

Initial Experience of Left Bundle Branch Pacing using the Abbott Agilis HisPro Catheter with stylet-driven leads

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Abstract

Aims Conduction system pacing has gained steady interest over recent years. While the majority of tools and delivery techniques were developed for His bundle pacing (HBP), the feasibility and reproducibility of using these similar tools for left bundle branch pacing (LBBP) has yet to be determined. We describe our technique for performing LBBP using the Abbott Agilis HisPro™ Steerable Catheter. Methods and results A series of 22 patients with a mean age of 71.7 years (16 males, 72.7%), underwent LBBP procedure with this catheter between May and October 2021. Nineteen patients (86%) had successful LBBP lead implantation. There were no major complications or mortality. Conclusion The Agilis HisPro™ catheter along with the stylet driven Tendril STS Model 2088TC lead is a safe and feasible delivery system for LBBP.

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Aims

Conduction system pacing has gained steady interest over recent years. While the majority of tools and delivery techniques were developed for His bundle pacing (HBP), the feasibility and reproducibility of using these similar tools for left bundle branch pacing (LBBP) has yet to be determined. We describe our technique for performing LBBP using the Abbott Agilis HisProTM Steerable Catheter.

Methods and results

A series of 22 patients with a mean age of 71.7 years (16 males, 72.7%), underwent LBBP procedure with this catheter between May and October 2021. Nineteen patients (86%) had successful LBBP lead implantation. There were no major complications or mortality.

Conclusion

The Agilis HisProTM catheter along with the stylet driven Tendril STS Model 2088TC lead is a safe and feasible delivery system for LBBP.

Word count: 128 words (limit 250 words)

Key words: Conduction system pacing; Left bundle branch pacing (LBBP); Agilis HisPro; Technique

Introduction

Since it was first described in 2000, His bundle pacing (HBP) as an alternative pacing site has gained interest steadily worldwide¹. The introduction of new tools, and the resultant improvement in implantation success rates only spurs this growth, with its adoption as a routine procedure in many centers. While providing a more physiological form of pacing is a strong indicator for HBP, it does have its limitations; the area to land the lead is often small and difficult to target, capture thresholds are higher, sensing issues are not uncommon, and the risk of developing distal atrioventricular block would necessitate the implantation of a “backup” right ventricular lead^{2,3,4,5}.

To address some of the issues faced in HBP, Left Bundle Branch pacing (LBBP) has emerged as an attractive alternative. By screwing deep into the septum, distal to the His bundle and capturing the left bundle branch in the process, the pacing parameters are often excellent. The target area to land the lead is also larger and easier to locate, and the development of distal atrioventricular (AV) block will no longer be an issue.

The current approach for LBBP relies heavily on the existing tools developed primarily for HBP. While these tools may prove adequate for HBP, its suitability for LBBP has yet to be determined. Issues such as the reach and support provided by the sheaths, torque transmission when the lead body is rotated, lead tip behavior (both fixed and retractable stylet driven leads) during deep septal lead deployment, lead stability and long-term lead performance remains to be determined.

We describe our method for performing LBBP using an Electrodes incorporated steerable (EIS) catheter (Abbott Agilis HisProTM), including maneuvers we adopted to overcome issues such as reach, torque transmission, and helix retraction in a stylet driven lead system.

Procedure description

Once vascular access is obtained, a guidewire is advanced into the right atrium (RA) or right ventricle (RV). A short 10.5F sheath is advanced over the wire to retain access. The EIS catheter is prepared normally. With the dilator inserted, the EIS catheter shaft can then be shaped for LBBP. The distal end of the EIS catheter, when maximally deflected forms two 90° deflections. The distance between the first deflection to the second 90° deflection is approximately 40.5±6.0 mm. While this distance has proved adequate for reaching the His bundle, it is too short for crossing the tricuspid valve and reaching the RV septum. Reshaping the EIS catheter proximal to the second deflection would extend our reach beyond the tricuspid valve, and in close proximity to our intended septal target. The further addition of a septal curve would allow us to

maintain a perpendicular catheter orientation to the RV septum (Figure 1). The distal 25 mm of the IS-1 pacing lead (Tendril STS Model 2088TC) is stiff and non-deflectable, the septal curve can only be effective proximal to this point. Any attempts at introducing the septal curve in the distal 25 mm of the catheter would inevitably result in straightening of the shaped septal curve when the lead is introduced. Shaping the septal curve should thus be performed only between the first and second deflection of the EIS catheter, as this point falls between 3 - 7 cm of the lead tip when the lead is fully inserted.

