



His bundle pacing: initial Slovenian single-centre experience

Spodbujanje Hisovega snopa: prve izkušnje v Sloveniji

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Abstract

Background: High right ventricular (RV) pacing burden may promote left ventricular dysfunction. Recently, His bundle pacing (HBP) has emerged as an alternative method to RV pacing that provides physiological ventricular activation by directly stimulating the conduction system.

Methods: Consecutive 75 patients (male 61.3%, age 65 ± 14 yrs, preserved ejection fraction 53.8%, atrial fibrillation (AF) 56%) in whom HBP was attempted at our centre between May 2018 and September 2020 were included. Acute implant success rate, complications and mid-term outcomes were assessed.

Results: Permanent HBP was acutely successful in 69 patients (92%). There were no acute procedure-related complications. Most common indication was AF with rapid ventricular response (38.7%) where HBP was performed in conjunction with atrioventricular node ablation. Median fluoroscopy time was lower during the second half of implants (6.35 (2.7 – 47) vs. 5.4 (1.3 – 13.6) minutes; $p = 0.004$). His capture parameters remained stable during the median follow-up of 193 (59 – 342) days. Eleven patients (11/69, 15.9%) with initially successful procedure experienced a significant rise in HBP threshold. Three patients (3/69, 4.3%) needed HBP lead revision or deactivation.

Conclusion: Our initial experience indicates that HBP is feasible and safe in various pacing indications. Further randomized clinical trials with long-term follow-up are needed to provide the grounds for wider clinical application of this promising physiological pacing technique.

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Key words: His bundle pacing; conduction system pacing; physiological pacing; pacemaker; initial experience

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Izvleček

Izhodišča: Visok delež stimulacije desnega prekata lahko vpliva na poslabšanje delovanja levega prekata. Spodbujanje Hisovega snopa je alternativa običajni stimulaciji srca, saj z neposredno stimulacijo prevodnega sistema omogoča fiziološko aktiviranje srca.

Metode: V analizo smo vključili 75 zaporednih bolnikov (moški 61,3 %, starost 65 ± 14 let, ohranjen iztisni delež levega prekata 53,8 %, atrijska fibrilacija (AF) 56 %), pri katerih smo v našem centru, med majem 2018 in septembrom 2020, poizkusili spodbujati Hisov snop. Pregledali smo uspešnost posega, zaplete in parametre stimulacije po srednjeročnem sledenju.

Rezultati: Uspešno spodbujanje Hisovega snopa smo dosegli pri 69 bolnikih (92 %). Akutnih zapletov nismo zaznali. Najpogostejša indikacija je bila AF s tahikardnim odgovorom prekatov (38,7 %). Pri teh bolnikih smo hkrati z vstavitvijo srčnega spodbujevalnika s stimulacijo Hisovega snopa opravili tudi ablacijo preddvorno-prekatnega vozla. Srednji čas trajanja diaskopije je bil statistično krajši pri drugi polovici posegov: 6,35 (2,7–47) vs. 5,4 (1,3–13,6) minut; $p = 0.004$. V času spremljanja pri 193 (59–342) bolnikih ni prišlo do pomembnih sprememb praga stimulacije. Pomemben porast praga spodbujanja Hisovega snopa smo zaznali pri 11 bolnikih (11/69, 15,9 %) že po uspešnem posegu. Trije bolniki (3/69, 4,3 %) so potrebovali popravilo ali izklop elektrode.

Zaključek: Naše prve izkušnje kažejo, da je metoda spodbujanja Hisovega snopa izvedljiva in varna pri različnih indikacijah za trajno stimulacijo srca. Za širšo klinično uporabo te obetavne metode, ki omogoča fiziološko spodbujanje srca, so potrebne nadaljnje randomizirane klinične študije z daljšim sledenjem.

1 Introduction

Right ventricular (RV) pacing-induced electromechanical dyssynchrony which results in an increased risk of heart failure (HF) and atrial fibrillation (AF) is well established (1-2). The pursuit of alternate pacing sites including RV septum and RV outflow tract produced only modest or no clinical benefits (3). Furthermore, several device programming algorithms to minimize ventricular pacing were developed which are ineffective with advanced atrioventricular (AV) block and mainly function at the expense of AV dyssynchrony further increasing the risk of AF (4). Compared to RV pacing, biventricular (BiV) pacing derived better results in patients with AV block and systolic dysfunction, however, the benefit was much less distinct in patients with preserved ejection fraction (5-6).

