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Conduction system pacing for ventricular pacing requirement is feasible and effective on patients with hypertrophic cardiomyopathy and cardiac dysfunction

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ABSTRACT

Objective: We aimed to evaluate the feasibility and safety of his-bundle pacing (HBP) and left bundle branch pacing (LBBP) in patients with hypertrophic cardiomyopathy (HCM) and heart failure (HF).

Methods: Patients with HF and interventricular septal thickness (IVST) $\geq$ 13 mm resulted from HCM, who accepted conduction system pacing (CSP) with a percentage of ventricular pacing > 40% from May 2018 to April 2022 were consecutively enrolled in our center. LBBP was preferred and HBP was the alternative therapy unless IVST $\geq$ 16 mm or LBBP failed, whereas LBBP would be the alternative therapy if HBP failed in patients with IVST $\geq$ 16 mm. All patients were followed up for at least one year. Data including clinical, echocardiographic parameters and electrocardiogram measurements, were collected and evaluated in patients with and without left ventricular ejection fraction (LVEF) < 50%.

Results: A total of 27 patients (65.93 ± 9.09 years old) were enrolled and only 3 patients failed in CSP (11.11%) via LBBP (6/13) and HBP (18/21) procedures. LVEF (P = 0.521), left ventricular end-diastolic diameter (LVEDD) (P = 0.816), and QRS duration (P = 0.928) did not worsen after CSP, and left atrial diameter (LAD) (49.58 ± 8.99 mm vs.47.04 ± 9.82 mm, P = 0.045) tended to improve slightly after 19.19 ± 7.71 months follow-up. Of note, LVEF (39.22%±7.51% vs. 45.22%±9.59%, P = 0.015), LVEDD (52.11 ± 10.10 mm vs. 48.33 ± 9.07 mm, P = 0.037), LAD (50.33 ± 8.93 mm vs. 46.11 ± 5.97 mm, P = 0.013) and New York Heart Association (NYHA) grade (2.67 ± 0.5 vs. 1.38 ± 1.02, P = 0.029) improved in 9 patients with LVEF < 50%, whereas LVEF (P = 0.372), LVEDD (P = 0.665), LAD (P = 0.093) and NYHA grade (P = 0.452) did not deteriorate in patients with preserved ejection fraction.

Conclusion: CSP was safe and feasible in patients with HCM and cardiac dysfunction, and did not worsen cardiac performance especially in patients with LVEF < 50%. HBP might be an effective alternative to LBBP in patients with significantly thickened interventricular septum.

1. Introduction

Hypertrophic cardiomyopathy (HCM) is a common inherited cardiac disease that varies in the phenotypic and genetic expression, clinical presentation, and natural history [1,2]. Permanent pacemaker implantation was required in approximately 8% of the HCM population during more than five years of observation, although there have been few reports of symptomatic bradyarrhythmia in patients with HCM [3]. The development of severe systolic heart failure (HF) was associated with rapid progression to death or transplantation and an overall

Abbreviations: ACEI, angiotensin-converting enzyme; ARB, inhibitor angiotensin receptor blocker; ARNI, angiotensin receptor enkephalin enzyme inhibitor; BiVP, biventricular pacing; CRT, cardiac resynchronization therapy; CSP, conduction system pacing; ECG, electrocardiogram; HBP, his-bundle pacing; HCM, hypertrophic cardiomyopathy; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; HOCM, hypertrophic obstructive cardiomyopathy; IVST, interventricular septal thickness; LAD, left atrial diameter; LBBB, left bundle branch block; LBBP, left bundle branch pacing; LV, left ventricle; LVAT, left ventricular active time; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; MR, mitral regurgitation; NYHA, New York Heart Association; RBBB, right bundle branch block; RVP, right ventricular pacing; SD, standard deviation; TR, tricuspid regurgitation.

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mortality of up to 11% per year [4,5]. In patients with dilated or end-stage HCM, the role for cardiac resynchronization therapy in this subset of patients remained unexplored.

