitting the delivery sheath in a right sided subclavian implant (n=1), and failed lead engagement into the septum (n=2). In one of the latter cases, LBBAP was eventually successful with the LLL delivered through the Selectra 3D sheath as bail out.

### Pacing and ECG characteristics during LBBAP

Pacing and ECG characteristics are summarized in Table 2. Implant pacing thresholds were low and comparable between the SDL and LLL group (unipolar pacing threshold 0.5±0.15 versus 0.4±0.17V at 1.0ms pulse width, p=0.251). Sensing values and lead impedances were comparable between both groups.

Paced QRS duration was 127±20.3ms in the SDL group compared to 131±23.6ms in the LLL group, p=0.570). Stimulus to LVAT measured 73±15.2ms in the SDL group compared to 71±11.2ms in the LLL group (p=0.703). In patients with narrow QRS, paced QRS duration increased significantly from 98±15.9ms to 121±17.7ms (p=0.005) with LBBAP, whereas in patients with left bundle branch block (LBBB) QRS duration decreased significantly from 170±16.7ms to 126±26.3ms (p= 0.011) with LBBAP. Changes in QRS duration for both narrow QRS and LBBB patients were comparable for SDL and LLL. LBBp were observed in 38% of the SDL patients compared to 13% of the LLL patients (p=0.198).

### Complications associated with LBBAP

All complications with LBBAP attempts are specified in table 2. Acute perforation of the LV septum, assessed during implantation, occurred in 1 SDL patients and 2 LLL patients, but this remained without clinical consequences.

Transthoracic echocardiography the day after implant detected a septal coronary artery fistula in 1 patient who underwent LBBAP with a SDL. This complication remained asymptomatic and without clinical consequences during 6 months follow up. No ventricular septal defects were detected on post procedural echocardiography.

### Pacing characteristics at follow up

Pacing characteristics at follow up are summarized in Table 2. Pacing thresholds remained low and stable during a mean follow up of $3\pm2.1$ months No significant differences in pacing characteristics were observed between the SDL and LLL during follow up. No lead revisions were required.

### Discussion

This study is the first to compare LBBAP using lumen-less pacing leads with fixed helix design to standard stylet driven leads with extendable helix design. The main findings of this study are that LBBAP with stylet-driven leads yields comparable implant success and similar pacing characteristics at implant and short-term follow up without affecting procedural safety.

LBBAP is a novel pacing technique aiming to capture the conduction system of the heart at the left side of the interventricular septum.[4] Compared to HBP, LBBAP aims to pace the conduction system more distally on the left bundle branch. Although no direct comparisons between HBP and LBBAP have been published, current evidence shows promising effects of LBBAP in terms of maintaining physiologic ventricular activation, hemodynamic benefits and the potential for cardiac resynchronization in patients with LBBB and heart failure.[3, 5, 13, 17] Moreover, LBBAP is associated with lower pacing thresholds, and higher sensing values compared to HBP. As such, LBBAP might overcome the limitations of HBP, as HBP has been associated with high pacing thresholds, especially in the setting of bundle branch block or infranodal disease, and is associated with two to three times more lead revision compared to RVP.[8, 9, 18]

Until now, LBBAP has been exclusively performed with a 4.1Fr thin lumen-less lead with a fixed helix (Select-Secure 3830 lead, MDT) delivered though a fixed curved delivery sheath (C315HIS, Medtronic).[4, 6, 7, 10, 11] This approach has been shown to yield high implant success and is associated with excellent pacing threshold both in patients with narrow QRS, atrioventricular block and bundle branch blocks. The main advantage of this type of lead is the isodiametric shape between the lead tip and the lead body which facilitates screwing the lead into the ventricular septum. Stylet-driven leads with extendable screws however lack the isodiametric shape at the location where the helix exits the helix case, which might limit lead penetration into the septum. Recently, the first two cases of LBBAP with an SDL delivered through a new preshaped sheath (Selectra 3D sheath) have been reported by Zanon et al.[15] In these two cases, HBP with the SDL failed and the same lead was implanted successfully at the area of the left bundle branch. In our experience, the combination of a standard stylet-driven lead (Solia S60) delivered through the Selectra 3D sheath performed excellent to achieve LBBAP with similar success rates as compared to thin lumens-less leads. Neither the larger lead diameter (5.6 Fr), nor the non-isodiametric lead design limit the screwing of the lead towards the left side of the septum. On the contrary, the larger outer diameter of the SDL allows more grip on the lead body when applying manual rotations. The screwing of an SDL into the septum was further facilitated by the extra support of the stylet and the wider (8,7 Fr) and sturdier Selectra 3D sheath. As described by Zanon et al[15], we tend to extend the helix and routinely add additional tension on the inner coil of the lead before screwing into the septum. This approach avoids unwinding of the inner coil and partial retraction of the helix when manual rotation on the outer lead body is applied and allows the applied torque to be transferred predictably to the lead tip.