Using a 0.035-inch guidewire, the entire assembly comprising the reshaped dilator and EIS catheter is advanced into the RA. The introducer and guidewire are then removed, followed by the introduction of a 58cm IS-1 pacing lead, which is advanced to the tip of the sheath. At this point, the distal tip of the lead need not be exposed beyond the sheath as the EIS catheter allows for both mapping and pacing via the distal platinum iridium electrodes.

The EIS catheter is connected to Merlin pacing system analyzer (PSA), and an electrophysiology recording system via the supreme electrophysiology cable and the use of stacked wires. The lead can also be connected in a unipolar fashion using threshold cables and stacked wires. The His bundle location can be mapped by using the EIS catheter and an X-Ray reference image set. Care should be taken during manipulation of the catheter in the RA, and inadvertent coronary sinus cannulation avoided by paying close attention to electrographic signals from the EIS catheter as well as fluoroscopic images.

The initial site for LBBP is approximately 1 to 1.5 cm distal to the His bundle location, in the RV septum along the line between the His bundle site and the RV apex in the right anterior oblique (30°) view. Advancing the reshaped catheter and with slight un-deflection would allow us to reach this area. Gentle counterclockwise rotation, and with the aid of the reshaped septal curve, a perpendicular septal orientation can be obtained (Figure 2).

The exact orientation of the EIS catheter to the septum should be determined in the left anterior oblique (30°) view. A more perpendicular septal orientation can be achieved by further un-deflecting and retracting the catheter, while maintaining gentle counterclockwise torque of the catheter. Pacing using the EIS catheter is then performed before lead fixation, with the aim of demonstrating a “w” pattern with a notch at the nadir of the QRS in lead V1, and discordant QRS morphology in the inferior leads (R in II taller than III), and in leads aVR/aVL (negative in aVR, positive in aVL, Figure 3A). The lead is advanced slightly beyond the sheath, and the helix extended. Unipolar pacing can be performed at this stage, and the pacing impedance documented.

Penetration of the lead into the septum can be achieved by rotation of the lead body. Unique to the EIS catheter, there are two specific points of resistance for effective transmission of torque to the lead tip; (1) the resistance incurred at the hemostasis valve on the lead body, which can be overcome with the insertion of the bypass tool (Figure 4A). Gentle forward pressure on the lead is required once the bypass tool is inserted to maintain pressure of the lead tip against the septum, (2) the two 90° deflection points can create resistance as well, especially when the stylet is fully inserted. This can be overcome by retracting the stylet proximal to both deflections (~9 to 10 cm, Figure 4B). The IS-1 pacing lead, with support from the sheath, has enough stiffness to allow for forward pressure to be applied and effective septal penetration without the need of a fully inserted stylet for support.

Clockwise rotation of the lead can be applied 3-4 turns at a time. The helix will inadvertently be retracted when the lead body is rotated clockwise (which can be confirmed with fluoroscopy). This can be overcome by re-extending the helix using the clip-on tool. Failure to re-extend the helix at this stage would lead to inadvertent lead dislodgement (Figure 5). The maneuver of lead body rotation and helix re-extension is repeated until the desired depth is achieved, and left bundle capture can be confirmed using previously described pacing techniques⁶ (Figure 3).

If perforation of the LV occurs, the lead should be withdrawn and repositioned. Withdrawing the lead should be done with counterclockwise rotation of the lead body while the helix is still extended. Retracting the helix prior to withdrawing of the lead body from the septum would entrap the helix in an extended position. The

helix should be retracted only when the lead is fully withdrawn into the sheath.

Once the lead is in position, the catheter can be removed. The lead with the stylet still retracted is advanced to allow for adequate slack, while un-deflecting and retracting the sheath. The slitter tool has a unique lead stabilization channel that cups the lead and engages the shaft of the sheath. The slitter tool with the cupped lead can then be advanced into the hemostasis valve before engaging the lead into the lead retention channel on the slitter tool. The rest of the lead can then be guided into the thumbpad groove and secured with your thumb. The shaft of the catheter is aligned to the slitter tool reference line, and the catheter slit with a smooth axial motion.