However, many studies revealed that traditional biventricular pacing (BiVP) might be not useful for dilated-phase hypertrophic cardiomyopathy or end-stage hypertrophic cardiomyopathy [6,7]. It is not clear whether conduction system pacing (CSP) might be applied to patients with HCM and HF. His bundle pacing (HBP) had emerged as the most physiologic pacing modality that preserved physiological activation of the ventricles and improved clinical outcomes [8]. However, how to deliver the lead successfully and maintain the threshold stable for long-term were still great challenges on the present state. Left bundle branch pacing (LBBP) was an attractive pacing strategy that delivered a low and stable threshold by pacing beyond the site of the block [9]. However, it was not clear whether LBBP was available for the thick and fibrosis septal myocardium was still uncertain. We aimed to explore the feasibility and safety of HBP and LBBP on HCM and demonstrate the impact of CSP on the cardiac performance in patients with HCM and HF.

2. Methods

2.1. Patient enrollment and study design

Patients with HF and interventricular septal thickness (IVST) $\geq$ 13 mm who accepted conduction system pacing (CSP) with ventricular pacing percentage $>$ 40% for brady from May 2018 to April 2022 were consecutively enrolled in our center. The patients were divided into different groups according to LVEF values [10,11]. LBBP was preferred and HBP was the alternative therapy unless IVST $\geq$ 16 mm or LBBP failed, while LBBP would be the alternative therapy if HBP failed in patients with IVST $\geq$ 16 mm. BiVP or right ventricular pacing (RVP) would be the rescue therapies if CSP failed depending on whether cardiac resynchronization therapy (CRT) was indicated of or not. All patients consented to their treatment, which was approved by the hospital's ethics committee.

2.2. Implantation procedure

The HBP and LBBP were performed using the Select Secure pacing lead (Model 3830, Medtronic Inc.) and a fixed-curve sheath (C315 HIS, Medtronic Inc.). His bundle electrograms were mapped in a unipolar configuration and recorded in the system (Prucka Cardiolab, GE Healthcare). The unipolar-tip paced QRS configuration and pacing impedance were monitored along with the measurement of peak left ventricle (LV) activation times in lead V_5 for LBBP [12]. If CSP was unsuccessful in patients with CRT indications, the LV lead was positioned with a standard technique in the lateral or posterolateral LV vein on patients with biventricular pacing if possible. The electrocardiograms of HBP and LBBP before and after CSP were detailed in Fig. 1.

3. Data collection and follow-up

The clinical data were collected before and after CSP. The pacing threshold, amplitude of R wave and impedance were recorded during the operation and follow-up. Regular follow-up was conducted at 1, 3, 6, 12 months, and every 6 months after the operation. The 12-lead electrocardiogram (ECG), echocardiography, postoperative complications, and pacemaker parameters were monitored. The events of thrombosis, infection, lead dislodgement, perforation, stroke, or death were recorded. All patients were followed up at least one year.

The left ventricular end-diastolic diameter (LVEDD), and left atrial diameter (LAD) were measured according to American Society of Echocardiography guidelines. Left ventricular ejection fraction (LVEF) was measured by the biplane Simpson's method, and the maximum mitral regurgitation (MR) and tricuspid regurgitation (TR) were measured by the vena contracta width with color- flow Doppler. The IVST and ventricular wall were determined during diastole. Representative IVST, which was usually the thickness of the point 25 mm below the right coronary sinus nadir, was also recorded to indicate overall thickness.

