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Application and Research of Left Bundle Branch-Optimized Cardiac Resynchronization Therapy in Ischemic Cardiomyopathy

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ABSTRACT

Objective: To investigate the efficacy of Left bundle branch optimized cardiac resynchronization therapy (LOT-CRT) in heart failure patients with reduced ejection fraction caused by ischemic cardiomyopathy.

Methods: 22 patients with ischemic cardiomyopathy who underwent pacemaker implantation in the Department of Cardiology of the Fifth people's Hospital affiliated to Chengdu University of traditional Chinese Medicine from March 2020 to March 2022 were divided into two groups based on different pacing methods: LOT-CRT group (n = 10) and brust of ventricular pacing (BVP) group (n = 12). The preoperative baseline data and intraoperative surgical X-ray exposure time of the two groups were compared. Pacing threshold, impedance, electrocardiogram QRS wave duration during pacing, ventricular pacing ratio during follow-up, and cardiac ultrasound related indicators for both groups immediately during surgery and 6 months after surgery follow- up.

Results

Baseline Data: There was no statistically significant difference (P > 0.05) between the two groups in terms of age, gender, comorbidities, cardiac ultrasound, cardiac magnetic resonance related indicators, NYHA grading of cardiac function, NT-proBNP levels, and clinical drug use.

Pacing Parameters and Intraoperative Indicators: Comparison between two groups of patients, the BVP group had higher Pacing threshold and impedance during the immediate and follow-up period (P < 0.001); The X-ray exposure time was longer in the BVP group than in the LOT-CRT group (P < 0.001).

Pacing QRS Wave Duration: There was no statistically significant difference in the baseline QRS wave duration between the two groups of patients before surgery (P > 0.05). Comparison between two groups immediately after surgery and during postoperative follow- up, the QRS wave duration in the LOT-CRT group was shorter (P < 0.001).

Echocardiographic Related Indicators and Cardiac Function Parameters: There was no statistically significant difference (P > 0.05) between the two groups in NYHA cardiac function grading, left ventricular ejection fraction (LVEF), and left ventricular end diastolic diameter (LVEDD). NYHA cardiac function grade, LVEF and LVEDD were improved in both groups 6 months after operation, but the improvement in LOT-CRT group was significantly better than that in BVP group (P < 0.001).

Conclusion: Compared with the BVP group, the LOT-CRT group has a significantly shorter QRS wave duration, the cardiac function of the patients was significantly improved, and is more physiological in nature. It may be an alternative treatment for patients with heart failure complicated with left bundle branch block caused by ischemic cardiomyopathy who are not satisfied with the efficacy of BVP.

Keywords: Ischemic Cardiomyopathy; Heart Failure; Cardiac Resynchronization Therapy; Left Bundle Branch-Optimized Cardiac Resynchronization Therapy

Abbreviations: CRT: Cardiac Resynchronization Therapy; BVP: Brust of Ventricular Pacing; LBBB: Left Bundle Branch Block; HF: Heart Failure; ICM: Ischemic Cardiomyopathy; LOT-CRT: Left Bundle Branch- Optimized Cardiac Resynchronization Therapy; NICM: Non Ischemic Cardiomyopathy

Introduction

Cardiac resynchronization therapy (CRT) usually refers to brust of ventricular pacing (BVP), It is an important treatment for patients with cardiomyopathy, left bundle branch block (LBBB) and advanced heart failure (HF). As many as 30% of patients treated with BVP go unresponsive, especially in ischemic cardiomyopathy (ICM), and there is an urgent need to explore new treatments to improve clinical outcomes for such patients. Recent studies have shown that physiological left bundle branch pacing (LBBP) can significantly shorten or even normalize the width of QRS waves, thereby improving clinical outcomes [1-5]. Other studies have confirmed that left bundle branch- optimized cardiac resynchronization therapy (LOT-CRT) can further improve the clinical prognosis of non ischemic cardiomyopathy (NICM) [6-8]. However, the application and efficacy of LOT-CRT in ICM are rarely reported, and in-depth study of this is of great significance for the treatment of ICM. Therefore, by analyzing the therapeutic effect of LOT-CRT on ICM patients, we aim to provide theoretical basis for the application of LOT-CRT in ICM and clinical ideas for the treatment of ICM.

