Cardiology Journal

VIA MEDICA

ORIGINAL ARTICLE

DOI: 10.5603/CJ.a2022.0079

ISSN 1897–5593
eISSN 1898–018X

The usefulness of His bundle pacing in a heterogeneous population of patients with impaired left ventricular systolic function

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Abstract

Background: *His bundle pacing (HBP) maintains a physiological activation pattern of ventricular activation, and in patients with intraventricular conduction delay (IVCD) it can normalize wide QRS duration.*

Methods: *A total of 181 patients from the HBP registry were enrolled into a the study, which was conducted at the Department of Electrocardiology in Katowice, Poland. The patients had left ventricular ejection fraction (LVEF) < 50% and were implanted between November 2015 and April 2019. The HBP indications were as follows: 1) bradycardia and atrioventricular conduction disturbances with expected high pacing burden, 2) IVCD, LVEF ≤ 35%, with an indication for resynchronization therapy, 3) the need to upgrade to resynchronization therapy due to pacing-induced cardiomyopathy. Pacing parameters and echocardiographic and clinical data were assessed for up to 2 years of follow-up (FU).*

Results: *His bundle pacing was successful in 154 (85.1%) patients. Eighty-two patients completed a 6-month FU. The mean age was 70.6 ± 9.23 years, and 79% were males. At 6 months FU LVEF improved from 35.3 ± 8.22% to 43.1 ± 10.14% (p < 0.0001), and indexed left ventricular end-systolic volume (LVESVi) decreased from 63.1 ± 25.21 mL/m^2 to 51.9 ± 22.79 mL/m^2 (p < 0.0001). In 53.1%, the LVESVi reduction was greater than 15%. The improvement in LVEF and LVESVi was also observed after 24 months of FU.*

Conclusions: *His bundle pacing in permanently paced patients when LVEF is reduced below 50% is associated with improvement in LVEF and reverse left ventricle remodeling.* (Cardiol J)

Key words: His bundle pacing, resynchronization therapy, heart failure, permanent pacing

Introduction

Permanent cardiac pacing is still predominantly achieved with right ventricle pacing (RVP). RVP, however, is associated with myocardial conduction. This slow cell-to-cell conduction leads to asynchronous electrical activation, with a left bundle branch block-like pattern [1] and dyssynchronous left ventricle (LV) contraction [2]. In 10–20% of patients with permanent RVP, LV systolic function deteriorates, and pacing-induced cardiomyopathy (PICM) develops [3]. Cardiac resynchronization therapy (CRT) yields excellent results in patients with reduced LV ejection fraction (LVEF) and interventricular conduction disturbances (IVCD), mainly with left bundle branch block (LBBB) [4]. Nevertheless, the activation through working myocardial cells may induce electrical [5] and mechani-

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Received: 12.06.2022 Accepted: 7.08.2022 Early publication date: 16.08.2022

cal [6] dyssynchrony. Permanent His bundle pacing (HBP) with direct conduction system stimulation results in physiological ventricular activation with a high probability of restoring electro-mechanical synchronicity in LBBB or right bundle branch block (RBBB) patients, and of preventing PICM in patients with a narrow QRS complex.

The present study evaluates how permanent HBP affects cardiac functions in patients with impaired LV systolic function and indications for CRT.

Methods

From our first HBP implantation in October 2015, until May 2021, 796 patients were consecutively enrolled in a single-center prospective registry of HBP or left bundle branch area pacing (LBBAP) in the Department of Electrocardiology of Prof. Leszek Giec Upper-Silesian Medical Center of the Medical University of Silesia in Katowice. The Local Ethics Committee approved the registry (KatHisREG) (KNW/0022/KB/17/18). Patients were qualified to attempt HBP/LBBAP by a heart team consisting of an electrophysiologist, a cardiologist with expertise in echocardiography, and a heart failure (HF) specialist, as needed. The registry includes patients with any indication for permanent pacing, including those with atrioventricular (AV) conduction disease and sinus node dysfunction with an expected high percentage of RVP and with indications for resynchronization therapy. Indications for pacing or resynchronization therapy were in accordance with European and United States guidelines. In CRT indications, physiological pacing was used either as primary therapy or as a bailout procedure when an LV lead placement was impossible. It should be noted that the prevention or treatment of PICM was one of the most typical indications. Baseline clinical, electrocardiographic, and echocardiographic data were collected in the registry for all patients. After a successful conduction system pacing lead implantation, patients were prospectively followed up, with the first visit after 1–3 months and subsequent follow-up (FU) visits every 6–12 months. Electrocardiogram (ECG), clinical data, and electrical pacing parameters were evaluated on each FU visit, and echocardiography was performed after 6 and 24 months.