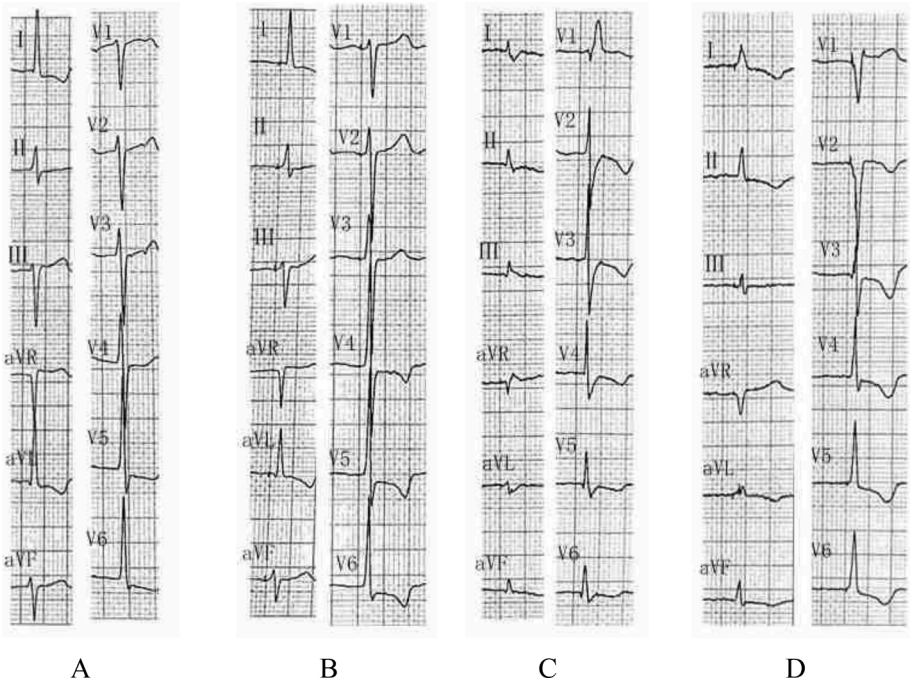

Fig. 1. ECG characters before and after CSP procedure Panels A and B demonstrated the ECGs of 12 leads before and after HBP ; Panels C and D demonstrated the ECGs of 12 leads before and after LBBP LBBP, left bundle branch pacing; HBP, his-bundle pacing; ECG, electrocardiogram.

3.1. Definitions and criteria

The clinical diagnostic criteria of HCM in adult patients was that the imaging with 2D echocardiography or cardiovascular magnetic resonance shows a maximal end-diastolic wall thickness of ≥ 15 mm anywhere in the left ventricle, in the absence of any other cause of hypertrophy in adults. More limited hypertrophy (13–14 mm) could be diagnostic when presented in family members of a patient with HCM in this study. The criteria of heart failure were the clinical syndrome consisting of cardinal symptoms that were accompanied by signs, abnormal echocardiography and/or type B natriuretic peptide value [10,11].

His bundle pacing was defined as capture of the atrioventricular bundle with direct activation of all its fibers. This part of the conduction axis of the heart is demarcated proximally by the distal atrioventricular node and distally by the division of the His bundle into the right bundle branch and left bundle branch. Criteria for left bundle branch capture comprised the right bundle branch conduction delay pattern in lead V_1, abrupt shortening of left ventricular activation time (LVAT) in $V_5 \geq 10$ ms at high output during deep septal position with subsequent short and constant LVAT at low output with further advancement of the lead, and LVAT < 75 ms in non-LBBB and < 80 ms in LBBB. Isoelectric interval might to be found in all 12 leads. LBBB or right bundle branch block (RBBB) correcting failure was also regarded as procedure failure.

3.2. Statistical analysis

Statistical analyses were performed using SPSS 23.0. Continuous variables are reported as mean ± SD (standard deviation) and were compared with paired *t* tests for normally distributed data. Categorical variables are expressed as percentages (%) and were compared with $\chi 2$ tests. Shapiro Wilk test was adopted to verify the normal distribution or not. The data without normal distribution were expressed as the median (P25, P75). Nonparametric tests were used if the data were not normally distributed. All statistical tests were two-tailed; $P < 0.05$ was considered to indicate statistical significance.