Case series

A total of 22 patients underwent LBBP using the EIS catheter in National Heart Centre Singapore between May 2021 and October 2021. These included 21 pacemakers (4 patients with symptomatic sinus node dysfunction, 6 Tachy-Brady syndrome, 11 patients with high grade AV nodal conduction disease), and 1 cardiac resynchronization therapy devices. The mean age of patients were 71.7 years and 16 (72.7%) were males. Baseline patient characteristics are shown in Table 1.

A total of 19 (86%) LBBP was successfully performed out of 22 patients. There were 3 unsuccessful LBBP attempts:

1. Patient 8 is a 75-year-old male with ischemic cardiomyopathy and left bundle branch block (LBBB) on baseline ECG. Attempts at LBBP in multiple positions did not result in a satisfactory narrowing of the QRS, suggesting that the conduction delay likely occurred distal to the septal LBB. An Abbott Quartet™ Quadripolar Traditional S-shape 86 cm coronary sinus lead was positioned in the lateral branch of the coronary sinus. Biventricular (BiV) pacing with SyncAV programmed on, resulted in a BiV paced QRS of 103 ms.
2. Patient 15 is a 74-year-old female with symptomatic complete heart block (CHB). There was initial successful LBBP implantation with a non-selective LBBP QRS of 115 ms. Lead dislodgement occurred within 24 hours, necessitating lead revision and conversion to a conventional RV mid-septum pacing lead position.
3. Patient 20 is a 79-year-old female with symptomatic tachy-brady syndrome. Repeated initial attempts at LBBP yielded unacceptably high pacing thresholds (the patient was on a Vaughan William Class 1C agent for rhythm control). The final position with acceptable pacing and sensing threshold likely captured only the left ventricular septum (paced QRS 130 ms, at both high and low outputs).

Discussion.

Our experience with the EIS catheter demonstrated its feasibility as a delivery system for LBBP. The catheter was originally designed as an effective delivery system for HBP, but with several simple but crucial modifying steps, it can be effectively adopted for LBBP:

1. Reshaping the catheter to allow for an extended reach and a septal curve.
2. The use of the bypass tool and retracting the stylet to allow for adequate transmission of torque to the lead tip.
3. Close attention to helix retraction during lead body rotation, and re-extension of the helix as necessary.

Failure to perform LBBP occurred in 3 patients, predominantly in the early phase of adopting the catheter for LBBP. The lessons learnt during these failed attempts, as well as lessons from porcine in vitro experiments, allowed us to formulate steps to overcome the inherent pitfalls of this catheter:

1. Without reshaping the catheter, it would not have enough reach to cross the tricuspid valve and arrive at the RV target septal area for LBBP. Without the addition of a septal curve, the sheath and the lead would have an oblique orientation to the RV septum, resulting in a longer (obliquely and superiorly directed) transseptal track to the LBB area. The majority of the failed attempts occurred because the

catheter simply could not reach the target area, and if it could, the oblique trajectory resulted in poor pacing outcomes (LV septal pacing).

2. Without the bypass tool and retracting the stylet, application of torque on the lead body would result in lead spiraling and insulation wrinkling, without further penetration of the septum, as torque is not transmitted to the lead tip.
3. Helix retraction during lead body rotation would result in lead dislodgement, often at the time of septal penetration. By re-deploying the helix, we can avoid dislodgements.
4. Repositioning of the lead, if required, should be performed by first rotating the lead body with the helix still extended. Attempts at retracting the helix with the lead buried deep in the septum would result in entrapment of myocardial tissue in the helix, damaging the lead tip, or trapping the lead tip in the septum, or both.

Conclusion

In our experience, LBBP using the EIS catheter, and the stylet driven IS-1 pacing lead is safe and feasible in routine clinical practice. The learning curve involved in adopting this delivery system is gentler, as it utilizes two existing platforms: namely the Agilis steerable introducer commonly used in electrophysiology studies, and stylet driven leads. The ability to shape, as well as to vary the deflection of the catheter would allow for better success rates at LBBP, especially in patients with challenging anatomies.