Materials and Methods

Research Object

People's Hospital Affiliated to Chengdu University of Traditional Chinese Medicine from March 2020 to March 2022. Inclusion criteria: age 18-65 years old; conformity with CRT treatment criteria: NYHA functional class III-IV, electrocardiogram showed complete left bundle branch block, QRS interval >120 ms, LVEF≤35%. All enrolled patients received at least 3 months of guideline-guided drug therapy [9]. Exclusion criteria: did not meet CRT criteria; did not meet diagnostic criteria for ICM; upgrade from common pacemaker to CRT; severe liver and kidney insufficiency; life expectancy less than 1 year, [10,11] Unwilling to participate in this investigator. During the study period, a total of 78 patients were selected from the center and classified into LOT-CRT (n = 39) and BVP (n = 39) according to the random number chart. In the LOT-CRT group, 2 patients were selected to perform biventricular pacing, 1 patient abandoned surgery, and 1 surgery failed, and 35 patients in the LOT-CRT group were included in the study; 2 failed patients in the BVP group and 2 LOT-CRT patients were included in the BVP group, so 39 patients in the BVP group were included in the study.

This study was approved by the Medical Ethics Committee of the Fifth People's Hospital Affiliated to Chengdu University of Traditional Chinese Medicine(Ethical Number: Ethical review 2022-009 (Section) -01), the volunteers volunteered participated in the study and signed informed consent. This study strictly adhered to the declaration of Helsinki, protected the privacy of the volunteers, and anonymized the volunteers in the data collection, analysis, and results reporting.

Research Method

All patients were treated with angiotensin-converting enzyme inhibitors (angiotension converting enzyme inhibitors, ACEI) / angiotensin receptor antagonists (angiotensin receptor blocker, ARB) and β receptor blockers according to the clinical guidelines for chronic heart failure. The diuretic dosage was adjusted according to the actual conditions of fluid storage and received standard medication for at least 3 months [12-14]. All surgeons had experience with CRT implants and at least 50 LOT-CRT implants. The LBBP was performed using the SelectSecure system (Model 3830 Lead, 69 cm; C315 His sheath, Medtronic, Minneapolis, MN). Specific implantation procedure: The 3830 pacing lead is placed in the right anterior oblique 30 fluoroscopy interval through the C315 His sheath. Using 2.0V/0.4ms unipolar pacing, the ideal pacing point was determined by the following criteria:

1) The pacing 3080 lead Tip end, the pacing QRS in V1 lasts longer than 120ms and has a "W" pattern with a stop at the lowest point or ascending branch; and

2) The electrode R wave sensing at the Tip end is at least 5.0 mV. 3830 Lead rotates approximately 5 to 6 times clockwise, And perform a 3080 lead Tip end monopolar pacing, With dynamic assessment of QRS morphology, QRSd, pacing impedance and R wave amplitude, When the electrode tip reaches the LBB area, The QRSd will be significantly reduced, Testing the left ventricular peak reaching time in V5 to V6, When stimulated with different output (>5.0V/0.4 and 2.0V/0.4ms), When the left ventricular peak reaching time was significantly shortened and remained stable, despin, The depth of septal entry by pacing test and left anterior oblique 45, Perform the unipolar and bipolar pacing tests, And to assess the LBB potential on the ECG.

