Permanent His-bundle pacing using stylet-directed, active-fixation leads placed via coronary sinus sheaths compared to conventional lumen-less system

Michael V. Orlov, MD, PhD,*† David Casavant, MS,‡ Ioannis Koulouridis, MD, MS,*† Mikhail Maslov, MD,*,† Aharon Erez, MD,*,† Amy Hicks, RT,* Ahad Jahangir, MS,* Joe Aoun, MD,*,† John V. Wylie, MD*†

From the *Department of Medicine, Division of Cardiology, Section of Electrophysiology, Steward St. Elizabeth’s Medical Center, Boston, Massachusetts, †Department of Medicine, Tufts University School of Medicine, Boston, Massachusetts, and ‡Boston Scientific, Marlborough, Massachusetts.

BACKGROUND The use of coronary sinus (CS) sheaths to deliver stylet-driven leads (SDLs) for His-bundle pacing (HBP) has not been described. Conventionally, HBP is achieved using a stylet-less lead delivered through a customized catheter.

OBJECTIVE The purpose of this study was to characterize the acute and early-term HBP experience with stylet-driven, active-fixation leads delivered through CS sheaths compared to the conventional approach.

METHODS Delivery of Medtronic 4471 and 7742 SDLs was attempted in 27 patients. Delivery was facilitated using CS guide catheters and custom-shaped stylets. Procedural characteristics and lead performance were compared to those of a group of 17 patients in whom delivery of 3830 lumen-less leads (LLLs) was attempted. Patients had heterogeneous pacing indications.

RESULTS HBP with SDL was successful in 24 of 27 patients (89%) compared to 15 of 17 patients (88%) in the LLL group. Mean procedural and fluoroscopy times in the SDL and LLL groups were 129 ± 43 minutes vs 104 ± 43 minutes and 9.6 ± 5.2 minutes vs 8.3 ± 5.0 minutes, respectively (both P = NS). There was a significant difference in procedure and fluoroscopy times within the SDL group between the first and second halves of the series, probably secondary to a learning curve. Acute HBP thresholds were higher with SDL than with LLL (2.6 ± 1.5 V vs 1.5 ± 1.2 V; P = .02) and remained stable at 8.4 ± 5.3 months. Both SDLs exhibited similar pacing thresholds. Two crossovers between groups occurred (1 in each group). Four patients with SDL and 1 patient with LLL exhibited high thresholds during follow-up.

CONCLUSION Permanent HBP using stylet-driven, active-fixation leads delivered through conventional CS sheaths is feasible. Procedural characteristics and lead performance were clinically acceptable.

KEYWORDS Active fixation lead; Coronary sinus sheath; Electrophysiology; Fluoroscopy; His-bundle pacing

Introduction

Direct His-bundle pacing (HBP) was first described in 1967 in open chest canines by Scherlag et al.1 The same group later reported the acute hemodynamic benefit of HBP2 and the ability to percutaneously pace the His bundle (HB) in man.3 In 1978, transvenous distal HBP capture to bypass bundle branch block and narrow the QRS was reported in 7 patients and led to the concept of longitudinal dissociation.4

Permanent His-bundle pacing (PHBP) in man was first reported in 2000 by Deshmukh et al.5 An independent report closely followed.6 In both series, conventional stylet-driven pacing leads were guided by an electrophysiological mapping catheter with a success rate of 67%. In 2006, Zanon et al7 reported the first use of the model 3830 (Medtronic, PLC, Dublin, Ireland) 4.1F, lumen-less lead (LLL) delivered through the model C304 deflectable guide catheter (Medtronic). The success rate was >90%. Deliverability of the 3830 lead to the anterior septum for HBP was further facilitated by the specifically shaped model C315 guide catheter (Medtronic).8,9

Recent reports have demonstrated a high degree of success in bypassing intra- and infrahisian conduction block, including left bundle branch block (LBBB) with a pacemaker lead.10–14 Moreover, patients with a pacemaker indication have shown improved clinical response and greater 5-year survival with PHBP compared to right ventricular (RV) pacing.15 In patients with heart failure and LBBB, PHBP has

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been shown to achieve cardiac resynchronization therapy (CRT),11,16–21 and some investigators have suggested PHBP as first-line therapy.21,22 Detailed how-to publications8,9,23 and a recent guidance publication have further contributed to adoption of PHBP use.24

Although the “stylet-less” 3830 lead and the C315/C304 guide catheter family have been used in >99% of PHBP cases, its ability to adapt to anatomic variations (eg, dilated right atrium, superior right-sided venous approach) is limited. The purpose of this study was to determine whether stylet-driven leads (SDLs) delivered through various shaped coronary sinus (CS) guide catheters are a viable alternative.