Patient selection and data collection

A total of 181 consecutive patients with HBP and LVEF below 50% from the registry mentioned above, implanted between November 2015 and April 2019, were included in the study.

Clinical data, 12-lead ECG, and electrical stimulation parameters were assessed at baseline and FU visits. The hemodynamic response was assessed using two-dimensional and color Doppler echocardiography (EPIQ 7 ultrasound system, Philips). The LV volumes, indexed to the body surface area, and LVEF were determined using Simpson's biplane method [7]. The severity of mitral regurgitation (MR) and tricuspid regurgitation (TR) was graded on a three-point scale (mild = 1, moderate = 2, severe = 3) with comprehensive assessment using the ratio of the regurgitation area to the atrial area and proximal isovelocity surface area method.

Selective HBP (sHBP), nonselective HBP (nsHBP), and correction of IVCD were determined according to previously published criteria [8]. IVCD was defined according to American College of Cardiology/American Heart Association (ACC/AHA) recommendations [9]. PICM was defined as congestive HF worsening accompanied by a decline in LVEF < 50% with a right ventricle (RV) pacing burden of ≥ 40% [10]. The positive hemodynamic response in responders to synchronic HBP stimulation was defined a reduction ≥ 15% in indexed LV end-systolic volume (LVESVi). Clinical response was defined as an improvement of New York Heart Association (NYHA) functional class by one or more class.

Data were analyzed by subgroup depending on the biventricular pacing (BVP) indication: group I — patients with bradycardia and AV conduction disturbances with expected high pacing burden; group II — participants with IVCD, LVEF ≤ 35%, and indication for CRT but with HBP instead of LV pacing; and group III — patients upgraded to resynchronization therapy due to PICM.

Implantation procedure

The SelectSecure pacing lead (model 3830, Medtronic Inc., Minneapolis) was used for mapping and pacing in all cases, as previously described [11]. Predominantly, a fixed-shaped (C315HIS, Medtronic) or very rarely deflectable (C304, Medtronic) catheter was used to deliver the lead. HB potentials were recorded in a unipolar fashion with a Medtronic pacing system analyzer (model 2290) or an electrophysiological recording system (WorkMate Claris, Abbott, Sylmar). Pace mapping was used to locate the target destination when the HB electrogram was not recordable. An HB capture threshold < 2.0 V at 1.0 ms was accepted in

patients with bradycardia indications and < 3.5 V at 1.0 ms in patients with indications for cardiac resynchronization therapy. The RV backup lead was implanted when the HV interval was > 100 ms and/or pacing at > 120/min revealed an AV conduction block. When the RV backup lead was implanted, the HBP lead was connected either to the LV port in patients with sinus rhythm (SR) and to the atrial channel of a pacemaker, or to an implantable cardioverter-defibrillator in patients with atrial fibrillation (AF).

Statistical analysis

Continuous variables were expressed as means ± standard deviation. All data passed the test for normality. The independent two-sample t-test was used to compare data between groups, and the paired t-test was used to compare data within the same group if the data were normally distributed. Categorical data were presented as numbers and percentages and compared with χ^2 tests or Fisher's exact tests, as appropriate. Statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant. Analyses were performed using MedCalc Statistical Software version 19.2.1 (MedCalc Software Ltd., Ostend, Belgium; https://www.medcalc.org; 2020) by our university lecturer in medical statistics.

Results

Baseline characteristics

His bundle capture was achieved in 154 out of 181 (85.1%) consecutive patients. In 15 patients the His bundle was not mapped, and in 12 patients the lead fixation was not achieved. We moved to traditional pacing in 41 patients because conduction disturbances could not be corrected (28 patients) or atrial oversensing could not be avoided (1 patient), and when the pacing was over 2.5 V at 1.0 ms (12 patients). One patient with loss of LV capture in a previously implanted cardiac resynchronization therapy defibrillator (CRT-D) was excluded from the study. Three patients died before the 6-month FU echocardiography examination during the follow-up period. An additional 28 patients, for various reasons, missed the 6-month FU echocardiography. Complete clinical and echocardiography data were obtained for at least 6 months of the FU in 81 patients. For 24 of them, we obtained complete clinical and echocardiographic data for the 24-month FU period. The mean FU duration was 11.7 ± 6.9 months.

