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Research Article

Long-Term Safety and Feasibility of Left Bundle Branch Pacing Through Ventricular Septum and Right Ventricular Apex Pacing

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Abstract

Objective: Right ventricular apical pacing can cause left and right ventricular asynchrony, left ventricular anatomy, and electrical remodeling, leading to atrial fibrillation, heart failure, and increased cardiovascular adverse events. this research aim to investigate the long-term safety and feasibility of left bundle branch pacing through ventricular septum and right ventricular apical pacing.

Materials and Methods: Patients were selected from the Second Hospital of Tianjin Medical University who were diagnosed as having an indication for permanent cardiac pacing or heart failure with complete left bundle branch block (CLBBB) as having an indication for cardiac resynchronization therapy (CRT). All patients signed an informed consent form and were randomized into a traditional right ventricular apical pacing group of 40 patients (RAV group) and a left bundle branch pacing group of 20 patients (LBBP group) based on a 2:1 randomization. Collect basic information about all patients, including concomitant diseases, clinical diagnosis, preoperative electrocardiogram, and echocardiography. After the 3830 electrode is in place, record the pacing pattern, QRS wave duration (PQRSd), and LVAT. Pacing threshold, perception, impedance parameters, and electrode parameters were tested after the active fixation electrode was in place, and were followed up for 6, 12, 18, and 24 months. Record the operation time, X-ray exposure time, and X-ray exposure dose. The success rate of LBBB surgery and all related complications during the perioperative and follow-up periods were recorded.

Results: A total of 60 patients were enrolled, including 27 males and 13 females in the RAV group, with an average age of 78.2 ± 10.2 years. There were 13 males and 7 females in the LBBP group, with an average age of 74.8 ± 6.2 years. There was no significant difference in gender, age, and etiology between the two groups. There was no significant difference in pacing threshold, pacing impedance, and pacing perception between the RAV group and the LBBP group during the acute phase of surgery, which were 0.81 ± 1.0V vs 0.72 ± 0.16V, 758.00 ± 102.00 Ω vs 743.00 ± 162.00 Ω and 7.60 ± 2.20V vs 10.40 ± 1.20V, respectively. The comparison of operating time between the RAV group and the LBBP group was 55.8 ± 10.2 min vs 55.6 ± 12.5 min, the comparison of X-ray exposure time was 5.12 ± 1.2 min vs 12.6 ± 3.4 min, and the comparison of X-ray exposure dose was 7.10 ± 2.2 mG vs 15.90 ± 3.2 mG. The X-ray exposure dose and X-ray exposure time in the LBBP group were significantly longer than those in the RAV group, with statistical differences. During the follow-up period, the pacing threshold was 0.78 ± 2.40 vs 0.72 ± 1.20 V, the electrode impedance was 644.00 ± 96.20 Ω vs 672.20 ± 101.60 Ω, and the perceived value was 8.20 ± 2.42 V vs 8.60 ± 2.68 V, There was no significant difference in electrode parameters between the two groups. There were no complications such as bag infection, breakage and displacement of pacing electrodes, hemothorax, and pneumothorax in both groups.

Conclusion: Compared with traditional RVA pacing, LBBP has the same high surgical success rate, stable long-term lead parameters, no significant differences in perioperative complications, and good safety.

Keywords: left bundle branch pacing; right ventricular apex pacing; safety; feasibility

1. Introduction

Traditional ventricular pacing leads are located at and around the apex of the right ventricle, and are simple to operate. Their long-term safety and efficacy in the treatment of bradyarrhythmia have been confirmed. However, CTOPP [1], MOST [2]and UKFACE [3] have found that long-term high proportion of right ventricular apical pacing can cause left and right ventricular systolic asynchrony, increasing the risk of heart failure and atrial fibrillation, so RVP is not the best physiological pacing method.