During the procedure, fluoroscopy and movie imaging were set to 4 frames per second, and movie images were set to 7.5 frames per second. In the traditional cardiac resynchronization treatment, a balloon catheter was placed through the axillary vein. After retrograde angiography exposure of the coronary vein, the left ventricular electrode was sent to the most distal end of the lateral or posterior lateral branch of the coronary sinus. After the test threshold, perception and other parameters were satisfied, the voltage was 10 V and the pulse width was 1.0 ms pacing to ensure no stimulation of the diaphragm, the right ventricular apical electrode and right atrial ear lead were implanted successively. Finally, the pacemaker generator was connected, the three-chamber pacemaker was put into the prefabricated pocket, the incision was closed layer by layer, the pocket was closed, the sterile dressing was covered, and the local sandbag was compressed for 6~8 h. All patients had successful intravenous implantation of a triple chamber pacemaker in patients without thoracotomy for LV electrodes.

Postoperative CRT programming was optimized for DDD or DDDR mode, sensing AV interval was 100 ms and pacing AV interval 130 ms, and lower limit frequency was set to make double-chamber pacing ratio> 90%, and upper limit frequency of 120-130 bpm. If LBBP can achieve perfect correction of LBBB, LBBP is applied separately, setting a maximum 80ms V-V delay, and the output of the RV or LV lead is set to 0.5V/0.1ms to avoid RV or LV pacing. If only LBBP was used intraoperatively and the QRSd was greater than 140ms, sequential pacing was fused with LBBP and CS-LV pacing and then programmed at appropriate LV-RV (V-V) intervals to further reduce the QRS. In patients with sinus rhythm, atrial-ventricular (A-V) delays were adjusted to optimize ECG performance. In patients with BVP, the operating surgeon regularly adjusts the A-V and V-V intervals to optimize to shrink the QRSd. For some patients with unsatisfactory QRS shortening, echocardiographic optimization was used to adjust for the A-V and V-V intervals.

Outcome Indicators

All patients were followed up at 3-month intervals in the arrhythmia outpatient clinic. At each visit, the use of diuretics and digitalis may gradually decrease if the patient's HF symptoms are significantly reduced. The dose of β blockers, spironolactone and ACEI/ARB or ARNI did not change during the first 6 months of follow-up. R wave amplitude, capture threshold, impedance, ventricular pacing percentage and 12-lead ECG were recorded at baseline and follow-up, regular follow-up for electrode related complications and QRSd measured at V1 at implantation and follow- up. Echocardiography was performed by experienced fixed ultrasound physician at baseline and 6 months after surgery. LVEF was calculated using a two-dimensional transthoracic echocardiography biplanar Simpson method, analyzed by an experienced sonographer who was blinded to all clinical data. Functional and plasma NT-proBNP levels of the New York Heart Association (NYHA) were assessed at each follow-up visit. During follow-up, all recorded rehospitalization for Hfailure and mortality. New York Heart Association (NYHA) cardiac function evaluation improvement of grade 1 and echocardiographic LVEF improvement of 5% were considered as CRT response.

Statistical Analysis

Statistical analysis was performed by SPSS 19.0 software, continuous variables conforming to normal distribution were expressed by mean±standard deviation (x±SD), two-sample independent t-test for group comparison, continuous variables not conforming to normal distribution were expressed by median and interquartile spacing, by Wilcoxon rank sum test, count data as percentage, by χ 2 test, $P < 0.05$ considered statistically significant.

Results

Preoperative Baseline Characteristics

The mean age of the LOT-CRT group was 55.8 ± 10.0 years and the mean LVEF was 26.00 ± 4.32; the mean age in the BVP group was 56.5 ± 10.4 and the mean LVEF was 26.83 ± 4.17. There were no statistical differences between gender, age at pacemaker implantation, NYHA cardiac function classification, LVEF, LVEDD, LVDS, MRA, LVESV, LVEDV, ACEI / ARB, β -blocker, digoxin, and LV electrode target vein selection (P > 0.05, (Table 1)). All patients received directive medical treatment for at least 3 months (Figure 1).