Conflict of interest: None declared

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Figures

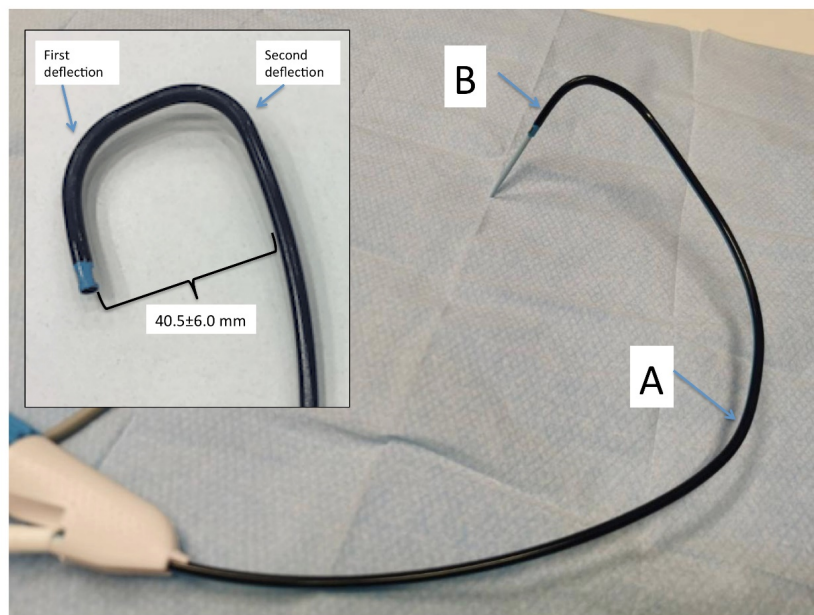


Figure 1: At maximal flexion, the Agilis HisProTM catheter forms two 90° deflections. Reshaping the catheter proximal to the second deflection (A), and the addition of a septal curve distal to the first deflection for LBBP (B).

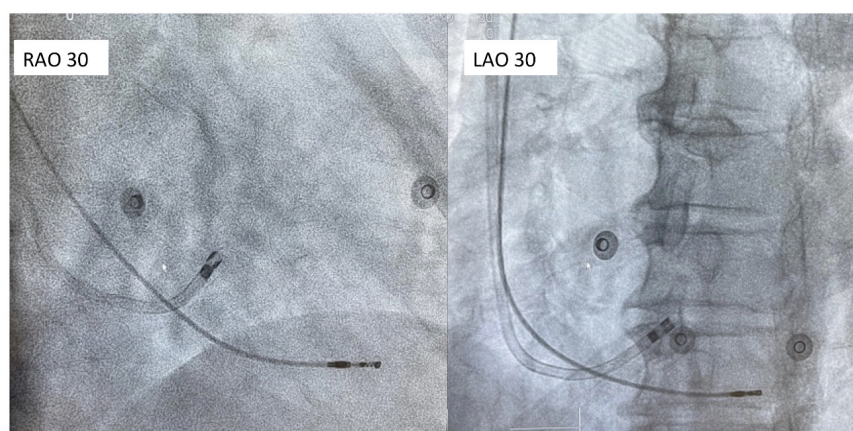


Figure 2: A 52 cm IS-1 pacing lead is used as back up pacing wire in the right ventricle. This will be used as the atrial lead eventually. Right anterior oblique (RAO) 30° and left anterior oblique (LAO) 30° view of the EIS catheter at the RV septum approximately 1 to 1.5 cm distal to the His bundle location, along the

line between the His bundle site and the RV apex.