Clinicians have been exploring physiological pacing methods. The concept of His bundle pacing (HBP) has been proposed for a long time. It directly stimulates the His bundle to transmit cardiac electrical activity through the His bundle Purkinje fiber system, achieving synchronous activation of the ventricles, and achieving true physiological pacing. In 1969, Scherlag [4] et al. first recorded His bundle potential via intravenous route, and in 1970, Narula [5] et al. first realized the recording of His bundle (HB) potential on the diaphragm surface of the tricuspid valve through an intravenous multi-electrode catheter in humans. In 1998, Deshmukh [6] et al. completed the first clinical application of permanent His bundle pacing (HBP) for patients with chronic atrial fibrillation and cardiac insufficiency who underwent atrioventricular node ablation and implanted cardiac pacemakers.

In the early stage, HBP was positioned and fixed with the help of a mapping catheter using shaped steel wires and active fixing wires. In 2004, the SELECT SECURE system was applied to clinical practice. Solid active fixation leads combined with dedicated delivery systems have promoted the development of HBP. Clinical studies have shown that its success rate has reached 92.1%, and follow-up pacing parameters are stable [7,8]. Abdelrahman [9] et al. showed that among patients with slow ventricular rate pacing, the HBP group had significantly lower primary endpoint events, death, heart failure, readmission rates, and upgraded BVP than the RVP group. The results of the HIS-SYNC study [10] show that HBP can achieve better electrical synchronization and significantly improve left ventricular ejection fraction compared to the biventricular synchronized pacing group. Huang [11] et al. have shown that HBP treatment for patients with atrial fibrillation and heart failure undergoing atrioventricular node ablation significantly improves their cardiac function grading and LVEF. However, HBP has shortcomings such as difficult surgical procedures, long X-ray exposure times, high pacing thresholds, a certain proportion of long-term threshold increases, and the implantation site does not cross the block site, making it difficult to widely apply to all pacing and CRT indications.

Traditional right ventricular apical pacing is a commonly used pacing electrode placement position in clinical practice due to its simple operation, short X-ray exposure time, and good electrode stability. However, right ventricular apical pacing can cause left and right ventricular asynchrony, left ventricular anatomy, and electrical remodeling, leading to atrial fibrillation, heart failure, and increased cardiovascular adverse events [1,2,3]. In recent years, physiological pacing methods have received increasing attention and become a hot research topic[12]. Huang [11] et al. first reported that left bundle branch pacing (LBBP) can correct left bundle branch block, improve heart failure, and improve left and right ventricular synchronization.

This study summarizes the data of 60 patients who underwent pacemaker implantation in the Cardiology Department of the Second Hospital of Tianjin Medical University from August 2020.08 to March 2023.03. The purpose of this study is to explore the central electrical characteristics, operating time, X-ray exposure time, electrode parameter stability, and complications of LBBP surgery, in order to further compare its feasibility and long-term safety.

2. Materials and Methods

2.1 Research object and patients:

Patients who were selected from the Cardiology Department of the Second Hospital of Tianjin Medical University and confirmed to be eligible for permanent cardiac pacing or heart failure with complete left bundle branch block (CLBBB) and eligible for cardiac resynchronization therapy (CRT) were selected. All patients signed an informed consent form and were randomized into a traditional right ventricular apical pacing group of 40 patients (RAV group) and a left bundle branch pacing group of 20 patients (LBBP group) based on a 2:1 randomization.

2.2 Operation and method:

Routine puncture of the left axillary vein, guided by a J-shaped guide wire, was conducted through the sheath tube of the His bundle and through the sheath tube, an active fixed electrode was sent. The electrode was fixed using a nine-point method combined with intracardiac mapping. The His bundle potential was measured at a right anterior oblique angle of 30 °. This was used as a marker to move the sheath tube 1-2 cm toward the apex of the heart, and a multi-channel electrocardiograph was connected, Record the 12-lead electrocardiogram and intracardiac electrogram. The lead tip is taken out of the sheath, and the right ventricular septal site with a W-shaped QRS wave is continuously pacing at 5V. After positioning, the 3830 electrode is inserted. First, the electrode is quickly rotated for 5-6mm, and then slowly rotated. Repeatedly test the monopole impedance and monopole pacing pattern of the 3830 electrode, and measure the left ventricular peak time (stimulation signal to left ventricular peak time, LVAT) under high voltage (5V) and low voltage (1V) pacing, whether there is a Purkinje potential (P potential). Test pacing threshold, perception, and impedance. After withdrawing the C315 sheath, retest the parameters. When satisfied, connect a pacemaker pulse generator (X3DR, Medtronic, USA), fully hemostasis, and stitch the wound.