Recently, permanent His bundle pacing (HBP) has emerged as a physiological alternative to conventional RV and BiV pacing. By capturing the His-Purkinje conduction system, HBP provides normal synchronous activation and preserves left ventricular (LV) function in patients who require a pacemaker due to bradycardia (7). In addition, several studies have shown the potential of HBP to correct underlying bundle branch block (BBB), improving the ventricular activation time and narrowing the QRS (8). However, due to the anatomic location and surrounding fibrous tissue, lead positioning in the His bundle area could be technically challenging, consequently extending procedural and fluoroscopy times compared to standard pacing methods.

In addition, there is concern about maintaining chronic pacing due to higher initial pacing thresholds, exit block and risk of progressive electrical block distal to the HBP lead. These uncertainties hinder wider clinical adoption of this physiological technique, although technical advancements and specialized delivery tools substantially improved recently reported success rates in experienced centres (9).

The aim of our study was to evaluate the feasibility, safety and mid-term outcomes during the implementation of the HBP programme in our centre.

2 Methods

2.1 Study design

We implemented HBP programme at the University Medical Centre Ljubljana in May 2018, and all consecutive patients in whom the procedure was attempted were included in this single-centre, observational, retrospective study. All HBP procedures were performed by a single operator (200 device implantations per year) without previous exposure to the technique or electrophysiology procedures. Implant success rate, specific implant characteristics, procedural complications and electrical HBP parameters during follow-up were analysed. The study complies with the Declaration of Helsinki and was approved by the institutional review board. The study design was approved by the Republic of Slovenia