The mean age of the patients was 70.6 ± ± 9.23 years, and the sex ratio was 79.0% males. Thirty-seven (45.7%) patients were in NYHA functional class III–IV. IVCD was present in 35 (43.2%) patients. Forty-seven (58.0%) patients had a second-degree or third-degree atrioventricular block (AVB), and 20 (24.7%) had sinus node dysfunction with I° AVB. Permanent AF was present in 43 (53.1%) patients. The patients were on optimal medical therapy: 64 (79.0%) were on angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, 77 (95.1%) on beta-blockers, 58 (71.6%) on mineralocorticoid receptor antagonists, and 63 (77.8%) on diuretics.

Baseline characteristics of the study population are listed in Table 1.

Hemodynamic and clinical outcomes

Overall, LVEF improved from 35.3 ± 8.22% at baseline to 43.1 ± 10.14% at the 6-month FU (p < 0.0001) (Fig. 1). In 55 (67.9%) patients, the improvement in LVEF was > 10%. LVEF improved in patients with baseline LVEF ≤ 35% from 28.8 ± 5.53% to 38.8 ± 10.54% (p < 0.0001) and in patients with baseline LVEF 36–49% from 42.1 ± ± 3.86% to 47.5 ± 7.57% (p < 0.0001). The LVESVi measurements were available for 76 patients. A significant reduction occurred in LVESVi from 63.1 ± 25.21 mL/m^2 at baseline to 51.9 ± 22.79 mL/m^2 at the 6-month FU (p < 0.0001) (Fig. 1). Echocardiographic response (LVESVi reduction > 15%) was present in 43 (53.1%) participants. Significant reductions in MR (1.4 ± 0.71 to 1.1 ± ± 0.81, p < 0.0001) and TR (1.3 ± 0.84 to 1.1 ± 0.92, p < 0.03) were observed during FU compared to baseline.

Left ventricular function improved significantly in each patient group, regardless of the type of indications for CRT implantation (Table 2). However, the improvement in LVEF depended on the IVCD type and was not statistically significant in patients with non-specific intraventricular conduction delay (NICD) (Fig. 1).

The improvements of LVEF, LVESVi, and MR, but not LVEDVi, extended to a 24-month FU (Fig. 2).

The improvement of ≥ 1 NYHA class occurred in 41 (50.6%) patients and was observed in each group (Table 2). The NYHA class improved from 2.4 ± 0.71 to 1.7 ± 0.59 (p < 0.0001). In 24 patients who completed the 24-month FU, the clinical benefit lasted with NYHA class 1.5 ± 0.72 compared to baseline 2.5 ± 0.72 (p < 0.0001). Four (4.9%) patients were hospitalized due to worsening HF. One patient was implanted with an LV assist device and is awaiting a heart transplant.

Table 1. Baseline characteristics.

Characteristic	Group I (n = 42)	Group II (n = 14)	Group III (n = 25)	Total (n = 81)
Age [years]	71.1 ± 6.96	66.1 ± 9.55	72.4 ± 11.66	70.6 ± 9.23
Males	34 (42.0%)	12 (14.8%)	18 (22.2%)	64 (79.0%)
Coronary disease	30 (37.0%)	10 (12.3%)	19 (23.5%)	59 (72.8%)
Myocardial infarction	18 (22.2%)	4 (4.9%)	11 (13.6%)	33 (40.7%)
Hypertension	29 (35.8%)	8 (9.9%)	19 (23.5%)	56 (69.1%)
Diabetes	14 (17.3%)	5 (6.2%)	9 (11.1%)	28 (34.5%)
Chronic kidney disease	12 (14.8%)	3 (3.7%)	10 (12,3%)	25 (30.9%)
Ischemic stroke	8 (9.9%)	3 (3.7%)	5 (6.2%)	16 (19.8%)
Baseline NYHA class:	2.2 ± 0.73	2.6 ± 0.63	2.6 ± 0.64	2.4 ± 0.71
NYHA class II/III	35 (43.2%)	13 (16.0%)	23 (28.4%)	71 (87.6%)
NYHA class IV	2 (2.5%)	1 (1.2%)	1 (1.2%)	4 (4.9%)
Baseline LVEF [%]:	38.3 ± 8.57	28.8 ± 6.84	34.1 ± 5.74	35.3 ± 8.22
≤ 35%	14 (17.3%)	14 (17.3%)	15 (18.5%)	43 (53.1%)
36–49%	28 (34.6%)	0 (0.0%)	10 (12.3%)	38 (46.9%)
Baseline LVESVi [mL/m^2]	54.2 ± 22.83	89.0 ± 21.91	61.7 ± 20.40	63.1 ± 25.21
Baseline mitral regurgitation	1.3 ± 0.66	1.6 ± 0.74	1.5 ± 0.75	1.4 ± 0.71
IVCD:	21 (25.9%)	14 (17.3%)		35 (43.2%)
LBBB	7 (8.6%)	3 (3.7%)		10 (12.3%)
RBBB	4 (4.9%)	10 (12.3%)		14 (17.3%)
NICD	10 (12.3%)	1 (1.2%)		11 (13.6%)
Baseline QRS duration [ms]	115.0 25.57	162.1 ± 14.77	178.4 ± 23.04	142.7 ± 37.38
II/III° AVB	28 (34.6%)	0 (0.0%)	19 (23.5%)	47 (58.0%)
SND with I° AVB	14 (17.3%)	0 (0.0%)	6 (7.4%)	20 (24.7%)
Atrial fibrillation	21 (25.9%)	3 (3.7%)	19 (23.5%)	43 (53.1%)

