Utility of a guiding catheter for conduction system pacing: An early multicenter experience

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BACKGROUND Conduction system pacing (CSP), either as His bundle pacing (HBP) or as left bundle branch area pacing (LBBAP), may be superior to right ventricular apical or septal pacing.

OBJECTIVE The study sought to present acute results for a new guiding catheter (Biotronik Selectra 3D) designed for CSP implantations of a retractable screw-in lead (Biotronik Solia S).

METHODS The primary endpoint of the prospective, international nonrandomized BIO|MASTER.Selectra 3D study was freedom from catheter-related serious adverse device effects (SADEs) within 1 week of lead implantation.

RESULTS Of 157 enrolled patients, CSP was achieved in 147 (93.6%) patients. No SADEs occurred within 7 days. LBBAP was achieved in 82 patients (45 as crossover from an HBP attempt) and HBP in 65 (44.2%) patients. In centers considering both HBP and LBBAP, the CSP implantation success approached 99%. Successful CSP implantations lasted on average ~50 minutes (fluoroscopy ~6 minutes). Most procedures (87.9%) needed only 1 catheter, even after switch from HBP to LBBAP. The catheter's handling was rated largely positive. In patients without bundle branch block, mean QRS duration increased from 106 ms (intrinsic) to 122 ms (CSP) ($P = .001$). In patients with bundle branch block, mean QRS duration decreased from 151 ms (intrinsic) to 137 ms (CSP) ($P = .004$).

CONCLUSION The Selectra 3D catheter is a valuable tool for HBP and LBBAP implantations of the stylet-supported pacemaker leads. When implanters considered both HBP and LBBAP, the success rate was ~99%. Flexibility to change between different approaches may be advisable in heterogeneous and challenging areas, such as CSP implantations.

KEYWORDS Cardiac pacing; Conduction system pacing; Pacing lead implantation; Left bundle branch area; His bundle; Guiding catheter; Catheter handling characteristics

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Introduction

For decades, the pacing lead of permanent cardiac pacemakers has been placed in the apex or septum of the right ventricle. The broad QRS complex commonly seen in pacemaker patients reflects a nonphysiological contraction sequence of the cardiac muscle, in which excitation starts from an atypical position with slow myocardial conduction. In the setting of a higher proportion of ventricular pacing, the contractile function can worsen, and increased risk of heart failure might occur due to this nonphysiological ventricular activation.[1–5] Alternatively, pacing at the bundle of His or in the left bundle branch area directly stimulates parts of the cardiac conduction system and is collectively referred to as conduction system pacing (CSP).[5–16] CSP is attracting increasing attention because it maintains the physiological contraction pattern and better preserves the mechanical function of the ventricles.

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KEY FINDINGS

- Conduction system pacing using a new dedicated guiding catheter (Selectra 3D) resulted in high implant success (93.6%) combined with a high safety profile without serious adverse device effects within 7 days of implantation.
- The catheter was used for both His bundle pacing (HBP) and left bundle branch area pacing (LBBAP) implantation, without the need for catheter exchange when switching from a failed HBP attempt to LBBAP.
- A switch from HBP to LBBAP occurred in 37.8% of all cases in which HBP was initially attempted. These findings reveal a tendency to drop the HBP attempt in favor of LBBAP relatively early on.
- A generally high success rate of LBBAP implantation (98.8% in our study) contributes to the increasing use of LBBAP in the rapidly developing field of conduction system pacing.

However, pacemaker lead implantation in the CSP position can be more challenging and requires a dedicated guiding catheter to position the pacing lead on the target site and allow proper capture of the conduction system.[2–7,11,17] The Selectra 3D guiding catheters (Biotronik SE & Co KG, Berlin, Germany) have been designed to facilitate CSP positioning of stylet-driven screw-in pacemaker leads. The present study was initiated to collect data on clinical safety, performance, and handling of the Selectra 3D catheter.

Methods

Study design

The prospective, international, multicenter, nonrandomized BIO|MASTER.Selectra 3D study evaluated the Selectra 3D catheter for the implantation of a Solia S lead in a CSP position (Biotronik SE & Co KG). The primary endpoint was freedom from serious adverse device effects (SADEs) related to the Selectra 3D catheter during 1 week of lead implantation. An external Endpoint Adjudication Committee adjudicated all potential SADEs. The major secondary endpoint was the success rate of Selectra 3D in supporting CSP lead positioning. Secondary endpoints not addressed in this acute data report are appropriate pacing and sensing during follow-up and Solia S–related SADEs.

The study was conducted in accordance with the Declaration of Helsinki, ISO14155:2011 Clinical Investigation of Medical Devices for Human Subjects, Good Clinical Practice 2011, and the corresponding national laws. The study is registered at ClinicalTrials.gov (NCT04323670). All patients provided written informed consent.