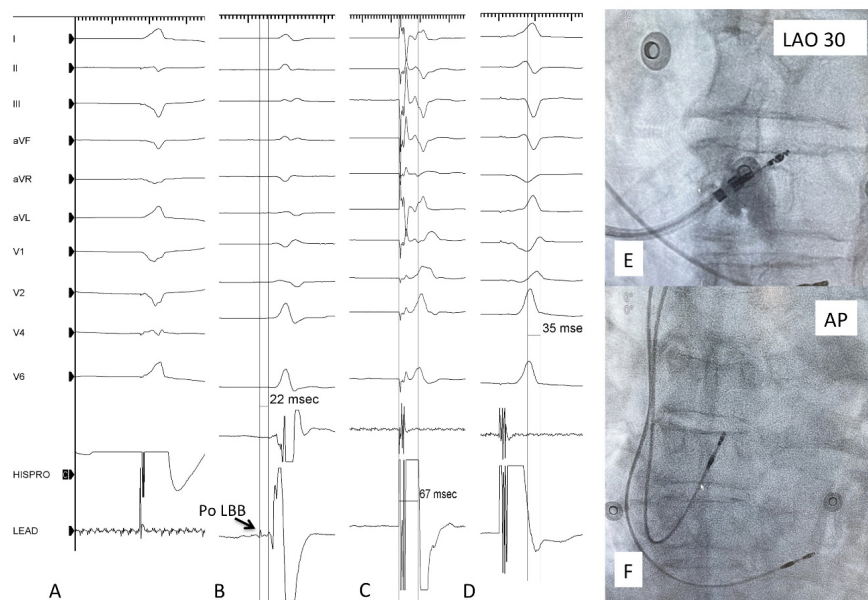


Figure 3: A: Pacing from the EIS catheter demonstrating a “w” pattern with a notch at the nadir of the QRS in lead V1, and discordant QRS morphology in the inferior leads (R in II taller than III), and in leads aVR/aVL(negative in aVR, positive in aVL). B: Unipolar recording of Left Bundle Branch potential in the lead (Po LBB). C: Stimulus-peak Left Ventricular Activation Time (Stim-LVAT) of 67 ms is constant at both high and low outputs. D: V6-V1 interpeak interval of 35 ms is recorded during non-selective LBB capture⁶. E: Left Anterior Oblique view (LAO 30°) septogram demonstrating depth of septal penetration of the lead. F: Final Anterior-Posterior (AP) view of the right atrial and LBB pacing leads.

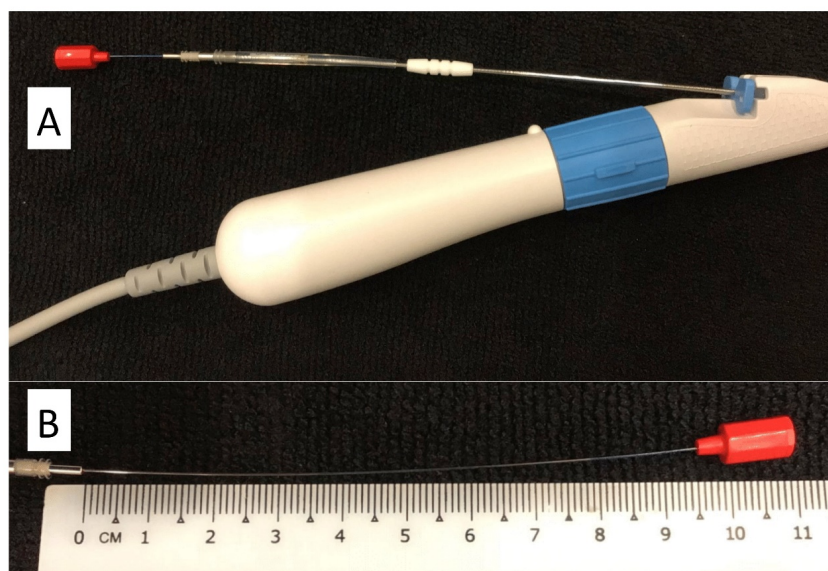


Figure 4: Maneuvers to ensure transmission of torque to lead tip for septal penetration during lead body rotation: A, Agilis HisPro™ catheter with lead and bypass tool inserted at the hemostasis valve. B, retraction of the stiff stylet to a distance of 9 - 10 cm from the lead pin, would ensure the stylet tip is now proximal to the two 90° deflections formed by the sheath.