Methods
Between April 2017 and November 2018, HBP was attempted in 44 patients (27 male and 17 female; age 78 ± 11 years) by a single operator without previous HBP experience (Figure 1). Due to restricted availability from the manufacturer, the Medtronic model 3830 LLL and C315 delivery catheter combination was not initially available at our hospital. Therefore, Boston Scientific (Marlborough, MA) SDLs and standard CS lead delivery sheaths were used in the 27 patients in the series.

Once the LLL system became available in our hospital, it was used as a first-line approach and attempted in 17 patients. Demographics, cardiovascular history, and indication for pacing are presented in Supplementary Table 1. In all patients there was a significant reason to suspect that traditional RV pacing would result in progressive left ventricular dysfunction, and all were given the option for attempted HB lead placement with the understanding that the failure rate was approximately 20%. All patients provided informed consent. The data extraction protocol was approved by the institutional review board.

Implant technique: access, mapping, catheters, and leads
Venous access was obtained via a cephalic and/or axillary approach. For the SDL group, the preferred delivery catheter for the HB lead was the model 8107 (Boston Scientific) Acuity Pro CS EH-S-R (ie, extended hook, straight, right-sided) having a 45-cm shaft (50 cm including hemostatic valve) and an inner diameter of 7.8F. The model 8109 EH-R (ie, extended hook, right-sided) was used in patients with anatomic requiring a more superior catheter tip placement, and the 8113 CS-MP (ie, multipurpose) was better suited for those requiring a more inferior tip orientation (Figure 2). For the LLL group, the Medtronic SelectSite C315 specialized delivery sheath was used.

An atrial lead was implanted in all patients who were in sinus rhythm and was placed before or after HB lead placement at the discretion of the implantor. In most patients, electroanatomic mapping of the interatrial septum using the EnSite Precision system (Abbott, Des Plaines, IL) was performed in order to characterize the HB region and ultimately to visualize the lead tip during lead placement (Supplementary Figure 1).25

Leads evaluated in this series included the 5.8F model 7742 Ingevity (Boston Scientific), which has a 1.8-mm (4.5-mm²) extendable-retractable, electrically active helix; the 5.1F model 4471 FINELINE II (Boston Scientific), which has a 1.6-mm fixed, nonconductive helix extending from a 5-mm² cylindrical electrode situated at the end of the lead body; and the SelectSecure 3830 (Medtronic PLC), which has a 1.8-mm electrically active helical electrode (Figure 3). All leads are steroid eluting, although the location of the steroid differs. SDL leads are bipolar, composed of polyurethane (55D) outer insulation, and incorporate dexamethasone steroid within a control-release capsule at the distal tip. The Ingevity lead body is coaxial in design, with multiple inner and outer (55D) polyurethane insulation layers and a central lumen. The FINELINE II lead body contains parallel wound (ie, co-radial) conductors arranged around the central lead core and lumen. Characteristics of the LLL SelectSecure lead and delivery catheters for HBP have been previously well described.7,9,23,26

The CS guiding sheath was typically positioned so that the tip was within 2–3 cm of the HB, and counterclockwise torque was held to orient it in the proper septal direction. Packed preformed J-stylets occasionally were successful without the need for alteration, but they typically were re-formed to include a secondary posteriorly directed curve in order to orient the lead tip along the perceived HB axis5 and to provide support (Supplementary Figure 2). Delivery of the 3830 lead with the C315 sheath was performed according to previously described methods8,9,23,26 Once a promising site was identified by a distinct HB potential, pacing was attempted before fixation using either the model EP-4 stimulator (Abbott) or the pacing system analyzer (PSA). In cases with no visible HB potential, pace mapping was attempted and guided by 12-lead electrocardiogram and criteria for selective (S) or nonselective (NS) HBP.24 If the pacing threshold was <10 mA at 2-ms pulse width measured via the electrophysiological stimulator, the lead was fixed and the threshold was validated by the PSA. Positioning of the lead tip was aided by 3 elements: electroanatomic mapping with real-time visualization of the lead tip (Supplementary Figure 1); real-time fluoroscopy (Figure 4); and the electrogram from the lead tip (Supplementary Figures 1 and 3), which was viewed on either the multi-channel recording system or the PSA. Sense and pace mapping for proper HB positioning in bipolar and unipolar mode was performed. Several attempts requiring helix disengagement and reinsertion were needed in some patients with the ultimate goal of achieving either S or NS acute HBP thresholds <5 V at 1.5 ms.22,25 Patient age, comorbidities, and life expectancy were all considered when accepting a higher threshold. Availability of devices having extended longevity batteries was an additional consideration when deciding whether to proceed with PHBP in a given patient. In patients having left or right bundle branch block and a CRT indication, the acute HBP threshold was defined as
the value that achieved ≥20% narrowing of QRS duration as described in recent recommendations (Supplementary Figure 3).²⁴