Patient selection

Patients were enrolled in the study if they had a standard indication for de novo pacemaker or cardiac resynchronization therapy pacemaker (CRT-P) implantation and were intended for a guiding catheter–based lead implantation to directly stimulate the conduction system. Patients had to be willing and able to attend on-site follow-up visits and accept Biotronik Home Monitoring.

Patients were excluded if they had any of the following conditions: atrioventricular block with either no escape rhythm or broad QRS escape rhythm, mechanical tricuspid valve prosthesis, severe tricuspid valve disease, <18 years of age, life expectancy <1 year, intolerance against dexamethasone acetate, planned cardiac surgical procedures or interventional measures within the next 6 months, or need for heart transplantation or ventricular assist device, or if they were pregnant, breastfeeding, or participating in another interventional clinical investigation.

Selectra 3D catheter and Solia S lead

The Selectra 3D is a single-use 7F guiding catheter designed to be introduced into a vein (typically, the left subclavian vein) toward the target position for a permanent pacing lead. The catheter is available in 3 different lengths (32, 39, and 42 cm) and with 3 different curves (40, 55, and 65 mm) (Figure 1).

The Solia S is a 5.6F stylet-supported endocardial pacing lead.[18,19] The electrically active fixation screw is extendable by 1.8 mm, in contrast to fixed screws in other leads for catheter-supported implantations.[17,19–21]

Study methods

Investigational sites had to have previous experience with at least 5 CSP implantations. They mainly had experience with His bundle pacing (HBP), as left bundle branch area pacing (LBBAP) was uncommon before the start of this study.[5,9,13–15]

Implantation procedures followed the clinical routine in the participating centers. The choice between HBP and LBBAP was at the discretion of the implanting physician, as was the possible switch from HBP to LBBAP or vice versa in the event of failure at the originally intended implantation site. The use of a Selectra 3D guiding catheter (choice of sheath curve and length were left to the discretion of the operator) and the use of a Solia S lead was mandatory for the first CSP implantation attempt per patient. In case of failure, any other commercially available product could be used.

The implantation technique to perform HBP or LBBAP using a stylet-driven lead has been previously described in detail and guided by product handling recommendations.[19,21,22] In brief, the 3D delivery catheter is advanced over the wire and directed to the superior border of the atrioventricular ring (in case of HBP) or through the tricuspid valve in the right ventricular cavity (in case of LBBAP) using fluoroscopic guidance. The guidewire was exchanged for the Solia S lead while maintaining the initial position of the Selectra 3D catheter. Mapping at the His bundle and right-sided septum was performed either with retracted helix (to avoid entanglement while mapping) or with extended helix, according to the operator's preference. The lead was orientated to the His bundle position guided

by the presence of sharp His bundle potentials or to the right-sided septum 1 to 2 cm below the His region if LBBAP was attempted. After determining the target position, the helix was extended (if not extended already) and the inner coil of the lead was pretensioned using the stylet insertion tool.[21] Clockwise rotations on the outer lead body allow fixation of the pacing lead in the His position or left-sided septum while ensuring that the helix remains extended in case of stylet-driven lead. Successful HBP and LBBAP were defined based on the electrocardiographic pacing responses as defined by recent consensus documents.[22] After the lead is advanced through the catheter's lumen and fixed in the target position, the catheter is slit and discarded.

A successfully implanted lead in the CSP position had to be connected to an Enitra 8 family pacemaker (single, dual, or triple chamber) (Biotronik) with Biotronik Home Monitoring activated.

Implantation time and fluoroscopy time were recorded, and adverse events were reported. After each implantation, the investigators rated the following 11 aspects of the Selectra 3D catheter handling on a 5-item scale ranging from "very poor" to "very good": catheter length, torqueability, maneuverability, form stability, lead delivery through catheter, tip control, mapping abilities, pushability, x-ray visibility, stability during slitting, and overall catheter handling with the slitter tool.

The same scale was used to rate 5 aspects of the Solia S lead, namely stylet-supported implantation, handling during screwing and fixation, torque transmission, screw length, and lead fixation.

Implanters also compared the Selectra 3D catheter with the performance of the system they had previously used for CSP lead implantation. In this comparison, the first 9 aspects of catheter handling listed previously were rated as better, the same, or worse with Selectra 3D vs the previous catheter.

Before hospital discharge, patients underwent standard pacing measurements. To allow comparisons with literature data, pacing thresholds were measured at 1.0 ms pulse width for HBP and at 0.4 ms in all other positions.[2,4,17] QRS duration during CSP was compared with the intrinsic QRS duration at baseline.

