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Upgrade to his bundle pacing in pacing-dependent patients referred for pulse generator change: Feasibility and intermediate term follow up

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ABSTRACT

Background: Right ventricular pacing (RVP) is associated with an increased incidence of heart failure and may impair cardiac function. Permanent His bundle pacing (HBP) has the potential to physiologically preserve and prevent cardiac dysfunction. This study was to evaluate the feasibility and intermediate follow-up results of upgrade to HBP implantation in patients referred for pulse generator change with long term RVP.
Methods: Twelve of 14 pacing dependent patients who were referred for pulse generator exchange underwent upgrade into HBP successfully in our center. QRS duration, New York Heart Association (NYHA) functional class, echocardiography, use of diuretics and lead parameters were measured at baseline and during the follow-up.
Results: Among the 12 patients attempted (mean age, 70.8 ± 8.9 years, 75% males) successfully, the average ejection fraction (EF) was 52.2 ± 11.2%. Nine of 12 patients underwent upgrade to HBP, and three patients with EF < 40% underwent HBP and biventricular pacing (BVP) as well. A significant reduction in mean QRS duration was observed compared with pre-implantation, from 157.8 ± 13.3 ms to 109.3 ± 16.9 ms ($p < 0.001$). After 6 months follow-up period, median NYHA functional class was improved from 2.7 ± 0.6 to 1.8 ± 0.6 ($p = 0.007$) and left ventricular internal diastolic diameter (LVIDd) was reduced from 5.5 ± 0.4 cm to 5.3 ± 0.3 cm ($p = 0.03$).
Conclusions: HBP improves heart failure symptoms with preserved EF by long term RVP. Permanent HBP is feasible and safe for upgrade in patients with long term RVP irrespective of LVEF.

1. Introduction

Studies have indicated conventional long-term right ventricular (RV) apex pacing can cause heart failure and increase mortality in patients with both reduced and preserved ejection fraction (EF) [1]. Long-term RV pacing produces wide QRS duration, left ventricular (LV) dyssynchrony, hemodynamic impairment, LV diastolic and systolic dysfunction in pacing-dependent patients [2]. However recent studies of non-apex pacing including septum pacing and right ventricular outflow tract pacing also have shown a detrimental effect on pacing-dependent patients and mortality in reduced or preserved EF [3,4]. His bundle pacing (HBP) can generate truly physiologic ventricular activation, and is an option in patients with pacemaker indication [5]. Thus the aim of our study was to assess the feasibility of upgrade to HBP in pace maker dependent patients when referred for pulse generator change.

2. Methods

2.1. Study protocol and patient selection

From July 2013 to April 2017, we prospectively enrolled patients with permanent atrial fibrillation and right ventricular pacing, who were referred for pulse generator change. Patients with right ventricular pacing burden >40% were included. Patients were presented the option of upgrade via permanent His bundle (EF ≥ 40%) and a coronary sinus lead as well if EF < 40% or too high HBP capture threshold during the implantation (>3.0 v/0.4 ms). All patients chose to undergo an initial attempt at placement of a His bundle lead, where a standard coronary sinus lead would be placed if EF < 40% or the failure of HBP. Three patients with EF < 40% had implantation of His bundle lead and coronary sinus lead placement as well. Among them, one patient had dual chamber pacemaker 5 years ago because of AVB. Since 3 years ago he was transferred to single right ventricular pacing because of permanent atrial fibrillation with AVB. The percentage of right pacing was 70% and his EF was 39% during the last follow up. The study was approved by the hospital institutional review board and informed consent was obtained from each patient.