Values are presented as mean ± standard deviation or number (%); AVB — atrioventricular block; IVCD — intraventricular conduction disturbances; LBBB — left bundle branch block; LVEF — left ventricular ejection fraction; LVESVi — indexed left ventricle end-systolic volume; NICD — non-specific intraventricular conduction delay; NYHA — New York Heart Association; RBBB — right bundle branch block; SND — sinus node dysfunction

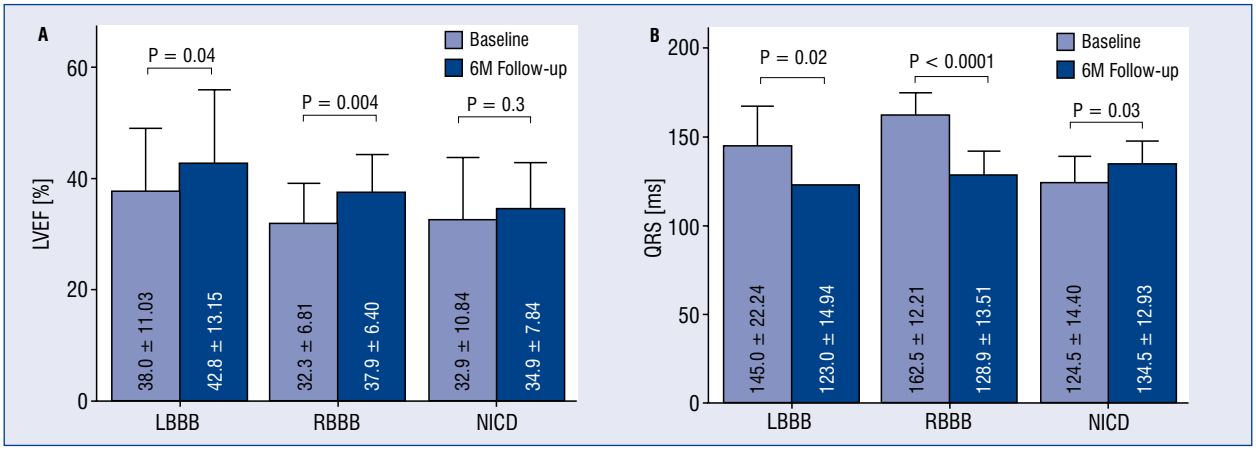

Figure 1. Left ventricular ejection fraction (LVEF; **A**) and QRS duration (**B**) at baseline (light blue) and during follow-up (dark blue) in patients with intraventricular conduction disturbances. Mean value ± standard deviation was placed in the bar with a p-value to compare baseline and follow-up values; LBBB — left bundle branch block; NICD — non-specific intraventricular conduction delay; RBBB — right bundle branch block; 6M — 6 months.