4. Results

4.1. Baseline characteristics and clinical events

A total of 27 patients with HCM who received CSP procedures were enrolled in the study, including 4 patients with hypertrophic obstructive cardiomyopathy (HOCM) and 2 patients with Morrow procedure. The CSP was successfully deployed in 16 cases with HBP and 8 cases with LBBP (24/27, 88.89%). HBP was successfully delivered in 16 patients, including 5 patients failed in LBBP and 11 patients with IVST ≥ 16 mm. LBBP was successfully delivered in 8 patients, including 2 patients failed in HBP and 6 patients with IVST < 16 mm. CSP failed in 3 patients (3/27, 11.11%) including one patient with HOCM, one with dilated-phase HCM and one with left bundle branch block suffered from HOCM surgery. Among the patients with CSP, 22 patients underwent pacemaker implantation due to atrioventricular block (AVB). The average age was 65.79 ± 9.31 years old, and the LVEF were 47.79%±9.57% in 24 patients with CSP. The procedure time was 101.52 ± 55.54 min and the follow-up duration were 19.19 ± 7.71 months. During the follow-up period, no infection, thrombosis, perforation, sudden death or lead dislodged occurred. Baseline characteristics were shown in Table 1.

4.2. Lead outcomes after conduction system pacing

The threshold of capture/correcting conduction system increased a little (1.09 ± 0.51 V/0.4 ms vs.1.42 ± 0.71 V/0.4 ms, $P = 0.013$) after follow-up in patients with all CSP patients. The impedance decreased a little (678.58 ± 108.0 Ω vs. 443.18 ± 46.37 Ω, $P < 0.001$), while the amplitude of R wave (6.78 ± 4.47 mV vs. 8.96 ± 5.91 mV, $P = 0.135$) did not change obviously after follow-up. The pacing percentage at the final follow-up was 84.14%±21.08%. No lead related complications were observed. All the changes were shown in Table 2. The correct threshold increased from 1.0 V@0.4 ms to 3.5 V@0.4 ms in one patient with complete left bundle branch block about one year after LBBP.

Table 1
Baseline characteristics of patients with HCM and CSP.

	patients with **CSP** (n = 24)
age (years)	65.79 ± 9.31
male (n, %)	16 (66.7%)
BMI (kg/m^2)	25.14 ± 2.53
atrial fibrillation (n%)	21(87.5%)
diabetes mellitus (n%)	3(12.5%)
coronary heart disease (n%)	4 (16.7%)
hypertension (n, %)	14(58.3%)
NYHA classification	2.08 ± 1.25
LBBB (n %)	2 (8.3%)
RBBB (n %)	2(8.3%)
LVEF (%)	47.79 ± 9.57
LVEDD (mm)	49.25 ± 7.33
LAD (mm)	49.58 ± 8.99
IVST (mm)	17.92 ± 2.61
anticoagulants (n, %)	16 (66.67%)
ACEI/ARB/ARNI (n, %)	15 (62.50%)
ACEI/ARB/ARNI after operation (n, %)	14 (58.33%)
β-blockers (n, %)	2 (8.33%)
β-blockers after operation (n, %)	22(91.67%)
Spironolactone(n, %)	15 (62.5%)
Spironolactone after operation(n,%)	16(66.7%)
diuretics (n, %)	15(62.50%)
QRS duration (ms)	123.01 ± 45.91
initial CR (umol/l)	81.39 ± 36.16
initial BNP (ng/L)	779.91(226.11–4240.12)
atrioventricular block (n, %)	22 (91.67%)
operation time (minutes)	101.52 ± 55.54

LBBB/RBBB: left or right bundle branch block; *ACEI:* angiotensin converting enzyme inhibitors; *ARB* angiotensin receptor blocker; *ARNI*: angiotensin receptor neprilysin inhibitors; *LAD* left atrium diameter; *LVEDD* left ventricular end-diastolic diameter; *LVEF* left ventricular ejection fraction; *VP:* ventricular pacing. DDD, dual-chamber pacemaker; CRT-P, cardiac synchronization therapy-pacemaker; CRT-D, cardiac resynchronization therapy-defibrillator; *IVST* interventricular septal thickness.