2.3 Success criteria for left bundle branch pacing:

① Pacing pattern: The V1 lead of unipolar pacing presents a right bundle branch block pattern (RBBB).

② LVAT: Measure the interval from the V5 lead pacing pulse to the peak of the R wave. The peak time of high voltage (5V) pacing is<70ms, and the pacing is performed at high and low voltage, respectively. LVAT remains unchanged.

③ Left bundle branch potential (P potential) was recorded.

④ On the X-ray screen, it can be seen that the electrode is negative enough to enter a sufficient depth, the pacing threshold is good, and the impedance is less than 1000 Ω. Compliance with clauses ① and ② is mandatory, while clauses ③ and ④ are non mandatory.

2.4 Observation indicators:

① Collect basic information about all patients, including concomitant diseases, clinical diagnosis, preoperative electrocardiogram, and echocardiography.

② After the 3830 electrode is in place, record the pacing pattern, QRS wave duration

(PQRSd), and LVAT.

③ Test the parameters after the active fixation electrode is in place and follow up for 6, 12, 18, and 24 months, including pacing threshold, perception, and impedance.

④ Record the operation time, X-ray exposure time, and X-ray exposure dose.

⑤ The success rate of LBBB surgery and all related complications during the perioperative and follow-up periods were recorded.

3. Statistical processing

All data were processed using SPSS 22.0 statistical software, and the measurement data conforming to the normal distribution were represented by Mean ± SD, and the comparison between groups was performed using t-test; Counting data were expressed as percentages, and comparisons between

groups were performed using X^2 test. P<0.05 indicates a statistically significant difference.

4. Results

4.1 Comparison of general data between two groups of patients

A total of 60 patients were selected in this study, including 27 males and 13 females in RAV group, including 30 patients with sick sinus syndrome (30/40 cases, 75%) and 10 patients with III AVB (10/40 cases, 25%), with an average age of 78.2±10.2 years. There were 13 males and 7 females in LBBP group, including 15 cases of sick sinus syndrome (15/20 cases, 75%) and 5 cases of III AVB (5/20 cases, 25%), with an average age of 74.8±6.2 years. There was no significant difference in sex, age and etiology between the two groups.

4.2 Comparison of intraoperative electrode parameters between the two groups

The pacing threshold, pacing impedance and pacing perception in RAV group and LBBP group were 0.81±1.0Vvs0.72±0.16V, 758.00±102.00Ωvs 743.00±162.00Ω and 7.60±2.20V vs 10.40±1.20V, respectively, during the acute stage of operation, and there was no significant difference.

4.3 Comparison of operation time and X-ray exposure time between the two groups.

Compared with LBBP group, the operation time in RAV group was 55.8±10.2min vs 55.6±12.5min min, the X-ray exposure time was 5.12±1.2min vs 12.6±3.4min min, and the X-ray exposure dose was 7.10 2.2 mg vs 15.90 3.2 mg. The X-ray exposure dose and X-ray exposure time in LBBP group were significantly longer than those in RAV group, with statistics. Especially, the X-ray exposure time of the first five patients with LBBP pacing was significantly longer than that of RAV group (13.20±3.6min vs 5.06±1.10min min), but there was no significant difference in the X-ray exposure time of the last 15 patients compared with RAV group (5.32±1.30min vs 7.12±2.20min min), which indicated that LBBP needed a learning curve, and the operation time and X-ray exposure time of both patients were needed after the technology was mature.