Statistical methods

For the sample size, an acute SADE rate of 3% was assumed and a hypothesis was set for the 7-day SADE-free rate to be >90%.[3,12] For a 1-sided hypothesis with an alpha of 2.5% and 90% power, a minimal sample size was 141 patients. Taking into account a dropout rate of 10%, the total calculated sample size was 157 patients.

Continuous data are reported as mean ± SD or median (interquartile range). Categorical data are reported as absolute and relative frequencies. The success rate of CSP implantation and 7-day SADE-free rate are provided with 95% confidence intervals (CIs). A P value $<.05$ was considered statistically significant. SAS statistical software version 9.4 (SAS Institute, Cary, NC) was used.

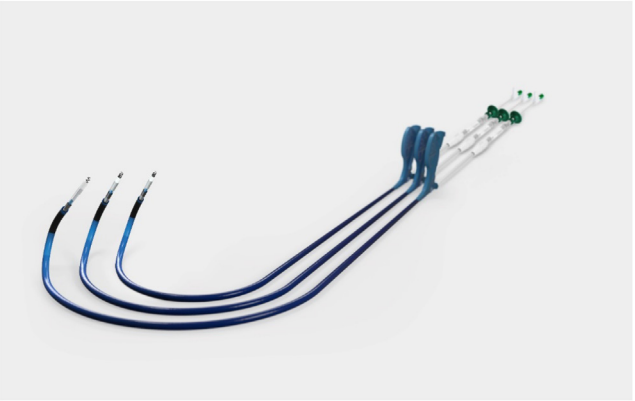

Figure 1 Selectra 3D catheters with 3 different curves: 40, 55, and 65 mm. The picture shows screw-in leads inserted in the catheters.

Results

Patients

Between October 2020 and November 2021, 157 patients were enrolled at 10 sites in 8 countries (Australia, Belgium, Czech Republic, France, Germany, Hong Kong, Italy, and the Netherlands). The patients were predominantly male (58.6%) and had a median age of 75 years (Table 1). Most patients had an indication for conventional pacemaker (96.2%; typically due to atrioventricular block or sinus node disease) and 3.8% had an indication for a CRT-P.

A dual-chamber pacemaker was implanted in 139 (88.5%) patients, a single-chamber pacemaker in 10 (6.4%), and a CRT-P in 8 (5.1%). Of the 8 CRT-P devices, 7 were connected to a CSP lead and a conventional right ventricular lead for ventricular backup pacing in case of CSP lead failure, and 1 was connected to a lead for left ventricular pacing in addition to CSP.

Implantation success and primary endpoint

In 147 of 157 CSP implantation attempts, the investigator successfully placed a Solia S lead in a position suitable for long-term CSP, corresponding to an overall success rate of 93.6% (95% CI 88.6%–96.9%). All implantations were performed exclusively with Selectra 3D catheters.

The SADE-free rate related to the Selectra 3D catheter at 7 days was 100% (95% CI 97.7%–100%).

CSP lead position

In 147 successful CSP implantations, the final lead position was suitable for LBBAP in 82 (55.8%) patients and HBP in 65 (44.2%) patients. The 82 successful LBBAP implantations resulted from 83 attempts (98.8% success); in 1 patient, a right ventricular septal (non-CSP) position was accepted after LBBAP failure. Of 119 HBP attempts, 65 (54.6%) established HBP, 45 (37.8%) were successfully switched to LBBAP, and 9 (7.6%) were switched to a right ventricular (non-CSP) position. In all patients, Solia S lead was implanted, in whatever position.

Most non-CSP implantations were reported from 2 investigational centers in which only HBP was attempted, with 8

Table 1 Baseline characteristics of study patients

Parameter	Value
Age, y	75 (69–82)
Sex	
Female	65 (41.4)
Male	92 (58.6)
Body mass index, kg/m^2	27.0 (24.5–29.0)
Ischemic heart disease	47 (29.9)
Cerebrovascular disease (stroke/TIA)	19 (12.1)
Heart failure	30 (19.1)
Hypertension	104 (66.2)
Valvular heart disease	40 (25.5)
Atrial fibrillation history	59 (37.2)
Bradycardia indication	151 (96.2)
Atrioventricular block	67 (42.7)
Sinus node disease	55 (35.0)
Bundle branch block	7 (4.5)
Other	22 (14.0)
CRT-P indication	6 (3.8)
Diabetes	46 (29.3)
Chronic renal insufficiency	25 (15.9)
Medication	
Beta-blocker	49 (31.2)
Diuretic	46 (29.3)
ACE inhibitor or ARB	81 (51.6)
Anticoagulant	57 (36.3)
Platelet aggregation inhibitor	54 (34.4)

Values are median (interquartile range) or n (%).