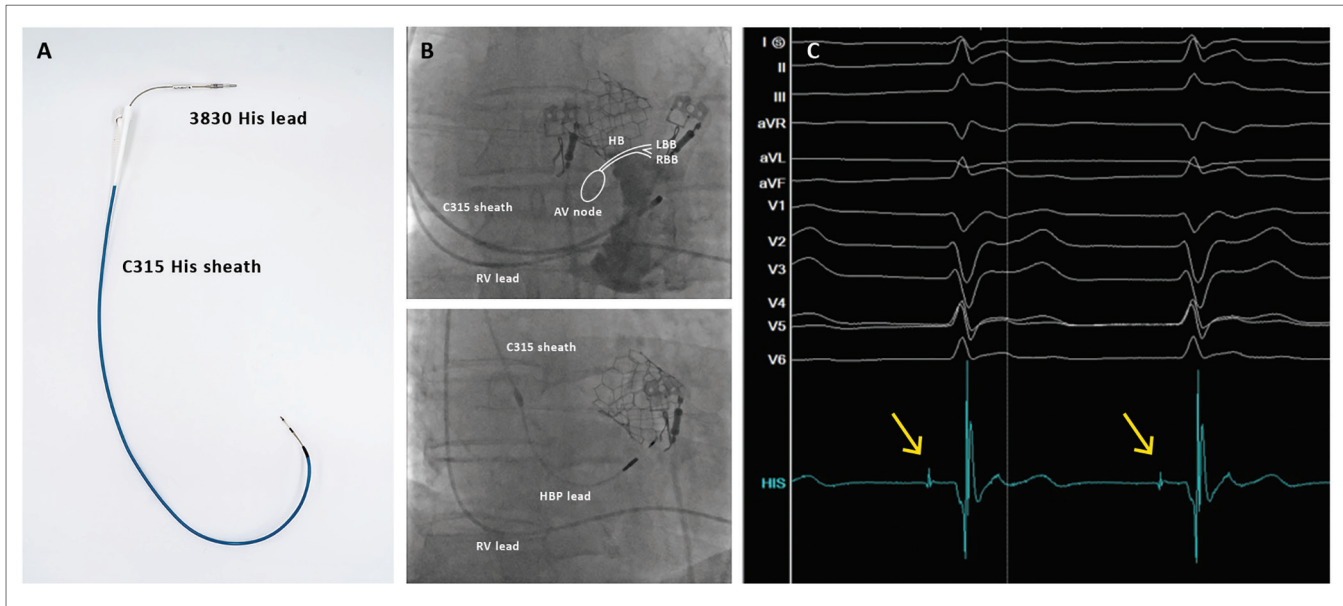


Figure 1: His bundle pacing procedure. (A) Dedicated implantation tools: fixed dual-plane curve C315 His sheath and 4.1 Fr bipolar active fixation SelectSecure 3830 His pacing lead. (B) Fluoroscopic image with contrast injection through the C315 His sheath to show the tricuspid valve annulus and potential site for His bundle pacing (HBP) with schematic representation of the conduction system - atrioventricular (AV) node, bundle of His (HB), right bundle branch (RBB), and left bundle branch (LBB). Final HBP lead position after the sheath is withdrawn to the high right atrium until an adequate loop is formed (bellow). Right ventricular (RV) lead was used as a backup. (C) Distal His bundle potential (arrows) followed by a large ventricular signal in the unipolar setting after HBP lead fixation.

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National Medical Ethics Committee (decision no. 0120-95/2019/18 on 28. 10. 2019).

2.2 Patient population

All consecutive patients who underwent an attempt at permanent HBP from May 2018 to September 2020 in our centre were included. There were no pre-specified inclusion criteria, however, HBP was initially preferred in AF patients with bradycardia, in AF patients in whom AV node ablation was also scheduled, and in patients with prolonged AV intervals where high burden of ventricular pacing was expected. As our experience deepened, HBP was expanded to patients with advanced AV block, BBB and complete AV block with stable escape rhythms. In advanced AV block pacing indications, nonselective HBP was preferentially targeted to enhance safety by ensuring the capture of ventricular myocardium. In patients who required temporary pacing, HBP was not attempted.

2.3 Implantation techniques and tools

The procedure was performed as previously described (8-12). In short, a 4.1 Fr bipolar active fixation

lead (SelectSecure 3830, Medtronic, Minneapolis, MN, USA) and dedicated delivery sheath (C315His or C304, Medtronic, Minneapolis, MN, USA) were used for His bundle area mapping under fluoroscopy (Figure 1A). His bundle potential mapping was performed in a unipolar setting with the use of the electrophysiological system LAB system Pro, BARD (Boston Scientific, Lowell, MA, USA) or EP-TRACER 2 Portable (CardioTek B.V., Sitard, The Netherlands) at a sweep speed of 100 mm/s. Additional visualization of the tricuspid valve annulus via contrast injection through delivery sheath was usually performed before mapping to delineate the anatomical landmark of His bundle area (Figure 1B) (11). After localizing the His bundle potential (Figure 1C), preferably the most distal His deflection with ventricular to atrial electrogram ratio >3:1, pacing was attempted before the lead fixation to confirm HB capture. The lead then screwed into position with 4 or 5 clockwise rotations and acute HBP threshold $\leq 2.5V$ at 1ms was considered acceptable. Selective or non-selective HBP was categorized according to the recently proposed definitions (13). Additional backup RV lead was implanted only in few initial cases and in all patients undergoing concomitant AV node ablation. In latter cases, HBP lead was connected to the atrial port of the dual-chamber device.