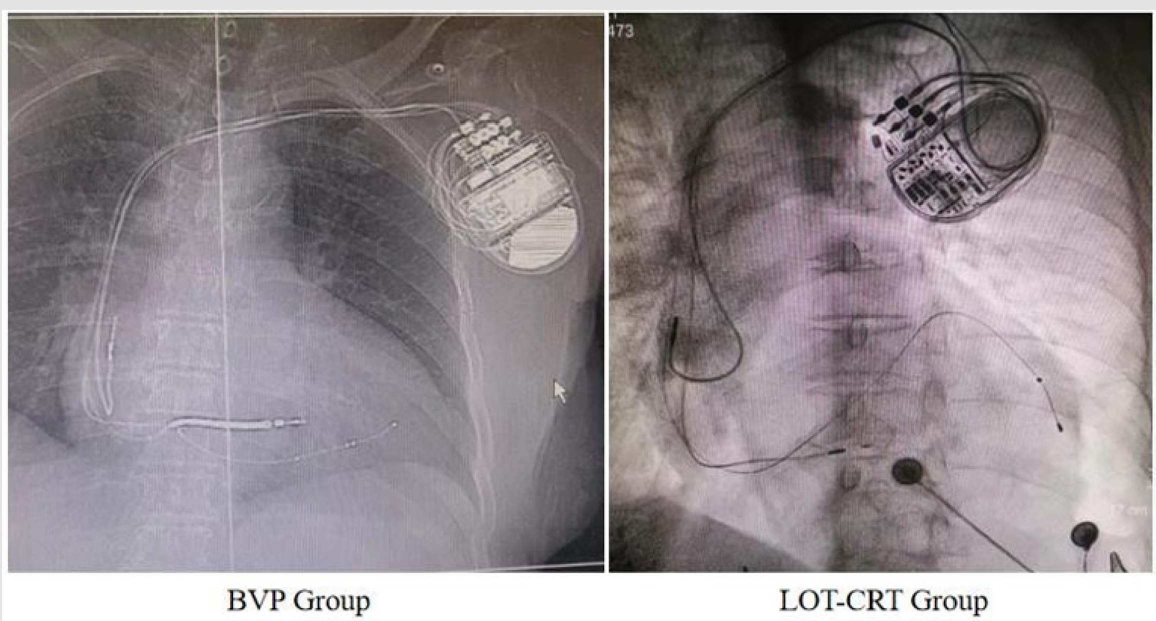

Figure 1: Typical chest X-ray on the postoperative day in both groups.

Table 1: Baseline characteristics.

	BVP(N=35)	LOT-CRT(N=39)	P value
Age, years	56.5 ± 10.4	55.8 ± 10.0	0.801
Male, n (%)	21(60.0)	24(62.0)	0.703
NYHA	2.9 ± 0.7	2.8 ± 0.9	0.955
NYHA II, n (%)	9(26.7)	8(20.5)	
NYHA III, n (%)	20(57.1)	19(48.7)	
NYHA IV, n (%)	6(17.1)	12(30.7)	
Hypertension, n (%)	12(34.3)	11(28.2)	0.654
Diabetes Mellitus, n (%)	6(17.1)	8(20.5)	0.923
Atrial fibrillation, n (%)	9(25.7)	8(20.5)	0.557
Baseline QRSd, ms	173.2 ± 22.3	175.5 ± 18.1	0.277
Left atrium, mm	43.3 ± 5.4	42.2 ± 5.0	0.822
LVEDD, mm	70.6 ± 8.0	71.2 ± 7.6	0.835
LVDS,mm	63.3±9.0	63.7±8.3	0.901
MRA, cm^2	5.2±2.4	5.2±2.2	0.224
LVESV, ml	222.3±95.6	222.5±105.2	0.463
LVEDV, ml	300.6±98.2	301.8±107.6	0.367
LVEF, %	26.83±4.17	26.00±4.32	0.439
RV, mm	23.9± 5.9	24.0 ± 5.7	0.117
NT-proBNP, pg/mL	1714.5 (914.7, 2514.3)	1757.1 (997.2, 2517.0)	0.532
Drug therapy			
Digitalis, n (%)	23(66.7)	27(69.0)	0.570
Diuretics, n (%)	35(100.0)	10(100.0)	1.000
ACEI/ARB, n (%)	35(100.0)	10(100.0)	1.000
Mineralocorticoid receptor antagonist, n (%)	35(100.0)	10(100.0)	1.000
Beta-blocker, n (%)	32(91.4)	31(79.0)	0.087

