Permanent His-bundle pacing for cardiac resynchronization therapy: Initial feasibility study in lieu of left ventricular lead

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BACKGROUND Permanent His-bundle pacing (HBP) has the potential to physiologically normalize wide QRS duration in patients with bundle branch block and cardiomyopathy.

OBJECTIVE The purpose of this study was to assess the feasibility of incorporating a His-bundle lead for cardiac resynchronization therapy (CRT) in lieu of a coronary sinus lead.

METHODS Patients with an indication for CRT (n = 21) underwent attempted implantation of an HBP placed into the left ventricular (LV) lead port. Intracardiac intervals, QRS duration, New York Heart Association functional class, ejection fraction (EF), echocardiography, and lead characteristics were measured at baseline and at follow-up.

RESULTS Of the 21 patients in whom implantation was attempted, HBP was successfully implanted in 16 (age 62 ± 18 years, 4 females, EF 25 ± 8). A significant reduction in mean QRS was observed, with narrowing from 180 ± 23 ms to 129 ± 13 ms ($P < .0001$). During the follow-up period, median New York Heart Association functional class improved from III to II ($P < .001$), and mean LV EF and left ventricular internal dimension in diastole (LVIDd) improved from 27% ± 10% to 41% ± 13% ($P < .001$) and from 5.4 ± 0.4 cm to 4.5 ± 0.3 cm ($P < .001$), respectively. At median 12-month follow-up, no dislodgments were observed, and only one patient lost nonselective capture that resolved with increased pacing output.

CONCLUSION Permanent HBP is feasible for patients with an indication for CRT using the LV port in lieu of a coronary sinus lead. In this initial experience, narrowing of QRS duration was achieved in 76% of patients with bundle branch block, and improvements in clinical and echocardiographic measures were observed with HBP. Future prospective comparative studies with HBP to achieve CRT are justifiable.

KEYWORDS Cardiac resynchronization; His bundle; Pacing; Bundle branch block; Heart failure

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Introduction

Direct stimulation of the His bundle has been proposed to represent the most physiologic mode of ventricular pacing.[1] The safety and efficacy of His-bundle pacing (HBP) have been demonstrated in patients with sick sinus syndrome and complete heart block.[2–5] Normalization of bundle branch block has been demonstrated from pacing at the distal His bundle. Although several case reports have reported successful cardiac resynchronization therapy (CRT) achieved with HBP,[6–8] incorporation of a permanent HBP into an implantable cardioverter–defibrillator system in lieu of a left ventricular (LV) lead has been reported in only a few small series to date.[9–11] We performed an initial pilot study to assess the feasibility of implanting an HBP for CRT using the LV port in patients with cardiomyopathy and wide QRS.

Methods

Patient selection

Patients who had indications for CRT (bundle branch block with QRS >120 ms, New York Heart Association [NYHA] functional class II–IV, ejection fraction [EF] <35%) over a 2-year period (2014–2016) at 2 academic centers were included, and data were retrospectively analyzed. One patient with EF <50% with anticipated pacing burden >40% was included. Patients in this feasibility pilot study were given the option of standard resynchronization via a coronary sinus lead or permanent HBP. Two patients underwent

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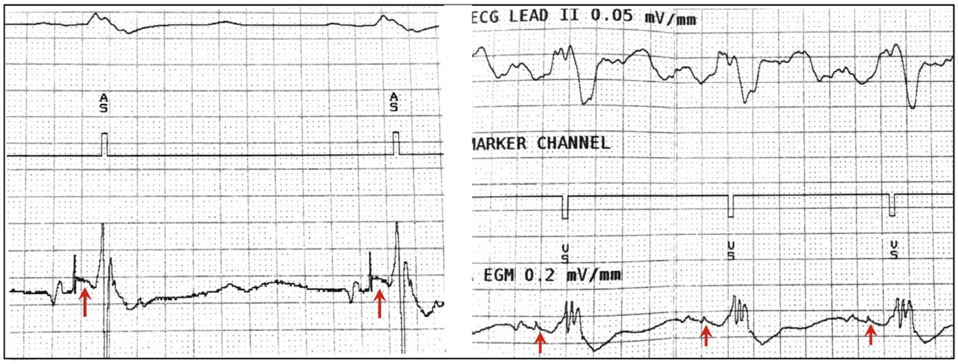