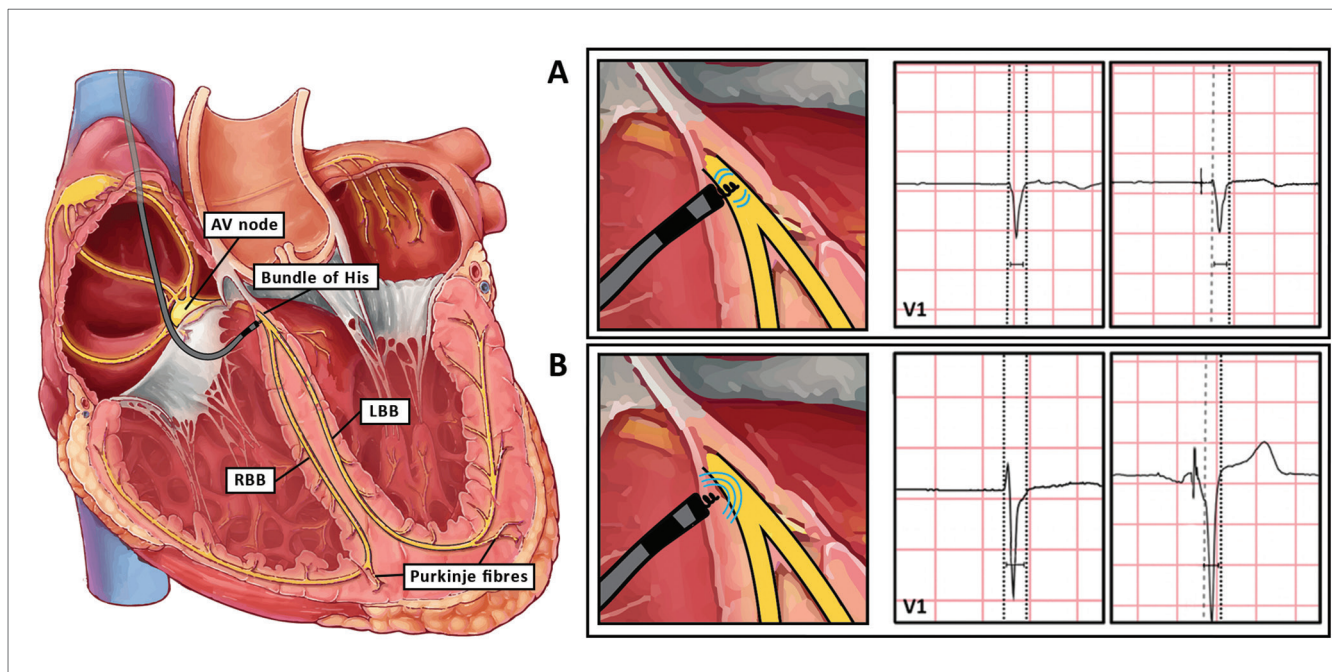


Figure 2: Forms of His bundle pacing. (A) During selective His bundle (HB) capture, ventricular activation occurs directly over the His-Purkinje system. There is an isoelectric line between the pacing stimulus and the QRS which is identical to the native QRS. (B) In nonselective HB pacing there is fusion capture of HB and adjacent myocardial tissue resulting in the presence of pseudo-delta wave. Although paced QRS duration is slightly increased (by the H-QRS interval), the overall electrical axis of the paced QRS is concordant with the electrical axis of the intrinsic QRS.

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2.4 Procedural outcome definitions and follow-up

The procedure was considered successful when ventricular activation occurring over the conduction system was proven. Selective or non-selective HBP was categorized according to the recently proposed definitions (13). Briefly, selective HB capture ventricular activation occurs solely over the His-Purkinje system (Figure 2A), while non-selective HB capture results in a fusion capture of HB and adjacent ventricular tissue that could be recognized by the absence of isoelectric interval between pacing stimulus and QRS. The capture of the local myocardium beside His-Purkinje system produces a pseudo-delta wave on the 12-lead ECG (Figure 2B). Assessment of selective or nonselective HB capture was made by increasing or decreasing pacing output and the simultaneous observation of QRS morphology changes in the standard 12-lead ECG. Patients with selective HBP with an output near HB capture threshold values but non-selective at the final programmed pacing output were classified as nonselective (Figure 3). If HBP could not be achieved, the lead was inserted in the RV mid-septum. Procedure duration was defined as the time from subcutaneous injection of local anaesthetic until the last

skin suture. Fluoroscopy time was generally limited to 25 minutes. His bundle and myocardial capture threshold, R waves, lead impedance, intrinsic and paced QRS duration were measured at implant for each patient. HBP threshold testing was performed at a pulse width of 1ms (13). In cases with underlying BBB, the output necessary to correct the BBB was noted as a final threshold. Patients were evaluated in the device clinic 1 month after implantation, at 6 months, and every 6 months thereafter. During each follow-up, device interrogation and 12-lead ECG were performed. An increase in HBP capture threshold of $>1V$ at 1ms compared to the implant measurement was considered significant. The impact of the learning curve on acute procedure success rate, fluoroscopy time and HBP thresholds was assessed by comparison of the initial half of the cases with the remaining cases.