2.2. Implantation technique and HBP testing

Each patient underwent implantation procedures as described previously [6]. Briefly, the delivery sheath (model C304 or C315, Medtronic, Inc., Minneapolis, MN) was inserted via the left axillary or subclavian vein into the His bundle region. The Select Secure™ lead

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(model 3830, Medtronic, Inc., Minneapolis, MN) that was used for HBP was advanced through the sheath. The HV interval (time interval between the His bundle electrogram and the earliest intrinsicoid deflection on the surface QRS on the 12-lead electrocardiogram) was similarly measured on the recording system (BARD Labsystem PRO Review or Albort, Shanghai). Prior to fixation, high-output unipolar pacing was performed to assess for His capture. If HBP parameters were not adequate, the first Select Secure™ lead was left in place as a marker while the second Select Secure™ lead was inserted to identify an optimal His bundle location where HBP parameters were accepted. An electrogram from the lead tip electrode along with 12 lead surface ECG was displayed and recorded (BARD Labsystem PRO Review or Albort, Shanghai). Acute injury current in the local His was recorded and thresholds were analyzed as previously described [7].The three LV lead in CRT-P patients were implanted in the lateral vein, posterior lateral vein and lateral vein respectively. The HBP lead was connected to the atrial port while LV lead and RV lead were connected to the routine LV and RV port, respectively. The device was then programmed to maximize HBP. Among these 12 patients, ten patients had implantation with left sided access, whilst two patients had the implantation with previous right pocket, the delivery sheath via the left axillary vein into the His bundle region was gained and the impulse generator was embedded in the right pocket through a hypodermic tunnel needle. To minimize current drain, the RVP threshold was acutely programmed at threshold.

2.3. Clinical follow up

These patients had routine clinical follow-up at standard time periods (3 and 6 months and yearly). Functional status was assessed by NYHA classification. Echocardiograms were performed as clinically indicated for follow-up. The severity of mitral regurgitation (MR) was assessed by mitral jet area as the percentage of left atrial area. The severity of tricuspid regurgitation (TR) was assessed by the proportion of jet area in the right atrial area. The severity of valve regurgitation was classified as 0, none; 1, mild; 2, moderate; 3, severe [6]. Device parameters were collected and checked, and adjusted as needed to maximize battery longevity.

2.4. Statistical analysis

Continuous variables were reported as mean ± standard deviation (SD). Paired *t*-tests were performed if the data were normally distributed. All data analysis was performed using SPSS version 11.0 (SPSS, Chicago, IL). A signed rank-sum test was applied for the comparison between the baseline and the specific time point during HBP for an ordinal variable such as NYHA class and valve regurgitations. The univariate analysis of variance for repeated measures was used to assess LVIDd, LVEF, HBP threshold and sensed R-wave amplitude. Post hoc tests with the least significant differences were performed for the variables that showed a statistically significant difference. A p value ≤0.05 was considered statistically significant.

3. Results

During the study period, upgrade to permanent HBP was attempted in 12 of 14 patients successfully at our center. 14 patients who fulfilled the inclusion criteria were enrolled for HBP upgrade. The flow chart of the study was shown in Fig. 1. Among 14 patients, two subjects were excluded because of failed HBP lead fixation after His bundle recording and the successful rate of HBP was 85.7%. Of note, one of two patient with right-side access was initially gained into the His bundle region in the atrioventricular (AV) septum superior to the tricuspid valve but the threshold increased to 4.0 v at 0.4 ms after fixation. Among the 12 patients, nine patients underwent HBP upgrade, while another 3 patients with EF < 40% underwent left ventricular lead implantation as well. No acute complications happened. The HBP paced QRS duration was 109.3 ± 16.9 ms, representing a narrowing of QRS compared with pre implantation ECG with RV pacing (157.8 ± 13.3 ms) ($p < 0.001$). The clinical characteristics of twelve patients were summarized in Table 1. The mean LVEF was 52.2 ± 11.2% (range 33%–65%). The mean duration of pacing therapy before HBP upgrade was 107 ± 38.4 months and all 12 patients completed 6 months follow up.