ACE = angiotensin-converting-enzyme; ARB = angiotensin receptor blocker; CRT-P = cardiac resynchronization therapy pacemaker; TIA = transient ischemic attack.

failures out of 14 HBP attempts. Two other centers also never attempted LBBAP, but all 23 HBP attempts were successful. One center attempted only LBBAP and failed in 1 of 28 cases. The remaining 5 investigational centers attempted both HBP and LBBAP, and failed to achieve CSP in only 1 of 92 cases.

Figure 2 shows implantation outcomes over time. Failures to achieve CSP were more frequent in the first months, when the switch to LBBAP was rare. Thereafter, the switch to LBBAP after HBP failure became more frequent and CSP success improved. In the next phase, also direct LBBAP implantations became more common.

Implantation time and lead repositionings

Table 2 summarizes total operation time and fluoroscopy time for 4 different scenarios: HBP success, direct LBBAP success, LBBAP success after HBP attempt, and CSP failure. Successful HBP and direct LBBAP implantations lasted on average ~50 minutes with fluoroscopy time ~6 minutes, with LBBAP implantations taking slightly less time than HBP implantations. LBBAP after an unsuccessful HBP attempt required more time, ~80 minutes (fluoroscopy time ~12 minutes). The fluoroscopy time in these cases was still shorter than when no CSP position was reached (~18 minutes).

In successful CSP implantations, the median number of lead positioning attempts was 2 for both HBP and direct LBBAP procedures and 3 when the implanter switched from HBP to LBBAP (Table 3). When no CSP was achieved, the median number of lead positioning attempts was 6.

Catheter use and handling evaluation

The number of Selectra 3D catheters used per procedure was 1 in 138 (87.9%) patients, 2 in 17 (10.8%) patients, and 3 in 2 (1.3%) patients. In 34 of 45 cases in which the implanter switched from HBP to LBBAP, only 1 catheter was needed. The most frequent catheter length and curve were 39 cm (84.3% of patients) and 55 mm (81.5%), respectively. There was no clear difference in length/curve selection between HBP and LBBAP. The catheter was predominantly inserted from the left side (88.6%), through the subclavian vein (52.3%), through the axillary vein (27.5%), or through the cephalic vein (16.8%).

Handling characteristics of the catheter are summarized in Figures 3A and 3B. Positive ratings largely prevailed, with "very good" in a mean over all items of 37.2% and "good" in 49.9% (total 87.1%). The best ratings were obtained for direct LBBAP attempts. Even in cases when no CSP was achieved, the ratings were generally positive (Figure 3B).

The comparison of Selectra 3D with the previously used catheters for CSP implantations is summarized in Figure 4. Implanters perceived Selectra 3D as advantageous, particularly in terms of form stability, torqueability, maneuverability, tip control, stiffness for pushability, mapping abilities, and lead delivery. In 0.6% to 4.5% of implantations, Selectra 3D showed some disadvantages compared with previous catheters.

Lead implantation details

All CSP lead implantations were performed with the support of a stylet, mostly a stylet that was not preshaped (94.9% [n =

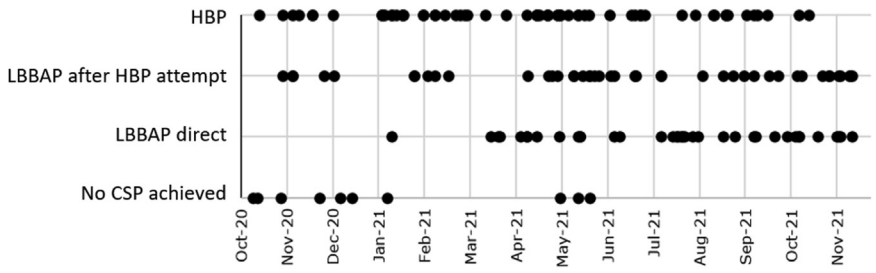

Figure 2 Implantation outcome vs day of the procedure from study beginning to study end. CSP = conduction system pacing; HBP = His bundle pacing; LBBAP = left bundle branch area pacing.

Table 2 Implantation and fluoroscopy times

Parameter	Mean ± SD (min)	Median (IQR) (min)	n
HBP implantation			65
Time to suture	53.8 ± 23.7	47.0 (35.0–70.0)	65
Fluoroscopy time	6.7 ± 4.8	5.3 (3.4–7.8)	64
Direct LBBAP implantation			37
Time to suture	47.9 ± 13.6	45.0 (37.0–57.0)	37
Fluoroscopy time	5.9 ± 3.4	5.0 (3.9–6.8)	37
LBBAP implantation after HBP attempt			45
Time to suture	80.8 ± 25.5	80.0 (60.0–90.0)	45
Fluoroscopy time	11.8 ± 8.9	8.9 (6.1–13.8)	40
Non-CSP implantation			10
Time to suture	76.9 ± 22.8	75.0 (55.0–92.0)	9
Fluoroscopy time	17.9 ± 5.8	20.0 (11.7–21.6)	9

CSP = conduction system pacing; HBP = His bundle pacing; IQR = interquartile range; LBBAP = left bundle branch area pacing.