For SDL, after an acceptable site had been located, the screw was deployed while the sheath and stylet were held in place with continued torque allowing pressure on the septum. The CS sheath was then withdrawn several centimeters and split in the usual fashion (Figure 4).

Typically, the FINELINE II lead body was rotated 4–5 full turns clockwise while maintaining a counterclockwise torque on the CS sheath. The Ingevity lead IS1 pin was rotated 15–20 full turns in a clockwise direction using the rotation tool while maintaining a counterclockwise torque on the sheath until the extended helix was verified on fluoroscopy. To ensure deep helix penetration into the fibrous septum, the Ingevity lead body was rotated an additional 2–3 turns clockwise. The implant technique for non-SDLs has been previously described.⁸,⁹ Importantly, to maximize the working lengths of the 59-cm model 7742 and 58-cm model 4471 leads for use within the 50-cm Acuity Pro guide catheters, the anchoring sleeves were temporarily removed by either sliding over the distal tip or cutting the sleeve using the slitting tool packaged with the Acuity Pro guide catheter. Slitting of the guide catheter was performed before reattachment of the suture sleeve, and standard tie-down methods were used.

Figure 1  Patient flow chart. LLL = lumen-less lead; pt = patient; SDL = stylet-driven lead.
HBP validation, devices, programming and follow-up, and analysis data are described in the Online Supplementary Methods.

Results
Implantation procedure, acute procedural success, and implant data
HBP was attempted in 44 consecutive patients and successfully achieved in 40 (91%) (Figure 1 and Supplementary Table 2). In the SDL group (27 attempted patients), HBP threshold became unacceptably high in 1 patient after the access sheath was slit, and the lead was repositioned to the high RV septum. In 2 patients, technical difficulties led to an unsuccessful procedure due to either lead dislodgment or inability to achieve effective HBP. SDL were successfully implanted in the remaining 25 patients (1 crossover from the LLL group), and no lead dislodgments occurred. Nineteen of these patients received a backup RV apical pacing lead.

The Acuity Pro CS EH-S-R was the preferred sheath (Figures 2 and 4). The Ingevity lead was used in the first 11 patients. Ultimately this lead was considered to be more difficult to engage into the tissue at the desired location because it required simultaneous holding of counterclockwise torque on the CS delivery sheath and the lead while rotating the helix in the clockwise direction. This maneuver required assistance from a second person in all cases. The FINELINE II fixed-screw lead was used exclusively in the second half of this series. It ultimately was preferred for its deliverability and because its use did not require assistance from a second operator. This lead was successfully implanted in 14 patients (including 1 patient who crossed-over from the SelectSecure LLL group as described) (Figure 1).

In the LLL group, the specifically shaped model C315 SelectSite delivery catheter was used to deliver the SelectSecure lead; this was attempted in 17 patients. In 1 patient, the lead could not be delivered despite multiple attempts. However, by using different delivery catheters, an SDL (FINELINE II) was successfully implanted. This patient was considered an acute crossover (Figure 1). In addition, there was 1 acute procedural failure in which the SelectSecure lead could not capture the HB and was left in a septal position.

Fluoroscopy and procedural times were $9.6 \pm 5.2$ minutes and $129 \pm 43$ minutes for SDL and $8.3 \pm 5.0$ minutes and $104 \pm 43$ minutes for LLL leads ($P = NS$). There was a significant difference between the first and second half of the SDL series in both parameters. The Ingevity lead was used in the first half and was associated with significantly longer fluoroscopy and procedural duration ($12.8 \pm 5.9$ minutes and $154 \pm 53$ minutes, respectively).