Table 2. Echocardiographic, clinical, and electrocardiographic outcomes at 6-month follow-up

	Characteristics					
	LVEF [%]	LVESVi [mL/m^2]	LVEDVi [mL/m^2]	MR	NYHA	QRSd [ms]
Group I (n = 42)						
Baseline	38.3 ± 8.57	54.2 ± 22.83	87.2 ± 28.25	1.3 ± 0.66	2.2 ± 0.73	116.0 ± 25.83
Follow-up	44.7 ± 9.80	46.1 ± 22.03	81.8 ± 29.21	0.9 ± 0.66	1.8 ± 0.62	117.9 ± 14.40
P-value	< 0,0001	0.001	0.07	0.001	0.0006	0.6
Group II (n = 14)						
Baseline	28.8 ± 6.84	89.0 ± 21.91	125.7 ± 26.42	1.6 ± 0.74	2.6 ± 0.63	162.1 ± 14.77
Follow-up	33.6 ± 7.55	73.1 ± 19.94	109.1 ± 22.59	1.4 ± 0.85	1.9 ± 0.53	131.4 ± 15.62
P-value	0.006	0.007	0.03	0.3	0.003	0.0002
Group III (n = 25)						
Baseline	34.1 ± 5.74	62.3 ± 20.40	93.7 ± 27.58	1.5 ± 0.75	2.6 ± 0.64	178.4 ± 23.04
Follow-up	45.5 ± 9.19	48.7 ± 18.40	85.7 ± 21.40	1.0 ± 1.00	1.6 ± 0.58	116.8 ± 14.92
P-value	< 0.0001	0.002	0.07	0.02	< 0.0001	< 0.0001
Total (n = 81)						
Baseline	35.3 ± 8.22	63.1 ± 25.21	96.3 ± 30.89	1.4 ± 0.71	2.4 ± 0.71	143.2 ± 37.10
Follow-up	43.1 ± 10.14	51.9 ± 22.79	88.0 ± 27.57	1.1 ± 0.81	1.7 ± 0.59	119.9 ± 15.53
P-value	< 0.0001	< 0.0001	0.0007	< 0.0001	< 0.0001	< 0.0001

Values are presented as mean ± standard deviation; LVEF — left ventricular ejection fraction; LVEDVi — left ventricular end-diastolic volume indexed to body surface area; LVESVi — left ventricular end-systolic volume indexed to body surface area; MR — mitral regurgitation; NYHA — New York Heart Association; QRSd — QRS duration