149]) and soft version (89.2% [n = 140]). The stylet was withdrawn by ∼4 cm during lead fixation in 21 (13.4%) patients and by ∼8 cm for catheter slitting in 108 (69.7%) patients.

Figure 3C summarizes the assessment of Solia S lead by implanters. Depending on the aspect, the ratings were "good" or "very good" in 76.7% to 93.6% of patients and "poor" in 0% to 2.7%.

Procedural complications

The most serious complication related to the CSP procedure was a death from sepsis that became apparent 9 days after implantation. Other patients were diagnosed with pericarditis on day 1 (n = 1), worsening heart failure on day 2 (n = 1), and pocket infection on day 14 (n = 1) after implantation. A lead screw damage during HBP implantation in 1 patient was resolved by lead extraction and replacement. Complications not requiring intervention were temporary atrioventricular block related to HBP implantation (n = 3), asymptomatic pneumothorax (n = 2), pocket bleeding (n = 2), and pocket hematoma (n = 2). No septal perforations or septal coronary artery fistulas were reported in the case of LBBAP.

According to the classification of complications reported from the large Multicentre European Left Bundle Branch Area Pacing Outcomes Study (MELOS),[23] we observed 8 (5.1%) generic device implant–related complications and 13 (8.3%) complications related to the transseptal route of the pacing lead in all 157 procedures.

Table 3 Number of lead positioning attempts

Final CSP position	Patients	Number of attempts
HBP	65	2 (2–3)
Direct LBBAP	37	2 (2–4)
LBBAP after HBP attempt	45	3 (2–4)
Non-CSP implantation	9	6 (5–11)

Values are n or median (interquartile range).

CSP = conduction system pacing; HBP = His bundle pacing; LBBAP = left bundle branch area pacing.

CSP measurements at the predischarge control

Pacing thresholds were remarkably lower in LBBAP (mean 0.7 ± 0.3 V at 0.4 ms) than in HBP (1.1 ± 0.9 V at 1.0 ms). R-wave sensing amplitudes were also more favorable in LBBAP (mean 12.5 mV vs 7.4 mV in HBP). Pacing impedance was similar for the 2 positions (Table 4).

An atrial signal was visible in half of the patients receiving HBP, but a measurable His signal was present in only 6.7% (n = 4 of 60).

In patients without bundle branch block at baseline, the mean intrinsic QRS duration of 106 ms increased to 122 ms during CSP at the predischarge control ($P = .001$, similarly for HBP and LBBAP). In patients with bundle branch block, the mean intrinsic QRS duration of 151 ms decreased to 137 ms during CSP ($P = .004$) (Table 5). This difference was visible only in LBBAP patients and not in HBP patients.

Discussion

The main findings of the study are that CSP lead implantation using the Selectra 3D guiding catheter is safe, with no SADEs observed in the perioperative period, and that CSP can be achieved with good overall success rate (93.6% in our sample, allowing a strategy to cross over from HBP to LBBAP in case of failed HBP attempt). The catheter was used for both HBP and LBBAP implantation, and usually no catheter change was necessary when switching from a failed HBP to LBBAP attempt. Because the implanters frequently chose this switch (in 37.8% of all cases in which HBP was initially attempted), it appears that they tended to drop the HBP attempt in favor of LBBAP relatively early on. The low HBP success rate (54.6% in our study) is probably not an indication of poor catheter performance in this position, but rather is related to well-known difficulties to pace the His bundle and also driven by an increasing tendency of implanters to accept LBBAP as a more feasible option for CSP. A generally high success rate of LBBAP implantation (98.8% in our study) is an important reason for the increasing use of LBBAP in the rapidly developing field of CSP.[9,11,13,14,16,19,24]