Acute pacing thresholds between the Ingevity and FINELINE II were comparable. Mean acute HBP thresholds were higher for SDL compared to LLL ($2.6 \pm 1.5$ V vs $1.5 \pm 1.2$ V; $P = .02$) (Supplementary Table 2). Thresholds in the narrow QRS vs wide QRS group in patients with SDL tended to be lower ($2.2 \pm 1.3$ V at $1.1 \pm 0.5$ ms vs $3.1 \pm 1.6$ V at $1.2 \pm 0.5$ ms, respectively; $P = NS$). There was a similar trend when both SDL and LLL patients were analyzed together.

Figure 2  Coronary sinus (CS) sheaths used in the study. See text for details. EH R = extended hook, right-sided; EH ST R = extended hook, straight, right-sided; MP = multipurpose.

Figure 3  A: Lead tip profile of the Boston Scientific model 7742 Ingevity lead with a 1.8-mm extendable–retractable, electrically active helix and a ring electrode located 11 mm from the tip. B: Lead tip profile of the Boston Scientific model 4471 FINELINE II lead with a distal electrode isolated from the 1.6-mm fixation helix and a ring electrode set back 16 mm from the tip. The dissolvable mannitol coating is not shown. C: Lead tip profile of the Medtronic 4.1F model 3830 SelectSecure lead with a 1.8-mm electrically active helix and a ring electrode located 9 mm from the tip. All 3 leads incorporate steroid elution. However, steroid type, delivery method, and location differ. In the Ingevity and FINELINE II leads, dexamethasone acetate steroid is contained within a collar situated at the tip of the lead. In the SelectSecure lead, beclomethasone steroid is coated on the helical electrode.
Pacing impedance was comparable between the SDL and LLL groups; however, pacing impedance was significantly higher with the Ingevity compared to the FINELINE II lead (588 ± 156 Ω vs 356 ± 53 Ω; P < .001) and the SelectSecure lead compared to the FINELINE II lead (522 ± 83 Ω vs. 356 ± 53 Ω; P < .001) (Supplementary Tables 2 to 4). Selective HBP was achieved in 5 of 25 patients in the SDL group and 3 of 15 in the LLL group. Nonselective HBP was achieved in the remaining patients.

When possible, R waves were measured at the time of implant and were relatively low (SDL 4.0 ± 1.9 mV; LLL 4.6 ± 3.0 mV; P = NS). One case of inappropriate oversensing of P waves by the HB lead was seen during temporary VVI threshold testing in a patient paced in Ap-Hp mode but was blanked during permanent pacing. Because demand pacing in the Ap-Hp mode in patients with intermittent AV conduction could not be reliably and safely achieved, all patients paced in the Ap-Hp mode were programmed to a sensitivity that resulted in committed HB pacing. This was a precautionary measure due to the absence of previous experience with the SDL and concerns raised in several of the initial patients.

Intermediate follow-up
Intermediate follow-up data (4.7 ± 1.8 months) was available for 28/40 (70%) patients (Supplementary Tables 3 and 4). There was 1 crossover from SDL to LLL in a patient with CRT indication (ie, LBBB) requiring distal HBP. Unacceptable threshold rise with loss of LBBB correction in a patient with CRT indication at 6 months dictated replacement of the Ingevity lead with the SelectSecure lead, and an acceptable threshold was achieved. Similarly, in the LLL group, loss of LBBB correction at follow-up dictated an upgrade to a standard biventricular device in 1 patient and lead dislodgment in another led to RV lead placement (Figure 1).