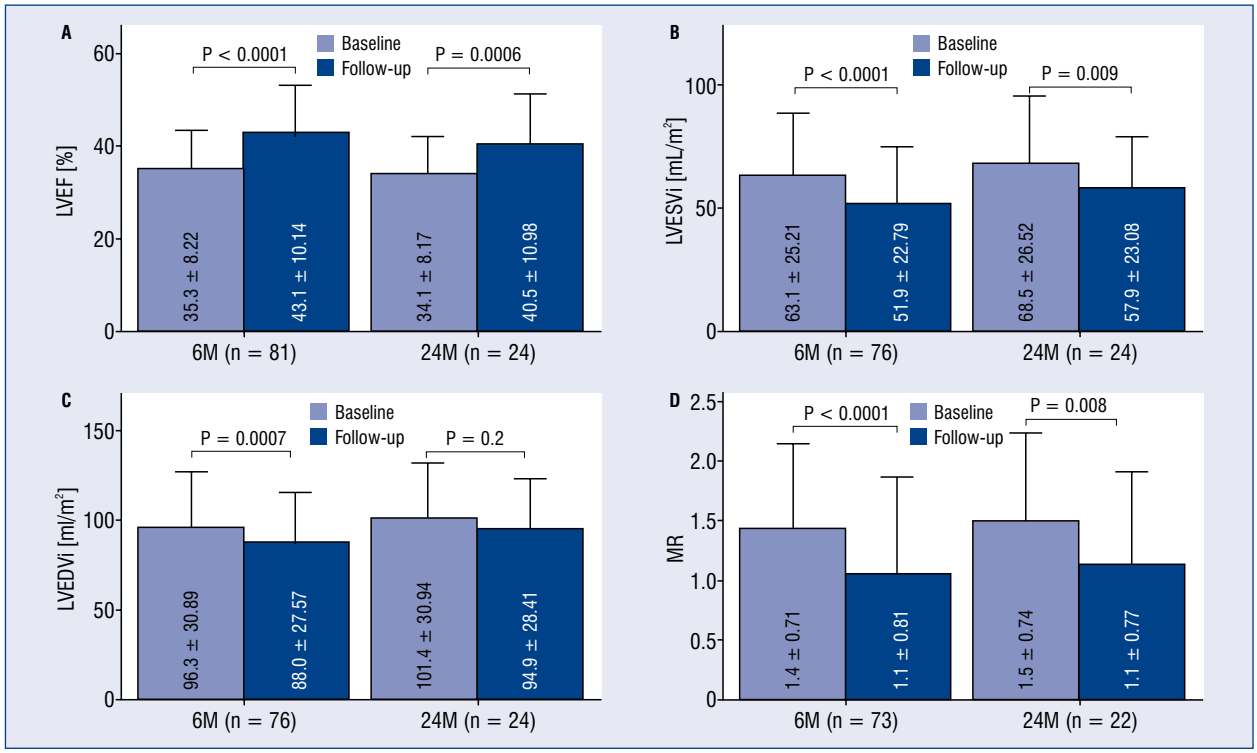

Figure 2. Echocardiographic measurements at baseline (light blue) and during follow-up (dark blue). **A.** Left ventricular ejection fraction (LVEF); **B.** Left ventricular end-systolic volume indexed to body surface area (LVESVi); **C.** Left ventricular end-diastolic volume indexed to body surface area (LVEDVi); **D.** Mitral regurgitation (MR). Mean value ± standard deviation was placed in the bar with a p-value to compare baseline and follow-up values; N — number of patients; 6M — 6 months; 24M — 24 months.

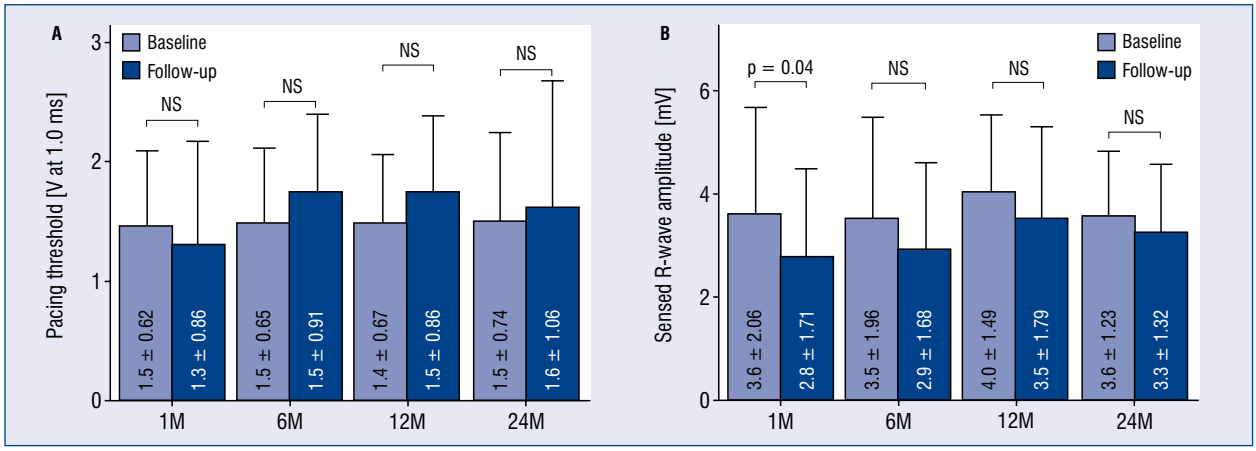

Figure 3. His bundle pacing electrical parameters at implant (light blue) and during follow-up (dark blue). **A.** Pacing threshold; **B.** Sensed R-wave amplitude. Mean value ± standard deviation was placed in the bar; 1M — 1 month; 6M — 6 months; 12M — 12 months; 24M — 24 months; NS — non significant.

Electrocardiographic and pacing outcomes

QRS duration (QRSd) decreased from 143.2 ± ± 37.10 ms to 119.9 ± 15.53 ms ($p < 0.0001$). The QRSd reduction was significant in groups II and III; in group I there was no significant change in QRSd (Table 2). The QRSd decreased in LBBB and RBBB patients. In patients with NICD, the QRSd increased not significantly (Fig. 1B).