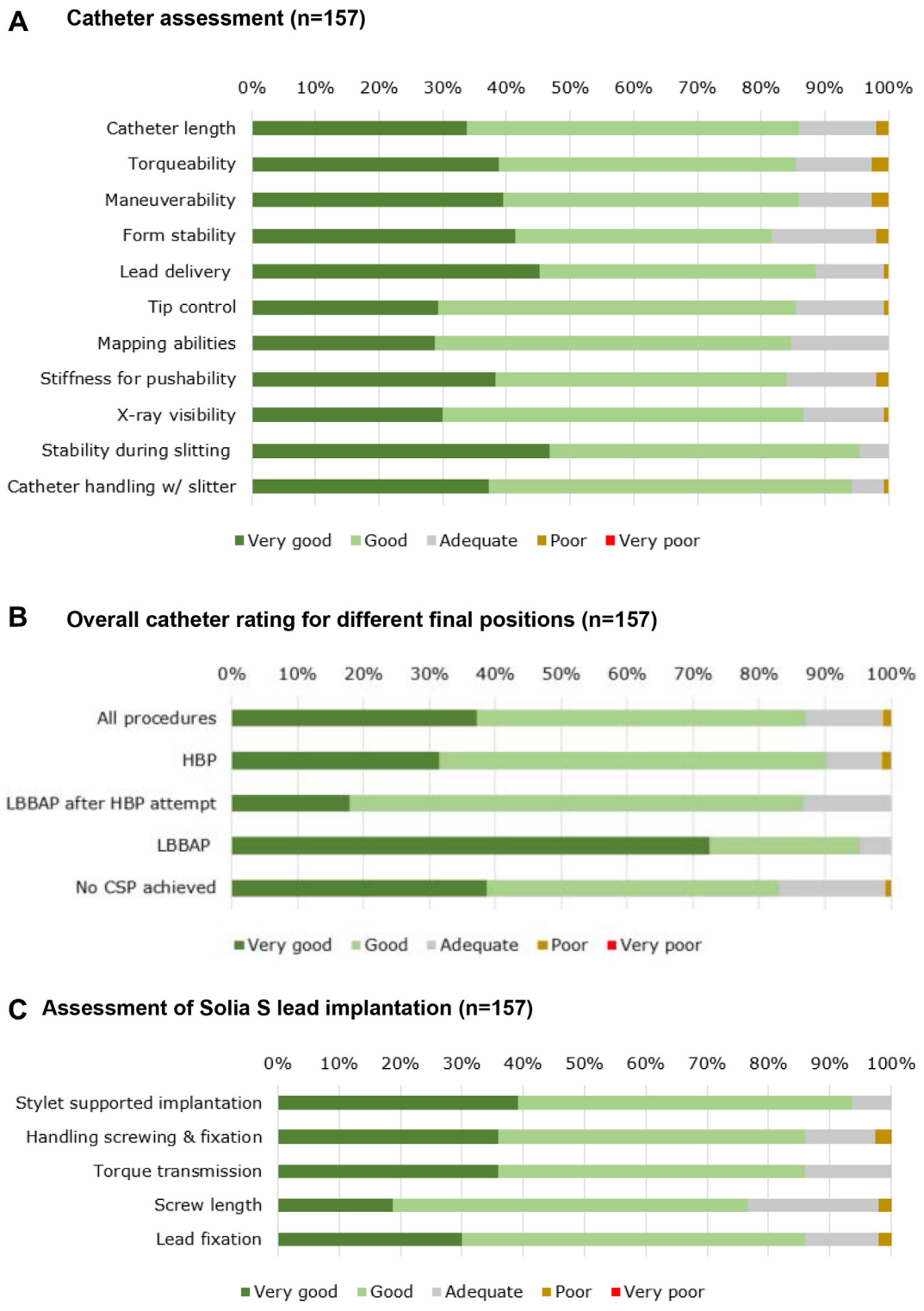

Figure 3 Handling characteristics of the Selectra 3D catheter (A, B) and Solia S lead (C) rated by implanters on a scale ranging from very good to very poor. In 19 patients in whom 2 or 3 Selectra 3D catheters were used, a single overall rating per patient was obtained. CSP = conduction system pacing; HBP = His bundle pacing; LBBAP = left bundle branch area pacing.

Excellently trained centers can achieve a higher HBP success rate than did investigational sites in our study with a limited experience (only 5 previous CSP implantations were required).[2,3,17,18,25] However, many publications reported much lower HBP implant success (63%–85%), especially in patients with left bundle branch block.[10,12,15,26,27] If CSP is to play a significant role in the world of pacing, it must be applicable outside highly specialized centers. In the present study, of the 10 cases in which no CSP could be established, 8 occurred in centers that had