4.3. Cardiac outcomes after conduction system pacing

In the patients with CSP and LVEF < 50%, the LVEF (39.22%±7.51% vs. 45.22%±9.59%, $P = 0.015$), LVEDD (52.11 ± 10.10 mm vs.48.33 ± 9.07 mm, $P = 0.037$), LAD (50.33 ± 8.93 mm vs.46.11 ± 5.97 mm, $P = 0.013$) and NYHA grade (2.67 ± 0.5 vs. 1.38 ± 1.02, $P = 0.029$) improved obviously after CSP. However, in the other 15 patients with LVEF > 50%, the LVEF (52.13%±1.84% vs. 53.00 ± 3.80%, $P = 0.372$), LVEDD (47.53 ± 4.64 mm vs.46.07 ± 6.56 mm, $P = 0.665$), LAD (49.13 ± 9.31 mm vs.47 ± 11.75 mm; $P = 0.093$) and NYHA grade (1.73 ± 1.43 vs.1.56 ± 0.92, $P = 0.452$) did not improve significantly. The improvements of cardiac performances after CSP were demonstrated in Table. 3.

HBP was an effective alternative to LBBP for high success rate especially in those with significantly thickened interventricular septum. During the follow-up period of 19.19 ± 7.71 months, LVEF ($P = 0.521$), LVD ($P = 0.816$) and QRS duration ($P = 0.928$) did not deteriorate after

Table 2
Lead outcomes before and after follow up.

	during operation	final follow-up	*P* value
threshold (V@0.4 ms)	1.09 ± 0.51	1.42 ± 0.71	0.033
impedance (Ω)	678.58 ± 208.02	443.18 ± 96.37	0.001
amplitude of R wave(mV)	6.78 ± 4.47	8.96 ± 5.91	0.135
pacing percentage(%)		84.14 ± 21.08	

Table 3
Clinical outcomes in patients with different LVEF.

	patients with LVEF < 50% (n = 9)	patients with LVEF ≥ 50% (n = 15)	*P* value
age	61.11 ± 11.71	68.60 + 6.44	0.06
Male (n, %)	4 (44.4%)	12 (80%)	0.09
initial NYHA classification	2.67 ± 0.5	1.73 ± 1.43	0.075
final NYHA classification	1.38 ± 1.02*	1.56 ± 0.92	0.432
initial QRSd (ms)	133.56 ± 49.15	116.67 ± 45.97	0.182
final QRSd (ms)	120.22 ± 22.01	121.6 ± 23.02	0.949
initial LA size (mm)	50.33 ± 8.93	49.13 ± 9.31	0.759
final LA size (mm)	46.11 ± 5.97*	47 ± 11.75	0.979
△LAD (mm)	−4.22 ± 2.53	−2.13 ± 2.88	0.670
initial LVEDD (mm)	52.11 ± 10.10	47.53 ± 4.64	0.142
final LVEDD (mm)	48.33 ± 9.07*	46.07 ± 6.56	0.195
△LVEDD(mm)	−3.78 ± 2.16	−1.46 ± 1.67	0.881
initial LVEF (%)	39.22 ± 7.51	52.13 ± 1.84	< 0.001
final LVEF (%)	45.22 ± 9.59*	53.00 ± 3.80	< 0.001
△LVEF(%)	6.01 ± 3.60	0.87 ± 0.76	0.038
pacing percentage (%)	90.44 ± 20.82	81.64 ± 23.24	0.326

NYHA, New York Heart Association; LAD, left atrium diameter; LVEDD, left ventricular end-diastolic diameter; LVEF, left ventricular ejection fraction; *$P <$ 0.05 significant difference before and after follow-up.

CSP. The LAD (49.58 ± 8.99 mm vs.47.04 ± 9.82 mm, $P = 0.045$) tended to improve slightly. The changes were shown in Fig. 2.

5. Discussion

We found that HBP and LBBP were feasible and safe in HCM patients with HF. The cardiac performance did not deteriorate after CSP in HCM, even the improvement of LVEF and reverse of cardiac remodeling were detected in those with systolic dysfunction. HBP might be an effective alternative to LBBP in patients with significantly thickened interventricular septum.