Selective HBP was present in 32 (39.5%) patients and nsHBP in 49 (60.5%) patients. The pacing threshold at implant was 1.5 ± 0.63 V at 1.0 ms and the sensed R-wave amplitude was 3.4 ± ± 2.00 mV. The electrical pacing parameters during follow-up are presented in Figure 3. The threshold rose ≥ 1 V in 4 (4.9%) patients. In 1 patient, the LBBB correction was lost during follow-up. In 1 (1.2%) patient, the HBP lead dislocated on the first day after the implantation procedure and was reimplanted. In 1 (1.2%) patient, the lead was extracted due to infection after 14 months. After 25 months, the CRT-D device was replaced due to battery depletion in 1 (1.2%) patient.

Discussion

The present study demonstrated that HBP is feasible and safe in heterogeneous populations with different resynchronization indications, leading to significant improvement in both clinical and hemodynamic outcomes.

Similar results were presented by Sharma et al. [12]. Their analysis included 95 patients with indications for CRT, including patients with narrow QRS complexes and AV conduction block, with bundle branch block (BBB), with indications for an upgrade to CRT because of an RVP percentage greater than 40%, and patients with failed BVP. They observed an improvement in LVEF of > 5% during follow-up in 73% of subjects. LVEF increased from 30 ± 10% to 44 ± 13%, regardless of indication. In contrast to the present study, the observations by Sharma et al. [12] did not significantly change the LV dimensions. Patients with BBB had greater improvement than those in our study. This may have resulted from a different definition of LBBB (Sharma et al. [12] defined LBBB as QRSd > 140 ms in men and > 130 ms in women with mid-QRS notching in 2 contiguous leads) and a higher percentage of patients with NICD in our study. NICD results from conduction disorders in pathological myocardium and/or distal parts of the cardiac conduction system, especially in Purkinje fibers with preserved conduction in the proximal portion of the conduction system, including the bundle of His and His bundle branches [13]. As a result, HBP in the patient is unlikely to correct the conduction disorders and improve cardiac function.

Among patients with BBB, we observed the most remarkable improvement in those with RBBB. Because traditional BVP using a LV lead in RBBB patients is associated with worse outcomes than in LBBB, as was shown in the MADIT CRT population subanalysis [14], HBP in RBBB may be an alternative to BVP. Clinical findings among patients with RBBB were consistent with those observed by Sharma et al. [15], who reported successful HBP with QRSd narrowing in 78% of cases and improved LVEF from 31 ± 10% to 39 ± 13% ($p = 0.004$).

His bundle pacing in patients with a high-degree AV block and even distal AVB is safe and achievable in most patients [16]. In addition, unlike BVP [5, 6], HBP in patients with a narrow QRS does not induce electrical dyssynchrony [17]. The LVEF improvement in group I can result from AV delay optimization in patients with SR and rhythm regularization in patients with AF. AV delay optimization is believed to be essential for improving cardiac function with CRT [18]. Moreover, AV-optimized HBP in patients with HF, PR interval > 200 ms, and without LBBB improves acute hemodynamics assessed by high-precision invasive systolic blood pressure measurements [19].

The LV function improvement was accompanied by the improvement in mitral and tricuspid valve function as an effect of LV reverse remodeling. The better tricuspid function after the procedure also results from the lack of a lead passing through the tricuspid orifice [20]. Admittedly, however, HBP can be achieved by pacing the ventricular part of the His bundle in some cases, but even with the HBP lead implanted at the ventricular location, the HBP does not affect tricuspid function [21].

The long-term reverse LV remodeling seems to be permanent. The improvement in LVEF, LVESVi, and mitral and tricuspid valve regurgitation was documented in the study group to be sustained at 24 months of FU. Beneficial effects of HBP in long-term FU were also demonstrated by Huang et al. [22], who found significant clinical and echocardiographic improvement even after a median of 37 months, but only for LV function and volumes.

The implant success rate, pacing outcomes, and complication rates were similar to those in previously published data [12, 22].

Limitations of the study

It is a single-center study involving non-consecutive patients without direct comparison to BVP. A relatively small number of patients in each subgroup, especially in the subgroup with CRT indication and HBP in place of BVP, require confirmation of results with a larger study.

Conclusions

His bundle pacing can be a viable alternative to any traditional BVP therapy. HBP is feasible and safe in patients with a wide range of indications for resynchronization therapy and is associated with significant improvement in clinical status and LV, mitral, and tricuspid function. Furthermore, in many patients, it achieves resynchronization or a priori synchronous pacing with a less complex pacing system.

Funding

This work was supported by the Medical University of Silesia, grant number PCN-1-044/N/0/K.

Conflict of interest: None declared

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