Intermediate pacing thresholds in the SDL and LLL groups were 2.7 ± 1.4 V at 1.2 ± 0.4 ms and 1.5 V ± 1.0 V at 1.2 ± 0.4 ms, respectively (threshold voltage: P = .02)

Long-term follow-up
Long term follow-up data (13 ± 2 months) was available in 11 patients with SDL (Supplementary Tables 3 and 4). Chronic (long-term) pacing thresholds were similar compared to intermediate follow-up in the SDL group (2.7 ± 1.7 V at 1.3 ± 0.2 ms vs 2.7 ± 1.4 V at 1.2 ± 0.4 ms; P = NS). Long-term HBP threshold was available for 2 patients in the LLL group (1.5 V at 1.5 ms and 2.0 V at 1.0 ms). Lead impedance with the Ingevity lead was significantly higher than with the FINELINE II lead (609 ± 127 Ω vs 358 ± 79 Ω, respectively; P = .003). Chronic HBP threshold elevation >4 V was present in 1 patient with the

Figure 4  A: Left anterior oblique (LAO) view showing the lead tip as directed by the coronary sinus guide catheter (Acuity Pro CS EH-S-R [extended hook, straight, right-sided]) before fixation (secondary curve from stylet not visible in this orientation). B: LAO view showing final right atrial and His-bundle lead positions after coronary sinus guide catheter and stylet removal. Patient is paced in the A-H modality in panels A and B. C: Final His-bundle and right ventricular lead positions in a patient paced in H-V modality. Coronary sinus guide catheter is pulled back but not yet removed.
FINELINE II lead and in 3 with the Ingevity lead. HBP was maintained by increasing the pacing output in 3 patients and discontinued in 1 patient (FINELINE II lead) at 1 year due to continuing rise in threshold \(>5.5\, \text{V} \) (Figure 1 and Supplementary Table 3). Four patients in the series died of unrelated causes during follow-up (3 SDL and 1 LLL).

**Battery longevity**

Extended longevity devices were preferred. In this series, with the HB channel programmed to 1 V above the threshold (but not \(<2.5\, \text{V}\) ) and the A and V channels at 2.5 V/0.4 ms, and assuming 50% atrial pacing and 100% HB pacing (and 100% pacing from the backup RV lead in CRT-pacemaker and CRT-defibrillator devices), the projected battery life estimate was \(7.0 \pm 2.0\) years (range 4.1–14 years). Had device models with extended life batteries been used exclusively in this series, the mean longevity would have been \(8.8 \pm 2.6\) years \(\left( P < .001 \right)\).

**Discussion**

This study demonstrated that PHBP using conventional CS delivery catheters and SDLs is feasible and safe in patients having a variety of pacing indications. Importantly, the operator in this series initially learned to perform PHBP using conventional active-fixation leads and CS sheaths. In doing so, unique insights into PHBP were gained into the practicality of using conventional CS lead delivery systems and stylet-guided, active-fixation leads. Comparison of this experience to that with 3830 SelectSecure lead and C315 SelectSite sheaths, considered the “gold standard” by many and the only system approved by the Food and Drug Administration for PHBP, \(^{28}\) became possible with the availability of the LLL system at our institution.

Deshmukh et al\(^1\) described a 12 of 18 (67%) success rate using a stylet-driven, fixed-helix model 4269 lead (Cardiac Pacemakers Inc, St. Paul, MN) without the aid of a fixed-shape delivery catheter, with a mean procedural time of 3.7 \(\pm 1.6\) hours. Mean threshold was \(2.5 \pm 0.9\) V at 0.5 ms. Using a steerable stylet and extendable-retractable Tendril 1488 and 1788 leads (Abbott, St. Jude Medical, Lake Bluff, IL) in patients with intrahisian block, Barba-Pichardo et al\(^{10}\) reported successful PHBP in 44 of 65 (68%) patients with narrow QRS and 57% success in patients with bundle branch block and narrowing of QRS to \(\leq120\) ms. In the current series, thresholds in the narrow QRS vs wide QRS group in SDL cohort \((2.2 \pm 1.3\) V at 1.1 \(\pm 0.5\) ms vs \(3.1 \pm 1.6\) V at 1.2 \(\pm 0.5\) ms, respectively; \(P = NS\) ) were somewhat higher than in the report by Barba-Picardo \((1.4 \pm 0.6\) V at 1.0 ms vs \(1.9 \pm 1.2\) V) but this likely was insignificant because their values were biased downward (patients with thresholds \(\geq2.5\) V were rejected). Chronic thresholds in patients with Tendril leads remained stable, similar to our data.