Note: ACEI: Angiotensin converting enzyme inhibitor, ARB: Angiotensin II receptor bloc; LVEDD: LV end-diastolic diameter; LVEF: Left Ventricular ejection fraction; NYHA: New York Heart Association; RV: Right Ventricle.

Comparison of ECG, Pacing Characteristics and Surgical Parameters Between the Two Groups at 6 Months after Surgery

Memean QRSd (P < 0.001), P < 0.001) at implantation (P < 0.001) and (P < 0.001) in LOT- CRT at 6 months compared with the BVP group.

At the 6-month follow-up, the QRSd in the LOT- CRT group remained narrower than in the BVP group (114.0±13.0 vs. 151.0±19.2ms, P < 0.001) and remained differences in LBBP thresholds and pacing impedance between the two groups (P < 0.001, (Table 2)) (Figure 2).

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Table 2: ECG, pacing characteristics, and surgical parameters at 6 months after surgery.

Variables	BVP	LOT-CRT	P value
	N=35	N=39	
CRT-D, n (%)	26(74.3)	31(79.5)	0.865
At implant			
Threshold, at 0.4 ms, V	1.28±0.59	0.83±0.40	0.002**
Paced QRSd, ms	157.6±21.8	128.0±16.7	< 0.001**
X-ray exposure duration (total), min	40.4±8.7	32.6±9.5	< 0.001**
Impedance, Ω	772.8±245.4	608.2±225.3	< 0.001**
follow-up			
VP%	96.1±2.2	98.3±1.5	0.265
Paced QRSd, ms	151.0±19.2	114.0±13.0	< 0.001**
threshold, at 0.4 ms, V	1.32±0.67	0.74±0.30	< 0.001**
impedance, Ω	726.3±151.3	562.8±185.4	< 0.001**

Note: *P < 0.05 **P < 0.001.

Figure 2: Typical ECG at 6 months after surgery in both groups.

Echocardiography and Clinical Findings in Both Groups at 6 Months After Surgery

In LOT-CRT, LVEF (P < 0.001), higher CRT overresponse rate (P < 0.001), significant improvement in NYHA cardiac grade (P < 0.001), significant reduction in plasma NT-proBNP level (P < 0.001), higher CRT response rate (90.0% VS 75.0%, P = 0.021). No events of HF rehospitalization or all-cause death were observed in either group at the 6-month follow-up (As shown in Table 3) (Figure 3).

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Table 3: Echocardiography and clinical findings in both groups at 6 months after surgery.

Variables	BVP N=35	LOT-CRT N=39	p value
Echocardiography parameters			
LVEDD, mm	62.6±7.5	47.4±7.9	< 0.001**
LVEF, %	34.0±5.6	55.5±6.2	< 0.001**
Echocardiographic response, n (%)	20 57.1	31 79.5	0.033*
uper-response, n (%)	6 17.1	16 41.0	0.001**
NYHA class	2.4±0.6	1.2±0.9	< 0.001**
NYHA I, n (%)	6 17.1	19 48.8	
NYHA II, n (%)	18 51.5	16 41.0	
NYHA III, n (%)	9 25.7	4 10.2	
NYHA IV, n (%)	3 8.6	0 0.0	
NT-proBNP, pg/mL	1224.3 (568.5,	432.9 (210.9,	< 0.001**
	2310.7)	709.2)	
Clinical response,n (%)	26 74.2	35 89.7	0.021*