In our experience, LBBAP with LLL and SDL reveals comparable procedural characteristics and safety.

Despite the larger lead diameter, the use of an inner stylet and a wider delivery sheath, LBBAP with SDL did not result in more septal perforations. However, we detected an asymptomatic septal coronary artery fistula on echocardiography in one patient who underwent LBBAP with SDL. Although perforation of septal coronary artery branches could occur with any transseptal lead, the risk might be considered higher with larger pacing lead diameters. This complication highlights the importance of routine echocardiographic screening to assure integrity of the interventricular septum after LBBAP.

Our study shows that both types of leads tend to have comparable LBBAP thresholds immediately post implant and at short term follow up. Both leads have an electrical active pacing helix and use steroids at the helix, although the steroid location differs. The LLL helix is steroid-coated, whereas the SDL leads contain steroids within a capsule at the distal lead tip. A recent study showed that with HBP, SDL leads with steroid containing capsules presented with higher acute HBP thresholds compared to LLL with steroid coated helices. Although no such difference in acute pacing thresholds was detected in our patients with LBBAP, further studies are needed to assess whether differences in lead design and steroid location could affect long-term LBBAP pacing thresholds.

**Limitations**

The small number of LBBAP patients is a limitation of this single-center study and our results need to be confirmed in larger studies. Both implanters (JDP and FVH) have experience with both HBP and LBBAP. Therefore, our results might not apply to implanters with less experience in these new techniques. Follow-up in this study was limited and longer follow-up in a larger population is needed to assess long-term pacing characteristics. As no lead revision occurred within our population, safety and feasibility of extraction procedures with different types of pacing leads implanted at the left side of the septum remains to be determined.

**Conclusion**

LBBAP with stylet-driven pacing leads and extendable helix design is feasible and yields comparable implant success to LBBAP with lumen-less leads using fixed helix design. Pacing characteristics at implant and short-term follow up are comparable among both types of leads.

**Tables**

**Table 1: Baseline patient and ECG characteristics of all patients**

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|---|---|
| **Baseline patient characteristics** | |
| Age, yrs | 70 |
| Female gender, n (%) Arterial hypertension, n (%) Coronary artery disease, n (%) Left ventricular ejection fraction, % | 22 |
| **Pacing indication** | |
| Sinus node disease, n (%) | 8 ( |
| Atrioventricular block, n (%) | 30 |
| Heart failure, n (%) | 12 |
| His bundle pacing failure, n (%) | 12 |
| **Baseline ECG characteristics** | |
| Sinus rhythm, n (%) | 27 |
| QRS duration, ms LBBB, n (%) RBBB, n (%) IVCD, n (%) | 12 |

ECG: electrocardiogram; LBBB: left bundle branch block, RBBB: right bundle branch block, IVCD; intraventricular conduction delay