2.5 Statistical analysis

Categorical variables were presented as counts and percentages, continuous variables were reported as mean \pm standard deviation or median (interquartile range), according to the distribution. Regression models were constructed to assess the correlation between procedure

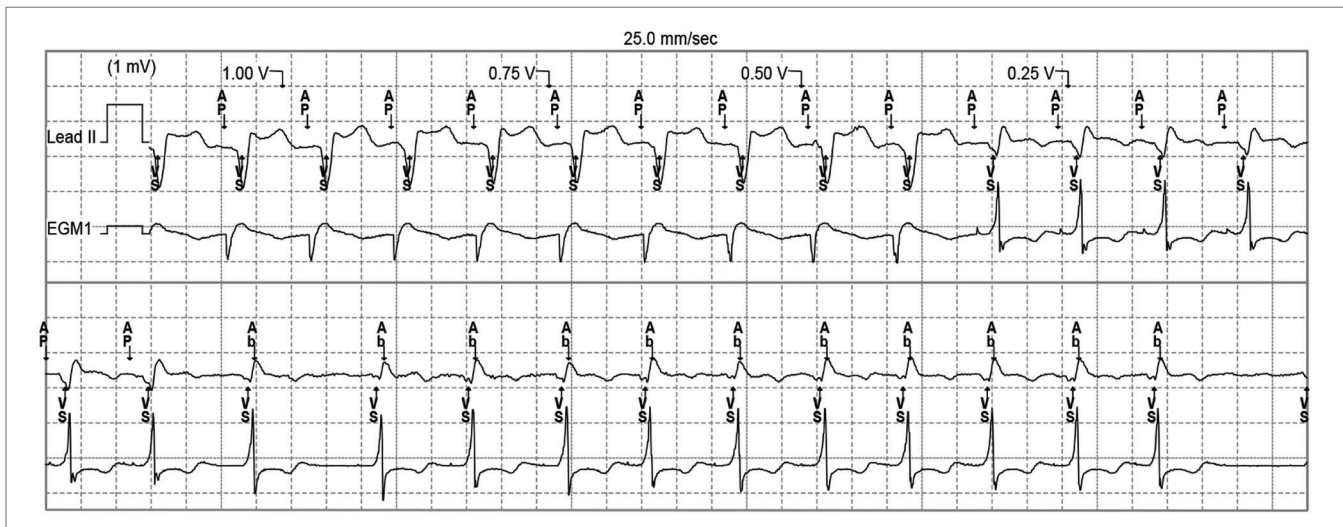


Figure 3: Output dependence of His bundle capture. Nonselective His bundle pacing (HBP) with fusion of ventricular and HB capture can be seen in lead II and electrogram (EGM) at higher pacing output. As the output decreases to 0.25V at 1ms, there is a transition to selective HBP with the presence of isoelectric interval between pacing stimulus and QRS. QRS morphology in lead II and EGM during selective HBP is identical to the native QRS (bellow). His bundle lead is connected to the atrial port of a dual-chamber device and right ventricular lead was used as a backup. After successful HBP procedure, atrioventricular node ablation was performed due to refractory atrial fibrillation with high ventricular rate. Image is from authors' own archive.

or diascopy time and operator's experience. The differences in mean values of the continuous variables were compared using paired or unpaired t-test if the data were normally distributed, otherwise Mann – Whitney U test or Wilcoxon Sign test were adopted. All hypotheses were two-tailed and p -value ≤ 0.05 was considered significant. The analysis was performed using SPSS version 22.0 (SPSS, Chicago, IL, USA).

3 Results

3.1 Clinical characteristics and pacing indications

Seventy-five consecutive patients in whom HBP was attempted were included in the study. Baseline characteristics are presented in Table 1. Mean age of the study population was 65 ± 14 years, 46 (61.3%) of the patients were male and 30 (46.2%) had reduced EF before the procedure. The youngest patient who received permanent HBP was a 5-year-old child. Most of the procedures were de-novo implantations. There were only 2 upgrade procedures: in one case with complete AV block where previous epicardial leads were replaced with endocardial leads and in an HF patient with implantable cardioverter-defibrillator (ICD) in whom pace and ablate strategy was indicated. His bundle pacing was mainly performed

in AF patients with a rapid ventricular response in conjunction with AV node ablation (29; 38.7%). Pacing indications are presented in Table 2.