Figure 1 Two examples of acute current of injury on the local His bundle electrogram indicative of adequate lead fixation through the pace–sense analyzer. Injury signal is indicated by the *arrows*.

implantation of a His lead after an unsuccessful attempt at coronary sinus lead placement. The remaining patients chose to undergo an initial attempt at placement of a His-bundle lead, in which a standard coronary sinus lead would be placed if nonselective or selective His-bundle capture with >20% QRS narrowing could not be achieved. Patients provided informed consent and demonstrated an understanding of HBP as a nonstandard approach to achieve physiologic pacing, counterbalanced by an up to 30% nonresponse rate with a standard LV lead. Data analysis was approved by the institutional review board at both centers.

Implantation technique

In the initial patients (n = 12), the His-bundle electrogram was mapped with fluoroscopic guidance of a diagnostic quadripolar catheter (CRD-2, St. Jude Medical, St. Paul, MN) placed from the femoral approach to map a discrete local His-bundle electrogram. The remaining patients underwent implantation without the aid of a diagnostic catheter to serve as a fluoroscopic landmark. The HV interval (time interval between His-bundle electrogram and earliest intrinsicoid deflection on the surface QRS of the 12-lead ECG) was similarly measured on the recording system (Prucka Cardiolab, GE Healthcare, Waukesha, WI) or the pacing system analyzer (Medtronic, Minneapolis, MN) printed at a sweep speed of 100 mm/s in the remaining patients in whom diagnostic catheter measurements were not performed (n = 9).

When indicated, a defibrillator lead was placed into the right ventricle (RV) using routine implantation techniques (n = 19). A pacing lead was placed in 2 patients for CRT-P due to advanced age in 1 patient and EF >35% in the other patient. As previously described, a SelectSite C315 sheath (Medtronic) and a SelectSecure 3830 lead (Medtronic) were advanced into the His-bundle region, and mapping was performed using the pacing system analyzer (100 mm/s speed) to identify a His-bundle electrogram.[12] Before fixation, high-output bipolar pacing at 10 mA at 1 ms was performed to assess for His capture. Fixation was performed by rotating the lead typically 4–10 turns, with the delivery sheath advanced up to the proximal electrode for guide support. Acute injury current in the local His and/or ventricular electrogram was assessed (Figure 1), and thresholds were analyzed as previously described.[3]

The lead position was accepted if His recruitment (selective or nonselective capture) with QRS narrowing was obtained at <5.0 V at 1 ms. Selective His-bundle capture was defined as an isoelectric segment (S–QRS) after the pacing stimulus equal or shorter than the HV interval with rapid-onset QRS activation. Nonselective His-bundle capture was defined as a pseudo-delta wave after the pacing stimulus and an S–QRS interval less than the HV interval. QRS narrowing was present when the paced QRS was less than the native QRS. If His capture did not result in >20% narrowing of the QRS, an LV lead was placed in the coronary sinus. An atrial lead was placed in a standard manner using a curved stylet in the right atrial appendage. The generator was attached to the leads and secured, and the incision site closed. Prophylactic intravenous antibiotics (Vancomycin or Ancef) were administered intraprocedurally. At the physician's discretion, the device was programmed to maximize HBP, with maximum LV pre-excitation to prevent fusion (–60 to –80 LV–RV offset). In cases of selective His-bundle capture, AV delay was shortened to account for the HV interval or the stimulus-to-QRS time to minimize the risk for fusion with intrinsic rhythm. To minimize current drain, the RV pacing threshold was acutely programmed at threshold.

Clinical follow-up

Patients were seen for routine clinical follow-up at standard time periods (1 month, 3 months, 6 months, and 12 months). Functional status was assessed by NYHA classification. Device thresholds were checked and adjusted as needed to maximize battery longevity. Echocardiography were performed as clinically indicated for follow-up.

Statistical analysis

Continuous variables are given as mean ± SD or median. Paired comparisons were made using a Student *t* test if the data were normally distributed, and with the Wilcoxon signed-rank test for nonparametric data. Paired categorical data (NYHA functional class) were compared using the Wilcoxon test. $P \leq .05$ was considered significant.