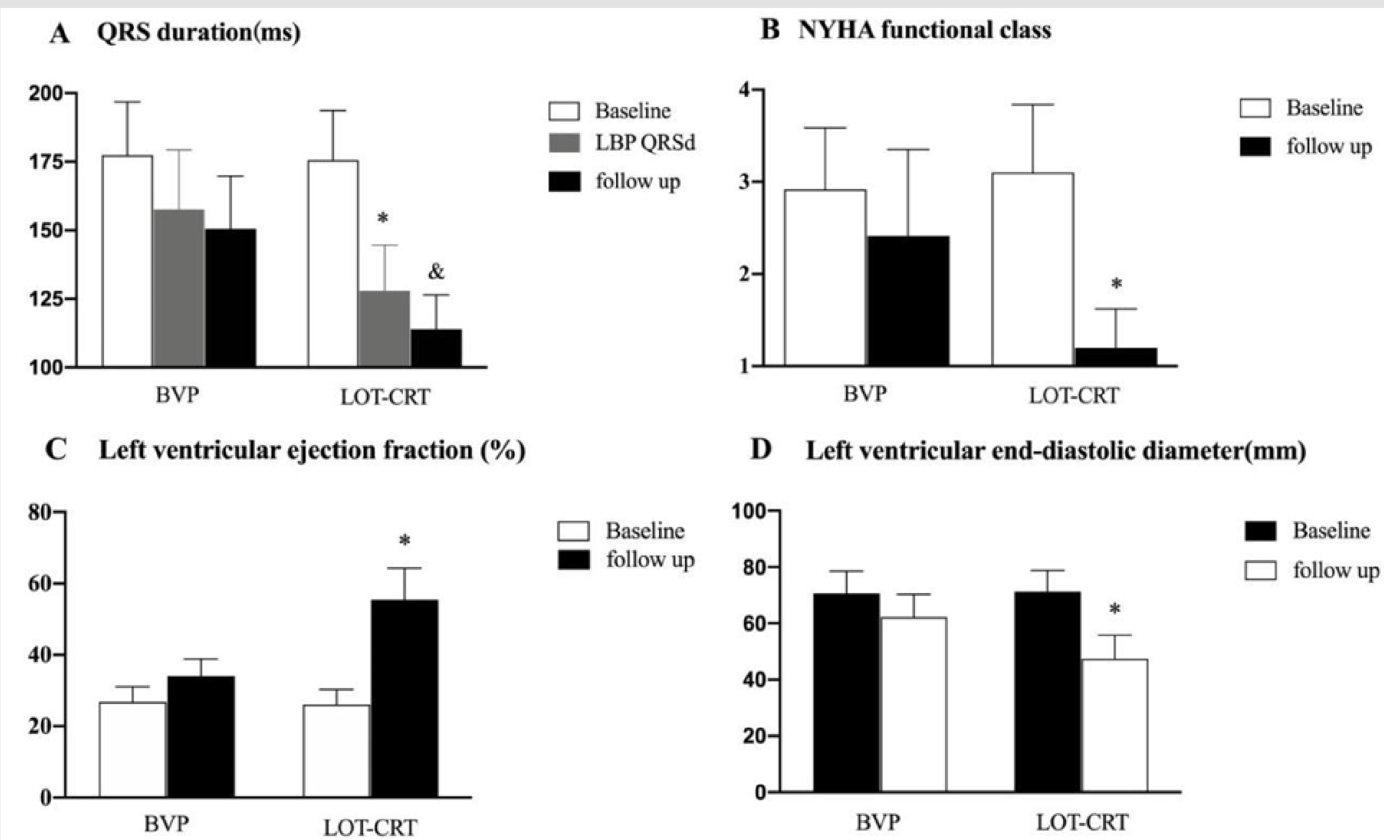

Figure 3: Duration of QRS and cardiac function at baseline and 6 months postoperative follow-up. Note: QRS time at baseline, LBP at implantation, reduced QRS time, and final pacing QRS time at follow-up (A); NYHA cardiac function grade and left ventricular ejection fraction from baseline to follow-up period (B, C); change in left ventricular end-diastolic diameters from baseline to follow- up period (D). NYHA: The New York Heart Association.&: P <0.05, as compared with the BVP group. *: P <0.05, as compared with the BVP group.