Table 1: Baseline characteristics.

Age [years]		65 ± 14
Gender	male	46 (61.3%)
Comorbidities	diabetes mellitus	20 (26.7%)
	hypertension	49 (65.3%)
	valvular disease	13 (17.3%)
	ischaemic heart disease	25 (33.3%)
	atrial fibrillation	42 (56%)
Left ventricular function, n = 65	preserved (EF > 50 %)	35 (53.8%)
	impaired (EF < 50 %)	30 (46.2%)
Intrinsic QRS [ms], n = 68		114 ± 27
	> 120ms	17 (22.7%)
	LBBB	11 (14.7%)
	RBBB	6 (8%)

Legend: EF – ejection fraction, LBBB – left bundle branch block, RBBB – right bundle branch block.

Table 2: Pacing indications.

Indications	Number (%)
Symptomatic 1 st degree AV block	7 (9.3%)
AV block 2 nd degree Mobitz II	9 (12.0%)
Complete AV block	13 (17.3%)
BBB	4 (5.3%)
AF with slow conduction	13 (17.3%)
AF with rapid ventricular response	29 (38.7%)

Legend: AV – atrioventricular, BBB – bundle branch block, AF – atrial fibrillation.

3.2 Implant success rate and procedure characteristics

Acute HBP was successful in 69 of the 75 patients (92%). Among 6 unsuccessful procedures, in 3 HB potential could not be located, high His capture threshold was considered unacceptable in 1 case, and in 2 cases LBBB correction could not be obtained. Acute success rate was higher (36/37, 97.2 %) in the second half of the implant attempts compared to the initial cases (33/38, 86.8%). There were no acute procedural complications. Median procedure time was 60 (50 – 80) minutes and median fluoroscopy time was 6 (4.5 – 10.1) minutes. Negative correlation was found between procedure time ($r = -0.246$, $p = 0.040$) or fluoroscopy time ($r = -0.325$, $p = 0.005$) and number of cases performed. There was also a statistically significant difference

between median fluoroscopy time in the first half of the implantations (success rate 86.1 %) and the subsequent procedures (success rate 97.2%) [6.35 (2.7 – 47) vs. 5.4 (1.3 – 13.6) minutes, $p = 0.004$] (Figure 4), indicating a learning curve. Defibrillator lead or back-up RV pacing lead implantation ($n=36$) did not affect the procedure [60 (50 – 72) minutes vs. 60 (50 – 83) minutes, $p = 0.767$] or fluoroscopy time [6.1 (4.5 – 9.8) minutes vs. 5.5 (3.8 – 9.7) minutes, $p = 0.626$].

3.3 Electrical parameters and clinical outcomes during follow-up

Compared to intrinsic QRS duration, HBP did not result in significant prolongation (114 ± 26 ms vs. 115 ± 20 ms, $p = 0.662$) of paced QRS duration. In 15 patients with underlying BBB, there was a significant reduction of paced QRS duration (153 ± 18 ms vs. 122 ± 20 ms, $p < 0.001$) compared to intrinsic QRS.

Median acute HBP threshold was 1.5 (1 – 2.25) V at 1ms. Nonselective HB capture was achieved in 36 patients (52.2%) with a median threshold of 1.5 (1 – 2.4) V at 1ms. Selective HB capture was observed in 33 patients (47.8%) with a median threshold of 1.5 (1 – 2) V at 1ms. Median threshold for bundle recruitment in patients with a baseline left ($n=9$) or right ($n=6$) BBB was 1.25 (1 – 2) V at 1ms. In addition, acute HBP thresholds were lower in the second half of the implants 1.75 (1.25 – 2.4) V vs. 1.1 (0.8 – 2) V, $p = 0.013$, again demonstrating a learning curve with increasing HBP experience.