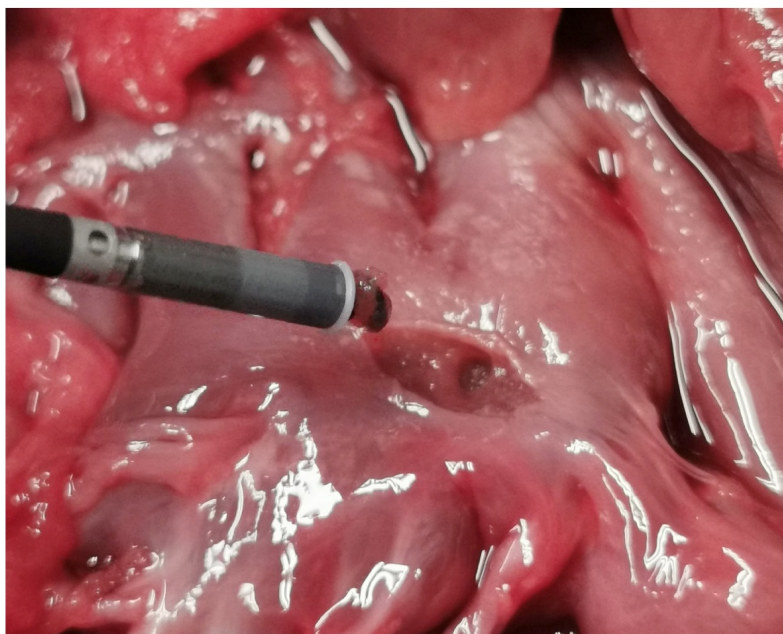


Figure 5: In vitro experiment with IS-1 pacing lead in a porcine heart. Attempts at septal penetration by torquing the lead body without re-extending the helix. Note retraction of the helix with only 1 turn of the

helix extending beyond the mapping collar of the lead. There is resultant tearing and retention of a small amount of myocardial tissue at the helix. Inadvertent lead dislodgement occurs, with a shallow lead tract demonstrated in the myocardium.

Table 1: Baseline characteristics, ECG and procedural details of all patients who underwent LBBP utilizing our technique

Patient	Clinical demographics	Clinical physiographics	Clinical physiographics	Clinical physiographics	Clinical physiographics	ECG	ECG	ECG	Procedural details	Procedural details	Procedural details	Procedural details	Procedural details
	Age (y)	Sex	PPM indi- ca- tion	Significa- Co- mor- bidi- ties	LVEF (%)	AF	Underly- BBB	Baseline QRSd (ms)	Procedural time, PT/ Fluo- ro- scopic time, FT (min)	Unipolar Impedance (ohms)	Bipolar threshold (mV)	R wave (mV)	LVA (ms)
1	60	Male	SSS	HTN, HLD	69	Yes	RBBB	129	PT: 120 FT: 28	650	0.8V @ 1ms	5.5	55
2	56	Male	CHB	IHD, MVP with severe MR s/p MV repair	60	Yes	Nil	100	PT:180 FT: 76.35	860	1.1V @ 1ms	7.7	70
3	69	Female	SSS	HTN, HLD, NICMP	48	Yes	Nil	88	PT: 150 FT: 49.5	996	1.1V @ 1ms	3.6	58
4	84	Male	CHB	DM, HTN, HLD	50	Yes	RBBB	159	PT:160 FT: 46.08	540	1.4V@ 0.5ms	4.7	80
5	72	Male	2:1 AVB	DM, HTN, HLD, prior CCF, CKD	65	No	Nil	98	PT:120 FT: 21.44	600	1.0V @ 0.5ms	8	60
6	62	Male	CHB	HLD, Severe AS s/p SAVR	62	No	LBBB	147	PT:80 FT: 16.12	480	0.8V @ 0.5ms	10	65