5.1. Feasibility and safety of CSP in patients with HCM

CSP had illustrated the feasibility and favorable clinical outcomes compared with RVP and BiVP [13]. However, the application of CSP in HCM patients was a great challenge for the thicker IVS and more myocardial fibrosis or scar [14–16]. Zheng et al. [15] showed that LBBP was a more feasible physiological strategy for patients after myectomy. Zhu et al [16] revealed that LBBP strategies should be cautiously considered in patients with HCM because of the low success rate of 36.4%. At present, there was no report on the application of HBP in patients with HCM. In our current study, we firstly demonstrated that the HBP maybe favorable for the higher success ratio (78.57% vs.46.15%) than LBBP, and CSP was feasible for the high successful ratio of 88.89% in patients with HCM and LVEF < 50%.

Since the initial description of HBP by Deshmukh et al. [17], multiple investigations had demonstrated its feasibility and safety in patients with high ventricular pacing ratio. LBBP was promising for physiological pacing via capturing the left proximal conduction system [18]. In 2020, Zhang et al [19] first reported a case of LBBP in patients with non-obstructive hypertrophic cardiomyopathy and recovered well. However, the failure of LBBP in patients with HCM was impossible to ignore. The HCM with septal myectomy and dilated-phase HCM were found to be associated with CSP failure in our study, which suggested that hypertrophied and/or fibrotic septum might be the hindrance for LBBP lead penetration and it might be the major reason of LBBP failure in

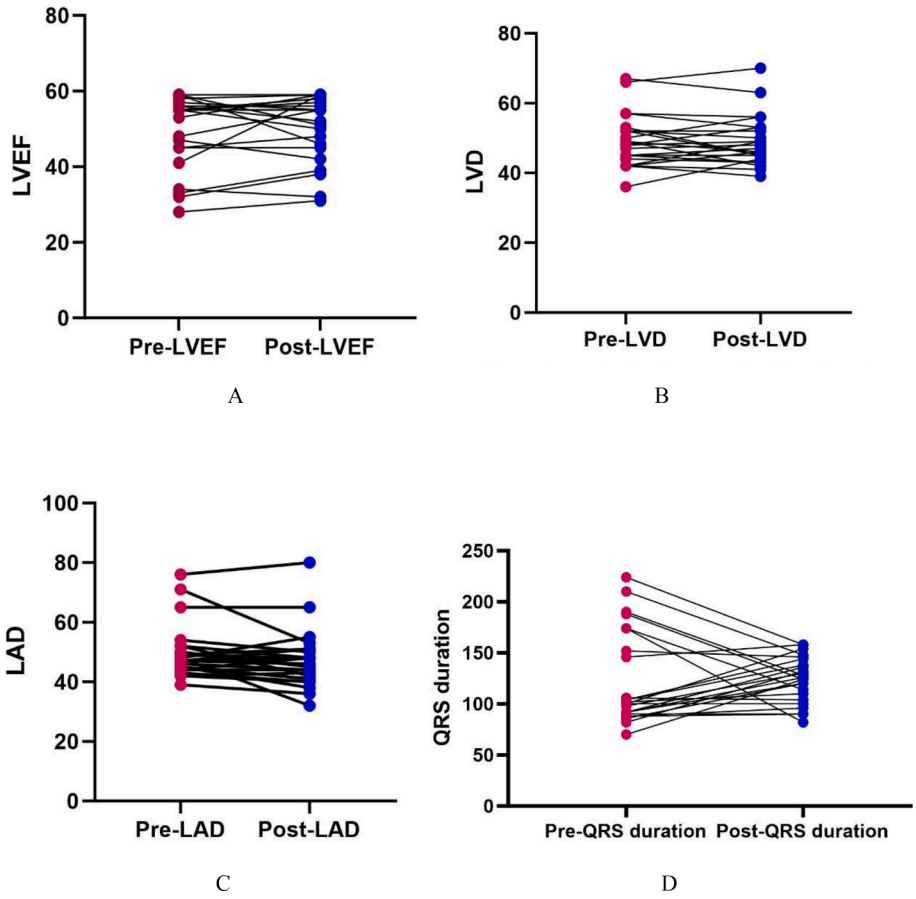

Fig. 2. Clinical outcomes before and after csp lad, left atrium diameter; lvedd, left ventricular end-diastolic diameter; lvef, left ventricular ejection fraction.

patients with HCM.