Permanent HBP was maintained in 66 patients

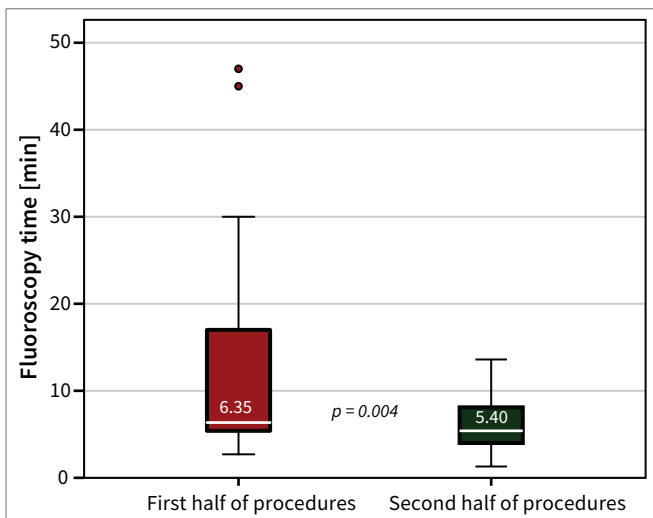


Figure 4: Comparison of fluoroscopy time between the initial half and the subsequent half of procedures.

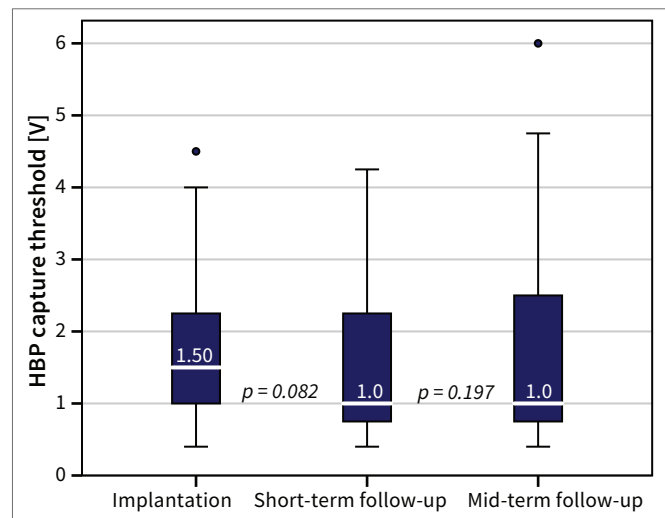


Figure 5: His bundle pacing capture thresholds during follow-up.

Table 3: Acute and chronic His bundle pacing thresholds.

	All (n=66)		Nonselective pacing (n=35)		Selective pacing (n=31)	
Initial threshold [V]	1.50 (1 – 2.25)		1.50 (1 – 2.50)		1.25 (1 – 2)	
Short-term follow-up threshold [V]	1 (0.75 – 2.25)	p = 0.082	1.25 (0.75 – 2.50)	p = 0.013	1 (0.75 – 2.25)	p = 0.903
Mid-term follow-up threshold [V]	1 (0.75 – 2.50)	p = 0.197	1.25 (0.75 – 2.75)	p = 0.092	1 (0.75 – 2.50)	p = 0.937

(66/69, 95.7%) with initially successful HBP procedure. During the follow-up of 193 (59 – 342) days His capture thresholds remained stable (Figure 5) regardless of whether selective or nonselective pacing was achieved (Table 3). However, 11 out of 69 patients (15.9%) experienced a significant rise in HBP capture threshold. Loss of capture necessitating lead revision or reprogramming occurred in 3 patients (3/69, 4.3%). In 2 patients, HBP threshold rose from initial 2.3V to 6.5V at 1ms and from 3.5V to 5.5V at 1ms after AV node ablation. In both cases HBP lead was deactivated and switched to back-up RV lead pacing. In 1 patient, HBP lead revision was required due to dislocation and only RV septal pacing was obtained after repositioning.

Two patients died during follow-up; the cause of death was unrelated to the procedure. One patient underwent heart transplantation.

4 Discussion

The findings of our study demonstrate that establishing HBP was feasible and safe in various pacing indications. We had a high acute implant success rate of 92% and His capture parameters remained stable during mid-term follow-up. A modest proportion of patients (15.9%) did experience a significant rise (more than 1V) in HBP threshold.