	Clinical demographic	Clinical physiographic	Clinical physiographic	Clinical physiographic	Clinical physiographic	ECG	ECG	ECG	Procedural details	Procedural details	Procedural details	Procedural details	Procedural details
7	58	Male	CHB	HTN, HLD, IHD, LA myx- oma s/p excision	35	No	LBBB	130	PT: 100 FT: 24.2	490	0.5V @ 0.4ms	7	75
8+	75	Male	CRT	HTN, HLD, IHD	15	Yes	LBBB	150	PT: 231 FT: 75.25	670	0.6 @ 0.4ms	10.9	N/A
9	69	Female	2:1 AVB	DM, HTN, HLD	63	No	RBBB + LAFB	131	PT: 80 FT: 13.02	800	0.6V @ 0.4ms	5.2	60
10	73	Male	2:1 AVB	DM, HLD, prior CCF	65	No	Nil	116	PT: 70 FT: 16.36	716	1.0V @ 1ms	9	70
11	67	Male	Tachy- brady	HTN, Per- sistent L sided SVC	64	Yes	Nil	105	PT: 115 FT: 38.34	890	0.4V @ 0.5ms	11	50
12	80	Male	SSS	HTN, HLD, IHD, CKD	63	Yes	Nil	98	PT: 90 FT: 27.1	530	0.5V @ 0.4ms	12	60
13	78	Female	Tachy- brady	DM, HTN, CKD, prior L breast Ca s/p SMAC	63	Yes	Nil	89	PT: 120 FT: 16.16	769	1.0V @ 0.5ms	9.3	70
14	77	Male	Tachy- brady	DM, HTN, HLD, NICMP	43	Yes	LAFB	108	PT: 150 FT: 34.54	650	0.75V @ 0.4ms	8	80
15+	74	Female	CHB	Bilateral visual impairment	64	No	Nil	114	PT: 120 FT: 15.29	652	0.7V @ 0.4ms	12.2	70

	Clinical demographic	Clinical phenotype	Clinical phenotype	Clinical phenotype	Clinical phenotype	ECG	ECG	ECG	Procedural details	Procedural details	Procedural details	Procedural details	Procedural details
16	73	Male	Tachy- brady	Nil	54	Yes	Nil	90	PT: 60 FT: 9.27	638	0.4V @ 0.4ms	7.7	60
17	92	Female	CHB	HTN, HLD, IHD, severe AS s/p TAVI	62	Yes	Alternating LBBB/ RBBB	147	PT: 92 FT: 13.11	558	0.4V @ 0.4ms	5.2	65
18	88	Female	Tachy- brady	DM, HTN, HLD, IHD, CKD	49	Yes	LBBB	142	PT: 60 FT: 6.21	500	0.6V @ 0.4ms	9	50
19	67	Male	CHB	DM, HTN, IHD	65	No	RBBB + LAFB	152	PT: 110 FT: 29.26	693	0.6V @ 0.4ms	5.9	62
20+	79	Female	Tachy- brady	HTN, HLD	59	Yes	Nil	106	PT: 130 FT: 23.5	543	1.7V @ 1ms	5	80
21	71	Male	CHB	DM, HTN, HLD, IHD,	55	No	RBBB	136	PT: 120 FT: 22.3	790	0.8V @ 0.4ms	12	65
22	69	Female	SSS	MVP with mod MR, mod- severe TR	65	Yes	Nil	83	PT: 130 FT: 30.4	559	0.6V @ 0.4ms	11.6	65

AF, atrial fibrillation; AS, aortic stenosis; AVB, atrioventricular block; BBB, bundle branch block; BiVp, biventricular pacing; Ca, cancer; CCF, prior congestive cardiac failure; CHB, complete heart block; CKD, chronic kidney disease; CRT, cardiac resynchronization therapy; DM, diabetes mellitus; ECG, 12 lead electrocardiogram; HLD, hyperlipidemia; HTN, hypertension; ICD, implantable cardiac defibrillator; IHD, ischemic heart disease; IVCD, intraventricular conduction delay; LA, left atrium; LAFB, left anterior fascicular block; LBBP, left bundle branch pacing; LBBB, left bundle branch block; LV, Left ventricle; LVEF, left ventricular ejection fraction; min, minutes; MR, mitral regurgitation; ms, milliseconds; mV, millivolts; MV, mitral valve; MVP, mitral valve prolapse; NICMP, non-ischemic cardiomyopathy; PPM, permanent pacemaker; QRSd, QRS duration; RBBB, right bundle branch block; RV, right ventricle; s/p, status post; SAVR, surgical aortic valve replacement; SMAC, simple mastectomy and axillary clearance; SSS, sick sinus syndrome; SVC, superior vena cava; Tachy-brady, tachycardia bradycardia syndrome; TAVI, transcatheter aortic valve implantation; TR, tricuspid regurgitation; VT, ventricular tachycardia.

+ Reason for each unsuccessful LBBP attempt has been previously described in the “Case Series” section.