The pacing threshold slightly increased during the follow up. And the threshold increased obviously in one patient with LBBP, which might result from the fact that the mechanical damage to the lead caused by ventricular septal contraction. Of note, CSP strategy on HCM should be cautious, and the long-term data would be necessary.

No infection, thrombosis, perforation, sudden death or lead dislodged occurred in this study. Of note, the possibility of mural haematoma, coronary artery injury, lead removal should be monitored, and more evidences were necessary to confirm the feasibility and safety of this novel CSP in hypertrophic cardiomyopathy.

5.2. Cardiac performance improvement in patients with HCM after CSP

BiVP might be considered in patients with HCM, left bundle branch bundle (LBBB), and LVEF $< 50\%$ according to previous guidelines recommendations [20]. However, previous data showed that BiVP was not associated with significant and sustained cardiac systolic function benefit in HCM [7,21]. The disease progression was not very influenced by BiVP, and new options for CRT should be focused.

Our study showed that in the patients with LVEF $< 50\%$, the LVEF, LVEDD, LAD and NYHA grade improved obviously after CSP. The physiological electrical conduction including the correcting of LBBB resulted from the CSP procedure played the major roles on the favorable outcome, however the benefit from drug treatment including β-blockers after CSP might partly contribute to the favorable results. Although CSP played a role in improving ventricular function, it was not effective in the treatment of ventricular hypertrophy. There was still possibility of developing ventricular arrhythmias and heart failure, thus the close follow-up might be important.

5.3. Comparison of pacing modality on patients with HCM

We firstly demonstrated that HBP was more favorable in HCM for the higher success ratio than LBBP (78.57% vs.46.15%). The technically challenges in HCM, including the thick septum, septal scar and myocardial fibrosis and the hyper contractility of LV in the long term, might be the hindrance for lead penetration in LBBP procedure. During the procedure in HCM patients, the length from the tip to the proximal end of the anodal ring is 14.8 mm. If the septum is too thick, the electrode will lose its support during the twisting process, making twisting more difficult. In addition, the the direction of electrode rotation is also more difficult to control. Of note, this study showed acceptable and stable threshold resulted from the distal HBP lead helix, which provided strong evidence for the utility of HBP in patients with HCM. The reticular distribution of the left conduction bundle might provide a better anatomical basis for LBBP [22].

QRS duration were not obviously different before and after CSP. And the key point resulting in this favorable outcome might be that the QRS duration did not prolonged significantly after CSP. The better electrical synchrony due to CSP might be the reason why CSP could improve or preserve the cardiac performance on patients with HCM and AV block. We found that the IVS thickness reduced after HBP, while no change in LBBP. The reason for the reduced thickness was unclear. Pacing threshold remained stable and no procedure-related complications occurred during a mean follow-up of 19.19 ± 7.71 months.

5.4. Limitations

This study was a retrospective study and all implantation were performed at a single center. More large-sample and randomized control multicenter studies might be necessary to confirm these results. There was no consensus on the definition of successful LBBP and HBP in general populations or patients with structural abnormalities including significantly hypertrophied. Feasibility of LBBP and HBP in HCM patients with severe hypertrophy is still unclear, especially LVOT obstruction.

6. Conclusion

CSP was safe and feasible in patients with HCM and cardiac dysfunction, and it did not deteriorate the cardiac performances especially in those with LVEF $< 50\%$. HBP might be an effective alternative to LBBP in patients with significantly thickened interventricular septum.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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