In the published literature, HBP implant success rates range from 75% to 99% (9,11,15-20). Our acute HBP success rate is in accordance with a recent meta-analysis which showed 92% implant success when catheter-delivered systems were used (14). However, pacing indication might have an impact on HBP procedure while studies reporting outcomes of HBP in patients with complete AV blocks and BBB recorded significantly lower success rates (17,19) compared to the studies that mostly included patients with AF, less advanced AV blocks and narrow QRS (9,10,18). Therefore, the fact that most of our patient population had less advanced conduction disorders could have

contributed to higher acute success rate compared to some reported in literature in more experienced centres (17,19).

His bundle pacing is associated with higher initial and chronic pacing thresholds compared to standard RV pacing (9,10,20). Acute median HBP capture threshold in our study population was 1.50 (1 – 2.25) V at 1ms, which is comparable with the results in several published studies (9,14,16,19). Moreover, our acute HBP thresholds were lower in more recent procedures, which is in line with Keene et al. (9) who acknowledged a learning curve of approximately 30-50 cases in HBP capture reduction. During mid-term median follow-up, no significant deterioration in the capture threshold was recorded in the majority of cases. However, 11 patients (15.9%) did experience a significant rise in HBP threshold that mainly required an increase in pacing output and potentially increased battery drain. Only 4.3% of the patients in our cohort required HBP lead intervention, which is comparable to 4.8% published in the recent meta-analysis (14) and lower compared to 6.7% (16) and 8% (17) reported in two studies with long-term follow-up. Although a relatively short follow-up in our study might have affected lower rate of HBP lead interventions, most revisions due to His capture threshold rising usually occur during the first 90 days (17).

The target area of His bundle is relatively small making HBP lead positioning and fixation technically challenging, consequently extending procedure and fluoroscopy times compared to standard pacing methods. Recent introduction of dedicated tools in form of specific pre-shaped or steerable His catheters improved success rates and reduced fluoroscopy times (7-14). Our median fluoroscopy time of 6 minutes was considerably lower compared to the published studies ranging from 10 to 12 minutes (10,14,19). This divergence is potentially associated with the utilization of additional radiation exposure-reducing implantation techniques in most of our procedures. First, visualization of the

tricuspid valve annulus via contrast injection through the delivery sheath enabled prompt identification of the target zone for His bundle area (11,21). Secondly, after the identification of the anatomical landmark, targeting His potential was mainly electrogram-guided, thus reducing fluoroscopy time (22). Thirdly, three-dimensional electro-anatomical mapping system was used in few cases, including in a small child (23), to facilitate the procedure and reduce the fluoroscopy time (24). Finally, further reduction was achieved with operators' experience as fluoroscopy times were significantly shorter in the second period of the procedures.

4.1 Clinical implications

Our initial experience indicates that HBP procedure is feasible and safe in various pacing indications. It can be readily learned in the hands of an experienced device specialist without previous exposure to the technique or electrophysiology procedures. There is a learning curve which not only affects procedure success rate but also the progressive reduction of fluoroscopy time and HBP capture threshold. The challenges with rising thresholds require close monitoring during the implementation of this pacing method. Still, current limitations of HBP compared to standard RV pacing might also reflect the early stage of new technology. Therefore, improvement of delivery tools, leads, battery capacity, implantation technique, and further randomized clinical trials with long-term follow-up are needed to provide the grounds for wider clinical adoption of

this promising physiological pacing technique.

4.2 Study limitations

The retrospective design of the study and a low number of patients limits the strength of our findings. Only mid-term follow-up may underestimate the concern of unpredictable increase in HBP thresholds, loss of HB capture, and lead interventions. We did not include any follow-up data on ejection fraction or clinical outcomes since this was beyond the scope of the present study that mainly focused on crucial procedure-related parameters that are important for the implementation of a new pacing strategy in routine clinical practice.

5 Conclusion

Our initial experience indicates that HBP procedure is feasible and safe in various pacing indications. There is a learning curve which not only affects procedure success rate but also the progressive reduction of fluoroscopy time and HBP capture threshold. The challenges with rising thresholds require close monitoring during the implementation of this pacing method. Further randomized clinical trials with long-term follow-up are needed to provide the grounds for wider clinical adoption of this promising physiological pacing technique.

Conflict of interest

None declared.

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