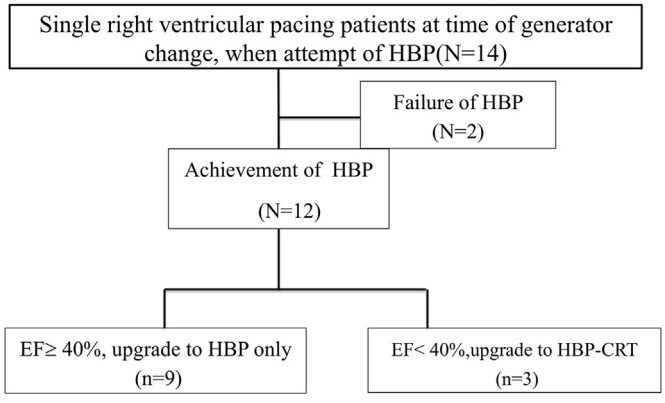

Fig. 1. Flowchart of the HBP upgrade in chronically right ventricular paced patients for generator change.

3.1. Clinical follow up

Follow-up after upgrade was 14.8 ± 12.4 months (a range: 6–48 months). The percentage of HBP was >70% during the follow up. During the 14.8 ± 12.4 months' follow-up after HBP, no dislodgements were observed and no deaths occurred at follow-up. Among these 12 patients who had completed 6 months follow up, no significant improvement of mean LVEF was observed (from 52.2 ± 11.2% to 58.4 ± 7.7%, $p = 0.06$) (Fig. 2). The NYHA functional status improved from the pre-HBP 2.7 ± 0.6 to 1.8 ± 0.6 ($p = 0.007$) and LVIDd reduced from 5.5 ± 0.4 cm to 5.3 ± 0.3 cm ($p = 0.03$). Significant mitral valve regurgitation reduced from 1.7 ± 0.8 to 1.3 ± 0.4 ($p = 0.03$) but with no significance in TR from 1.7 ± 0.7 to 1.5 ± 0.6 ($p = 0.16$). Among them, the three patients with EF < 40% remained on HBP mode at the time of manuscript preparation. They all had better response with improvement of EF and reduction of LVIDd (Fig. 2). Representative case of Fig. 3 demonstrated His lead placement with CRT-P in a patient where nonselective His bundles capture achieved QRS narrowing from 160 ms to 129 ms. In our study, eight (8/12) patients had oral diuretics at the baseline. Among these 8 patients, significant improvement of mean LVEF was observed (from 47.8 ± 12.3% to 52.7 ± 9.5%, $p = 0.02$) (Fig. 2) and NYHA functional status was improved from the pre-HBP 2.9 ± 0.9 to 2.0 ± 1.1($p = 0.02$) at the 6 months follow-up visit after HBP with improvement of LVIDd from 5.5 ± 0.3 cm to 5.3 ± 0.4 cm ($p = 0.01$).

Of note, during the follow up, at the 3 months follow up, 3 patients (3/8) had improved the symptom leading to a reduction in the diuretic dosage and another 3 patients (3/8) stopped the diuretics. At 6 months follow up, 4 patients (4/8) had stopped the diuretics and other 3 patients kept the same dose at 3 months and only 1 patient (1/8) had a diuretic. One year prior to the HBP implantation, 6 patients (6/8) experienced at least one heart failure-related hospitalization, and only 1 patient (1/8) experienced heart failure-related hospitalization after HBP.

3.2. HBP parameters and complications

The mean acute HBP capture threshold at 0.4 ms was 1.5 ± 0.7 V remaining stable at 1.6 ± 0.7 V after 6 months follow-up. ($p = 0.10$, compared with the acute threshold). The sensed R-wave amplitude and lead impedance also remained stable during the follow up period. There were no major complications during implantation or the study period. Of note, there were no lead dislodgements or device-related infection events during our follow up.

4. Discussions

The major findings of the present study are:

1) HBP could be performed successfully in 85.7% of chronic RVP patients with preserved EF who were referred for pulse generator.
2) HBP improved the symptoms and clinical parameters of patients by RVP who had indication for pacing with AF and AVB with preserved EF especially in symptomatic patients.
3) In 3 of 12 patients with EF < 40%, HBP prevented the symptom and echo parameters which demonstrated HBP with BIV back up in such patients is feasible. Though further research is needed to confirm our findings.