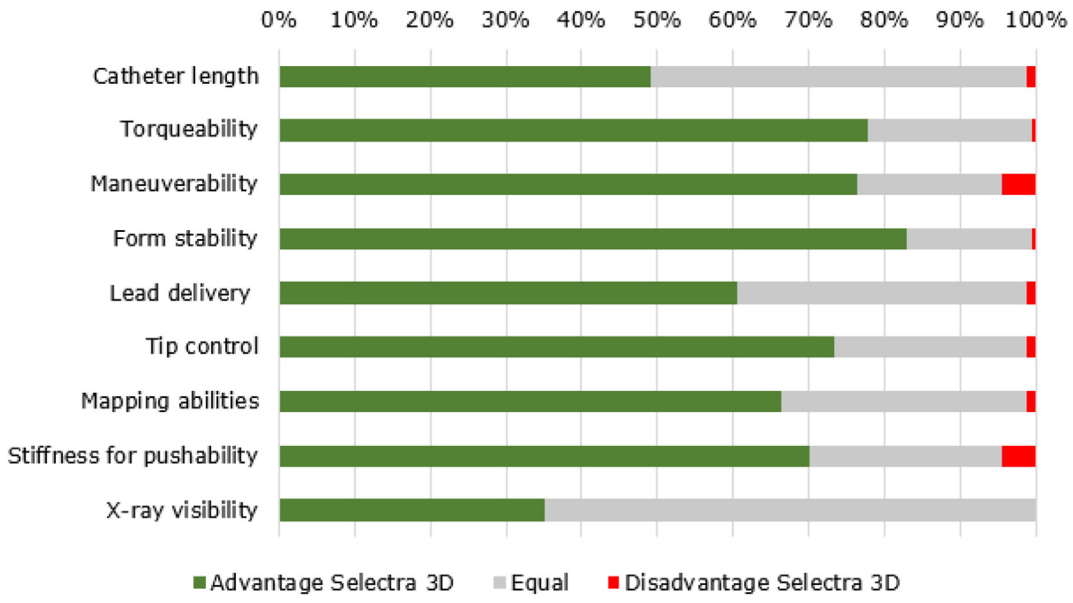

Figure 4 Comparison of implanters' experience with the Selectra 3D catheter (n = 157) and the catheters for conduction system pacing (CSP) lead implantations they had used in the past (a variety of models).

never tried LBBAP, and 1 case occurred in a center that had never tried HBP. If we look at only the 5 centers that considered both HBP and LBBAP, only 1 (1.1%) procedure did not reach a CSP position.

Successful direct LBBAP implantation was slightly faster (mean 47.9 minutes vs 53.8 minutes) and required slightly less fluoroscopy time (5.9 minutes vs 6.7 minutes) than successful HBP implantation. These values are at the lower edge of ranges published in literature for various catheters and leads (mean operation time 54.0–129.0 minutes and mean fluoroscopy time 5.2–18.0 minutes).[4,13,15,17,20,21,24,28] Among a number of other factors, also the Selectra 3D catheter may have contributed to this good result. The switch from HBP to LBBAP required an average of 30 minutes of additional operation time in our study but always resulted in successful CSP positioning. Failed HBP attempts lasted similarly whether or not there was a switch to LBBAP, but fluoroscopy duration was almost twice as long when no switch was made. This reflects a continued effort by some implanters to capture the His bundle, rather than to switch to LBBAP, which was often seen early in the study.

Implanters' assessments of catheter and lead

The Selectra 3D catheter received generally positive assessments of 11 aspects included in the questionnaire, with 82% to 95% "good" or "very good" ratings. The slight differences in ratings between the aspects suggest that stability, lead delivery, and slitting are strengths, while mapping and tip control for precise pacing/sensing site selection are more often "good" than "very good." Examining how ratings depended on the target implantation site suggests that they reflected the amount of effort required for implantation: the ratings were best in LBBAP implantations, less good in HBP cases, and worst when LBBAP was chosen as a bailout after an abandoned HBP attempt. Interestingly, the ratings in HBP attempts did not differ much between the 2 opposite outcomes: HBP success vs no CSP position achieved (9 of these 10 cases attempted HBP only). This implies that the lack of success was not attributed to the catheter. When implanters compared the study catheter with a previously used CSP delivery catheter, the Selectra 3D was judged predominantly favorably.

The handling of the Solia S lead was rated "good" or "very good" in about 85% of cases. This stylet-supported lead with

Table 4 CSP lead measurements before patient discharge

Lead parameter (bipolar configuration)	Mean ± SD	Median (IQR)	n
HBP			65
Pacing threshold, V at 1.0 ms	1.1 ± 0.9	0.7 (0.4–1.8)	64
Pacing impedance, Ω	575 ± 144	526 (487–624)	65
R-wave amplitude, mV	7.4 ± 4.2	7.3 (3.5–10.5)	61
LBBAP			82
Pacing threshold, V at 0.4 ms	0.7 ± 0.3	0.6 (0.5–0.8)	76
Pacing impedance, Ω	593 ± 69	585 (546–624)	81
R-wave amplitude, mV	12.5 ± 4.7	11.8 (8.4–15.6)	81

CSP = conduction system pacing; HBP = His bundle pacing; IQR = interquartile range; LBBAP = left bundle branch area pacing.