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Discussion

Ischemic cardiomyopathy (ischemic cardiomyopathy, ICM) refers to the left ventricular systolic dysfunction in coronary artery disease (Coronary Artery Disease, CAD), which is the most common cause of HF worldwide [15]. Previous studies have reported that the 5-year mortality of ICM patients with HF is as high as 50% to 84% [16]. Therefore, how to develop individualized treatment strategies for such patients in clinical practice has always been a difficult problem in the field of cardiovascular research at home and abroad. BVP is currently an effective and established treatment for patients with left ventricular systolic dysfunction (LVEF <35%) and LBBB-associated electrical uncontrolled heart failure, and is the standard treatment for HF recommended by current guidelines [17]. Some studies have found that BVP can improve heart failure symptoms and ventricular function by simultaneously stimulating the double ventricles, [18] But at least 30% of patients treated with BVP did not benefit from it and even some of them showed a deterioration of health status, related to load and distribution of LV scars, suboptimal site of LV electrode stimulation, gender and electrical or mechanical desynchrony [19]. Studies have found that although BVP can significantly improve hemodynamics, it has not proved to improve the long-term prognosis of patients [20].

However, compared with BVP, LBBP showed a significantly higher LVEF improvement rate [21-23] of and echocardiographic super- remission rate [24,25]. Other studies found that LOT-CRT significantly shortened the QRSd width and restored mechanoelectric synchronization compared with BVP, ultimately improving the clinical outcome of NICM [26-28]. The above studies suggest that LOT-CRT shows obvious advantages over BVP in NICM patients, but whether it can become a routinely used pacing mode to replace BVP, and its application and efficacy in ICM patients still need further research. Therefore, we made a preliminary exploration of the application of LOT-CRT in ICM-induced HF patients and compared it with the traditional BVP to analyze the clinical prognosis of such patients. Using a prospective randomized controlled study, we selected 78 patients eligible for inclusion and exclusion, including 39 in LOT-CRT group and 35 in BVP group, age, gender, combined disease, cardiac ultrasound, cardiac magnetic resonance, NYHA cardiac function grade, NT-proBNP level, and clinical drug use ($P > 0.05$).

After a 6-month advance follow-up schedule, Intention-to-treat analysis revealed that, Compared with the LOT-CRT group, lower immediate and follow-up national values and impedance ($P < 0.001$), shorter X-ray exposure time ($P < 0.001$), and narrower QRSd ($P < 0.001$); Analysis of echocardiography and clinical findings at 6 months in both groups found that, NYHA cardiac function grade, LVEF and LVEDD improvements were significantly higher in the LOT-CRT group than in the BVP group ($P < 0.001$), Higher CRT response ($P < 0.001$), significantly lower plasma NT-proBNP levels ($P < 0.001$), higher CRT response (90.0% VS 75.0%, $P = 0.021$). This is in line with the findings made in the NICM by Shunmuga Sundaram Ponnusamy et al, [29,30] it suggests that in patients with ICM to HF with LBBB, LOT-CRT can shorten the QRS time compared with BVP, improve the cardiac function of ICM to HF with LBBB, and the pacing mode is more physiological, which may become an alternative treatment for ICM to HF with LBBB patients with unsatisfactory efficacy of BVP. The disadvantage is that this study is a single- center, small sample size study and has a short follow-up time, which may lead to statistical bias. Therefore, the application and efficacy of LOT-CRT in patients with HF with LBBM require further confirmation by future randomized controlled prospective studies with larger samples and multiple centers.

Conclusion

In conclusion, we found that LOT-CRT in ICM induced HF with LBBB narrowed the QRSd, with better echocardiographic response and clinical outcome, possibly as an alternative to the superior resynchronous treatment modality of BVP in such patients.

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