* Comparison between SDL and LLL group

**Table 2: Procedural and pacing characteristics in patients with successful LBBAP**

| **Table 2: Procedural and pacing characteristics** | **All patients (n=44)** | **SDL group (n=20)** | **LL** |
|---|---|---|---|
| **Procedural characteristics** | | | |
| Screw attempts, n | 2 ±0.9 | 2 ±0.8 | 2 ± |
| Implant depth, mm | 13 ±1.4 | 13 ±1.0 | 13 |
| Total fluoroscopy time, min | 11 ±6.5 | 9 ±3.5 | 13 |
| Procedural time, min | 65 ±23.7 | 61 ±15.9 | 69 |
| **Paced ECG characteristics** | | | |
| Paced QRS duration, ms | 130 ±22.2 | 127 ±20.3 | 131 |
| Stimulus to LVAT, ms | 72 ±12.8 | 73 ±15.2 | 71 |
| **Pacing characteristics at implant** | | | |
| Unipolar threshold, V | 0.5 ±0.17 | 0.5 ±0.15 | 0.4 |
| Bipolar threshold, V | 0.5 ±0.26 | 0.6 ±0.09 | 0.5 |
| Unipolar R-wave sensing, mV | 13 ±7.1 | 12 ±9.5 | 15 |
| Bipolar R-wave sensing, mV | 13 ±6.1 | 13 ±6.2 | 13 |
| Unipolar impedance, ohms | 414 ±57.3 | 388 ±47.6 | 431 |
| Bipolar impedance, ohms | 592 ±68.3 | 557 ±87.0 | 617 |
| **Pacing characteristics at 1 month** | | | |
| Unipolar threshold, V | 0.6 ±0.33 | 0.7 ±0.22 | 0.6 |
| Bipolar threshold, V | 0.7 ±0.31 | 1.0 ±0.40 | 0.7 |
| Bipolar R-wave sensing, mV | 13 ±5.5 | 11 ±7.2 | 14 |
| Unipolar impedance, ohms | 399 ±84.2 | 372 ±98.9 | 412 |
| Bipolar impedance, ohms | 571 ±68.7 | 594 ±104.3 | 566 |
| **Complications** | | | |
| **Acute complications** | | | |
| Pneumothorax, n (%) | 1 (2) | 1 (5) | 0 ( |
| Septal perforation during implant, n (%) Tamponade, n (%) | 3 (7) 0 (0) | 1 (5) 0 (0) | 2 ( |
| **Echocardiographic evaluation post implant** | | | |
| Ventricular septal defect, n (%) Septal coronary artery fistula, n (%) | 0 (0) 1 (2) | 0 (0) 1 (5) | 0 ( |
| **Complications during follow up** | | | |
| Lead dislodgment, n (%) | 0 (0) | 0 (0) | 0 ( |
| Lead revision, n (%) | 0 (0) | 0 (0) | 0 ( |
| Increase in pacing threshold of > 2V | 0 (0) | 0 (0) | 0 ( |

* Comparison between SDL and LLL group

LBBAP: Left bundle branch area pacing. LVAT: Left ventricular activation time.

**Figure legend**

**Figure 1: Different systems used for left bundle branch area pacing**

Different systems used for left bundle branch area pacing (LBBAP). Panel A: Conventional 4.1Fr lumen-less lead with fixed helix design (SelectSecure 3830, Medtronic) with a fixed curved delivery sheath (C315HIS, Medtronic). Right panel: Stylet-driven 5.6 Fr lead with retractable helix (Solia S, Biotronik) delivered through a new dedicated sheath (Selectra 3D 55, Biotronik). The stylet-driven lead was prepared by extending the screw (red arrow) and applying additional tension on the inner coil (blue arrow) before screwing into the septum.

**Figure 2: Lead tip dimensions of different leads used for left bundle branch area pacing**

Left panel: The lumen-less SelectSecure 3830 lead (Medtronic, Inc) has a 1.8 mm long fixed helix. The stylet-driven Solia S lead has a retractable 1.8mm screw. Lead tip dimensions of both leads are shown with their respectively fluoroscopic appearance. LBBAP: Left bundle branch area pacing. LAO: Left anterior oblique.

**Figure 3: LBBAP using stylet-driven and lumen-less pacing leads**

Fluoroscopic localization, twelve-lead electrocardiogram and intracardiac recordings from LBBAP lead are shown. Upper panel: Representative example of left bundle branch area pacing (LBBAP) using a stylet-driven lead (Solia S). Unipolar pacing yielded a narrow paced QRS morphology with typical Qr pattern in lead V1, short paced QRS duration (pQRSD) of 105ms and short interval form stimulus to peak left ventricular activation time (LVAT) of 72ms. Note the presence of left bundle branch potential (LBBp) on the intracardiac (IC) electrograms. Lower panel: Representative example of LBBAP using a lumen-less lead with fixed helix (SelectSecure 3830 lead, Medtronic). LBBAP at this position resulted in a narrow (84ms) paced QRS morphology with short stimulus to LVAT (51ms) and typical Qr pattern in lead V1. At this site a LBBp was noted.

**Figure 4: LBBAP in patients with LBBB**

Two representative examples of left bundle branch area pacing (LBBAP) in patients with left bundle branch block (LBBB). Chest X-rays and twelve lead ECG recordings are shown. LBBAP with both stylet-driven (Solia S, Biotronik) and the lumen-less leads (SelectSecure 3830, Medtronic) was able to correct LBBB. Note the short paced QRS duration and stimulus to left ventricular activation time (LVAT).