More contemporaneous reports describe use of the 3830 SelectSecure lead delivered via a specialized C315 SelectSite sheath. With the aid of a deflectable CS catheter (Medtronic C304) not specifically designed for PHBP, Zanon et al\(^{7}\) described success in 24 of 26 patients (92%). Mean fluoroscopy and procedural durations were \(11 \pm 8\) minutes and \(75 \pm 18\) minutes, respectively, and were similar to those measured in the second half of this series with SDL after the initial learning curve. Our acute pacing thresholds with SDL were significantly higher compared to LLL, similar to Zanon et al.\(^{7}\) In a subsequent multicenter observational study using the deflectable C304 catheter, Zanon et al\(^{29}\) reported that PHBP was achieved in 87% patients with acute threshold \(2.5 \pm 2.3\) V at 0.5 ms, sensed R wave \(3.4 \pm 1.0\) mV, and impedance 695 \(\pm 283\). Five patients (5.7%) had threshold rise \(>5\) V. These numbers compare favorably to the results of the present study. Notably, mean pacing impedances in the present study were lower, most likely related to use of the FINELINE II lead, which is known to have a lower impedance.\(^{30}\)

Sharma et al\(^{31}\) performed a unique study that compared 94 attempted PHPB patients at a center proficient in PHPB to 98 conventionally paced patients from a second highly experienced pacing center. PHPB implanters were 80% successful, and fluoroscopy times were similar to those of RV pacing \((13 \pm 8\) minutes vs \(10 \pm 14\) minutes; \(P = NS\) ). The PHPB pacing threshold was \(1.4 \pm 0.9\) V at 0.5 ms and remained stable over 2 years. These pacing thresholds are similar to those of the LLL control group in the present study and lower compared to the SDL group. In a continuation of this study to include a 5-year follow-up, Vijayaraman et al\(^{15}\) reported stable thresholds with a lead revision rate of 6.7% in the PHPB group vs 3% in the RV pacing group.

Despite the electrically inert helix and a hemispherical electrode located at the base of the helix, the FINELINE II lead proved to have an acceptable electrical performance, even for distal HBP. This likely can be explained by the virtual electrode effect, which extends the reach of the depolarization pulse to cells beyond the borders of the physical electrode.\(^{32}\) Both SDL leads in this series contained steroid within a capsule at the distal tip of the lead. By comparison, the SelectSecure lead has a steroid-coated helix and has exhibited lower acute capture thresholds that remain stable during follow-up.\(^{13,32}\) Whether the difference in steroid location may affect the acute and long-term capture threshold differences between the leads is uncertain.

Although the CS guiding catheters used in this series did not direct the lead tip toward the HB, the flexibility to manipulate the lead using a secondary curve formed by the stylet, with additional reach from the “telescopings” ability of the system, provided the additional stiffness needed for successful lead placement. This stiffness may be helpful for placing the lead in the presence of turbulent flows, such as significant tricuspid regurgitation. Finally, a telescoping system with a lead having a stiff, shapeable stylet may allow improved accessibility to the HB region in patients with an enlarged right atrium or dilated tricuspid annulus, in whom the fixed curve C315 sheath is inadequate. This was illustrated by 1 patient in this series in whom the SelectSecure lead could not be placed with any delivery system. Successful distal PHBP with LBBB correction was achieved with the SDL instead.
With respect to battery life, the mean projected longevity of 7.0 ± 2.0 years in this series was within current-day expectation for conventional systems. Both SDL and LLL systems exhibited comparable longevities despite slightly higher thresholds with SDL.

**Study limitations**

This was a retrospective study of a relatively small series of patients having heterogeneous pacing indications and divided into subgroups, thus limiting intergroup statistical relevance. Success rate, procedural duration, and radiation exposure likely were affected by the high use of 3-dimensional electroanatomic mapping, thus limiting comparison to previous reports. Finally, because each type of lead was used by the same operator in sequence over the course of this study, increased skill and movement up the “learning curve” of PHBP likely may have affected the comparison.

**Conclusions**

PHBP using conventional CS delivery catheters and SDL is feasible and safe in patients with a variety of pacing indications. Overall, successful PHBP with SDL was achieved in 89% of patients. Comparison of this experience to LLL showed similar procedural characteristics. HBP capture thresholds with LLL were lower than with SDL at comparable pulse widths. SDL may present a reasonable alternative in difficult cases.

**Acknowledgment**

This manuscript is dedicated to the late Dr. Bernard Kosovosky (1937–2015). He was a pioneer of His-bundle pacing, and a mentor, colleague, and dear friend for many years.

**Appendix**

**Supplementary data**

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2019.08.017.

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