Table 5 QRS duration at baseline (intrinsic) and before hospital discharge (CSP)

Patient group	Patients	QRS type	QRS duration		*P* value
			Mean ± SD	Median (IQR)	
All patients					
No BBB	86	Intrinsic	106 ± 22	103 (89–119)	<.001
		CSP	122 ± 30	120 (100–141)	
BBB	44	Intrinsic	151 ± 22	151 (139–164)	.004
		CSP	137 ± 23	135 (120–150)	
HBP					
No BBB	41	Intrinsic	103 ± 21	97 (86–112)	.01
		CSP	118 ± 31	117 (92–132)	
BBB	17	Intrinsic	148 ± 31	142 (120–164)	.90
		CSP	150 ± 26	150 (130–160)	
LBBAP					
No BBB	45	Intrinsic	109 ± 23	106 (92–125)	.007
		CSP	124 ± 29	120 (104–142)	
BBB	27	Intrinsic	154 ± 16	152 (144–162)	<.001
		CSP	130 ± 17	131 (120–144)	

BBB = bundle branch block; CSP = conduction system pacing; HBP = His bundle pacing; IQR = interquartile range; LBBAP = left bundle branch area pacing.

a retractable screw is necessarily thicker than the lumenless fixed-screw lead mainly used in catheter-assisted CSP implantations. However, our results with Solia S (handling characteristics, evaluation of stylet-supported implant, helix length and lead fixation, pacing and sensing values) support the results of the published literature that this lead type is suitable for CSP.[14,16,17,19,21] The high success rate in our study was achieved with the combination of Selectra 3D catheter and the Solia S lead.

Lead measurements and QRS duration

At the predischarge control, LBBAP pacing threshold and sensing amplitudes were comparable to values known for conventional right ventricular pacing but were more challenging in HBP cases, confirming existing literature.[6,9,11–15,19] The fact that pacing thresholds are high enough to limit pacemaker battery life in a significant proportion of HBP cases is another reason for the preference of LBBAP by many implanters nowadays.[13–15]

Before patient discharge, QRS duration during pacing was similar for HBP and LBBAP. Overall, CSP leads to a wider QRS complex than during intrinsic rhythm in patients without bundle branch block and a shorter QRS complex than intrinsic in patients with bundle branch block. The latter was much more pronounced in LBBAP than in HBP. We have 2 possible reasons to explain this finding. First, because the QRS duration was measured from the pacing stimulus to the end of the QRS, a long stimulus-to-QRS interval may have contributed to an overall longer stimulus-to-end QRS interval. Second, it is known that correction of pre-existing bundle branch block is more difficult to achieve in HBP than in LBBAP due to the more proximal stimulation site in HBP. Although the present study made no direct comparisons, it is well known that CSP shortens QRS duration compared with traditional right ventricular pacing sites, which is the main reason for the increasing use of CSP.[2–4,6,9,12]

Taken together, our results confirm the notion that LBBAP may be preferred over HBP due to higher implantation success rates and better pacing and sensing performance.[9,11–15] However, late complications and long-term pacing performance must be considered before such a conclusion can be justified.[8,12–15]

Procedural complications

In contrast to conventional pacing, CSP requires a dedicated guiding sheath to target the pacing lead toward the His bundle area or basal septum. Therefore, sheath-related complications of CSP are difficult to compare to historical cohorts using conventional pacing sites. The recent observational MELOS registry reported a 8.3% complication rate related to the transseptal route during LBBAP implantation and an additional 3.5% complication rate attributed to generic device implant–related complications. However, the MELOS registry only included LBBAP and did not focus on guiding sheath-related complications. In the present study, the generic device–related complication rate was 8.3%, the specific CSP-related complication rate was 5.1%, and the guiding sheath–related complication rate was 0%.

Study limitations

The fact that we did not include a control group with standard right ventricular pacing leads prevents a direct comparison of implantation success, duration, and complications with traditional implantations. Our study is also not suitable for comparing outcomes in the His bundle and left bundle branch area positions because the assignment was not randomized and some investigational sites used only 1 of the 2 options, introducing a center bias. Furthermore, for the decision which of the 2 options is preferable, the long-term results will be most relevant.

Conclusion

The Selectra 3D catheter is a valuable tool for implantation of the stylet-supported Solia S pacemaker leads in both the His bundle position and the left bundle branch area. The catheter handling characteristics were rated positive and lead implantation was successfully completed in 93.6% of patients. In centers where implanters considered switching between the HBP and LBBAP, the success rate was nearly 99%. Flexibility to change between different approaches and techniques may be a driver for success in heterogeneous and challenging areas, such as CSP implantations.

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