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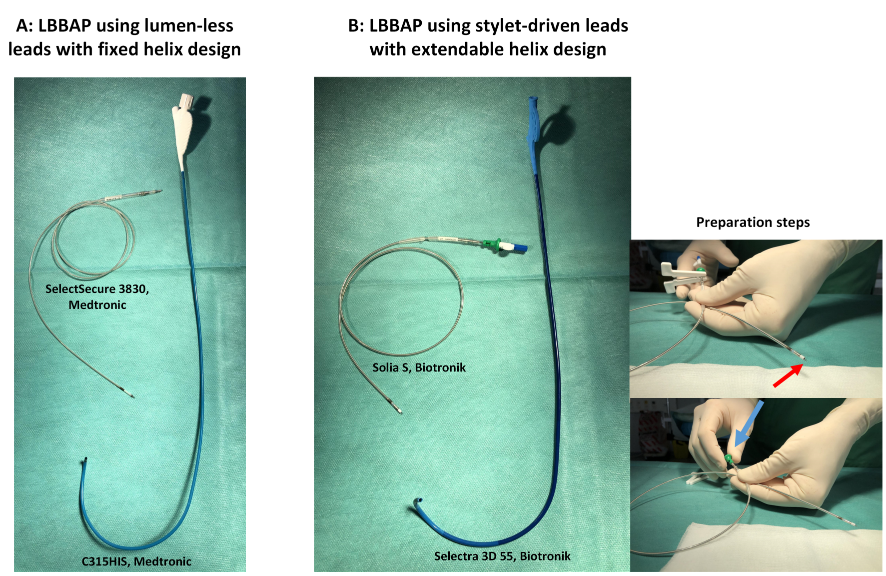
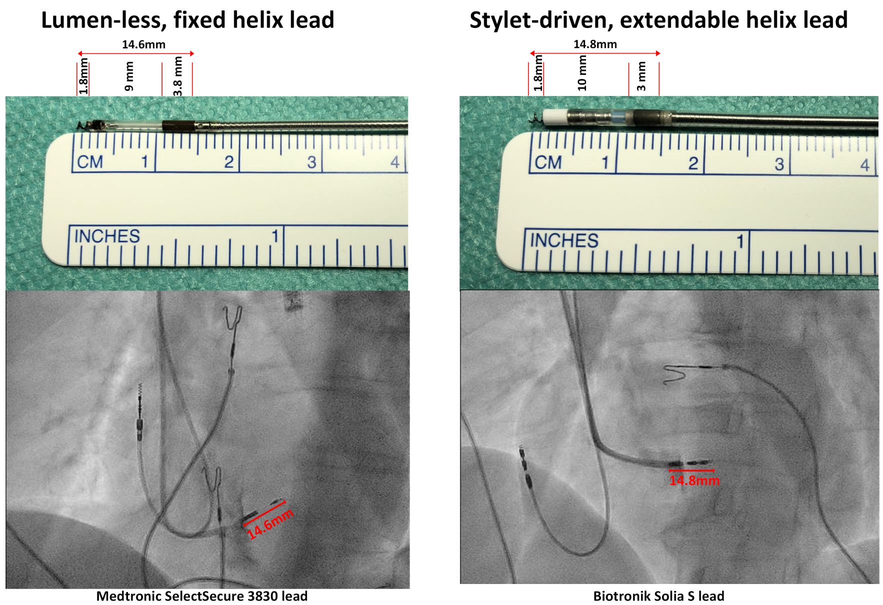
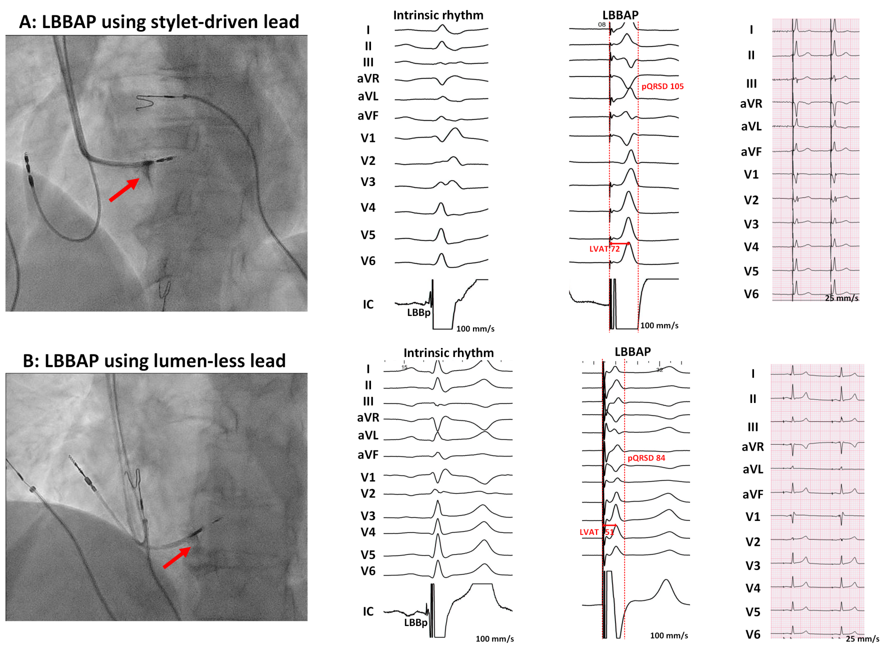
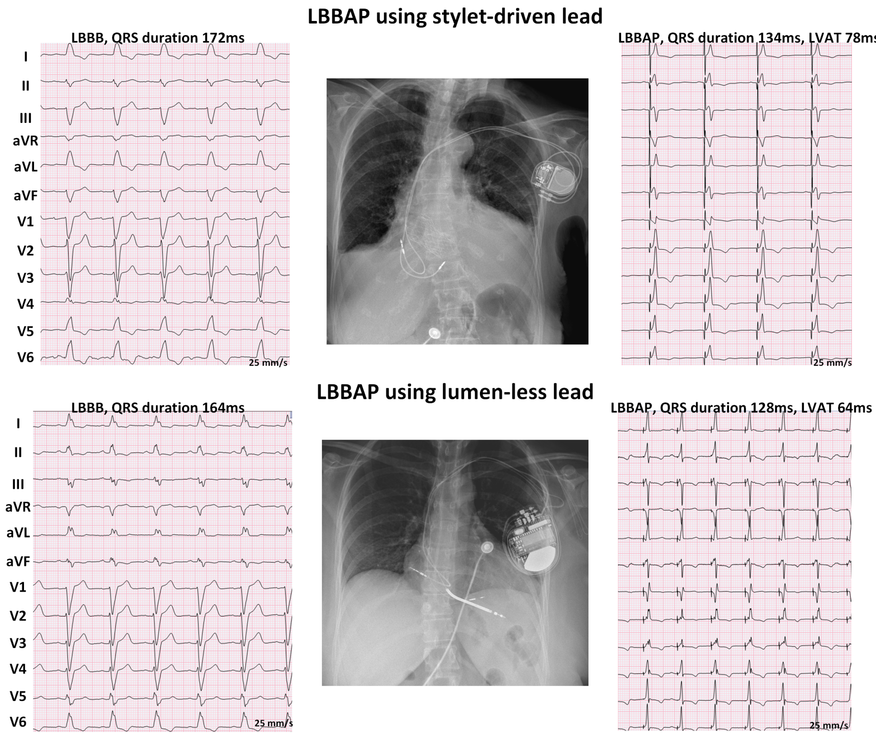



Lumen-less, fixed helix lead
Stylet-driven, extendable helix lead
14.6mm
1.8mm
9 mm
3.8 mm
14.8mm
1.8mm
10 mm
3 mm
CM
INCHES
14.6mm
14.8mm
Medtronic SelectSecure 3830 lead
Biotronik Solia S lead


A: LBBAP using stylet-driven lead
Intrinsic rhythm
LBBAP
pQRSD 105
LVAT 72
LBBp
100 mm/s
25 mm/s
B: LBBAP using lumen-less lead
Intrinsic rhythm
LBBAP
pQRSD 84
LVAT
LBBp
100 mm/s
25 mm/s
I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6
IC


LBBAP using stylet-driven lead
LBBB, QRS duration 172ms
LBBAP, QRS duration 134ms, LVAT 78ms
I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6
25 mm/s
25 mm/s
LBBAP using lumen-less lead
LBBB, QRS duration 164ms
LBBAP, QRS duration 128ms, LVAT 64ms
I
II
III
aVR
aVL
aVF
V1
V2
V3
V4
V5
V6
25 mm/s
25 mm/s