4.4 Comparison of operation-related complications

Complications related to operation in both groups were low. There were 2 cases (2/20 cases, 10%) in LBBP group, 1 case (1/40 cases, 2.5%) in RAV group, and 1 case in LBBP group had ventricular septal perforation, which occurred during electrode implantation. The pacing threshold was increased, the impedance suddenly decreased, the pacing parameters were satisfactory after adjustment, no pericardial tamponade occurred, and 1 case had capsular hematoma. In RAV group, 1 case developed capsular hematoma, which was improved by compression hemostasis. There were no complications such as capsular infection, broken and displaced pacing electrodes, hemothorax and pneumothorax in both groups.

4.5 Comparison of electrode parameters between the two groups during the follow-up period

All 60 patients completed the scheduled operation and postoperative follow-up with an average follow-up time of 18.60±3.20 months. During the follow-up period, the pacing threshold was 0.78±2.40V vs 0.72±1.20V V, the electrode impedance was 644.00±96.20 Ωvs 672.20±101.60Ω Ω, and the sensing was 8.20 2.42 V vs 8.60± 2.68V.

4. Discussion:

The results show that there is no significant difference in pacing threshold, pacing impedance and pacing perception between LBBP pacing and right ventricular apex pacing in acute stage. The average follow-up time was 18.60±3.20 months. There was no significant difference in pacing threshold, electrode impedance and perception between the two groups during the follow-up period. The operation time, X-ray exposure dose and X-ray exposure time in RAV group and LBBP group were significantly longer than those in RAV group. Especially, the X-ray exposure time of the first 5 patients with LBBP pacing was significantly longer than that of RAV group, but there was no significant difference between the latter 15 patients and RAV group, which indicated that LBBP needed a learning curve, and there was no difference in operation time and X-ray exposure time between them when the technology was mature. There was no significant difference between the two groups in operation-related complications, including capsular infection, broken and displaced pacing electrodes, hemothorax and pneumothorax, which showed that it had good safety and long-term stability of electrode parameters. The perioperative complications were similar to those of traditional apical pacing, without increasing the operation time and X-ray exposure time, especially for doctors with mature traditional pacing operations.

Pacemakers have been used in clinical practice since 1958, which has saved thousands of patients. However, the traditional pacemaker's ventricular electrode is placed at the apex of the right ventricle, which leads to the change of left ventricular depolarization order and the unsynchronized left and right ventricles, which significantly increases the incidence of atrial fibrillation and cardiac insufficiency. Therefore, clinicians have been pursuing physiological pacing. In 1998, Deshmukh [6] put pacemaker electrodes in the position of His bundle on human body for the first time and conducted pacing treatment. However, HBP pacing has a series of defects, such as low perception, high pacing threshold, and prone to far-field perception. Once the conduction system disease progresses, it will lead to loss of gain, so it is usually necessary to implant spare electrodes, and its long-term stability and safety are extremely unsatisfactory [13,14]. The left bundle branches are distributed in the left ventricular septal area in a network, which provides an anatomical basis for LBBP and a wider space for implanting pacing electrodes, and can achieve higher success rate and electrode stability [15,16]. In 2017, Huang [17] et al. applied LBBP pacing for the first time to treat a patient with LBBB with cardiac insufficiency, and achieved satisfactory results High voltage captures the myocardium and endocardium around the conduction bundle, which plays a good role as a backup electrode and has good stability. It is a new pacing technology worth popularizing. In 2018, Chen Keping [18] studied and compared the pacing patterns and various parameters of LBBP and RVP. The results showed that the QRS wave time limit of LBBP group was significantly shorter than that of RVP group, and the long-term follow-up lead parameters were stable, which once again confirmed the feasibility of clinical application of LBBP. Cai Binni [19] research on 102 cases of LBBP showed that the average LVAT was 64.9±10.5ms, which showed that the sum of the time for pacing from left ventricle endocardium to epicardium via septum to left ventricle and the time for stimulating signal to reach Purkinje's fibrous network via bundle branches was less than 70ms, and it was once again confirmed that LAVT was an important index for capturing the left conduction bundle. The team further evaluated the effects of left bundle branch pacing on left ventricular systolic function, global systolic synchrony and global myocardial systolic work by using two-dimensional speckle layered imaging technology. The results showed that there were significant differences in LSMID, LSEPI and GBS between the two groups, and there were significant differences in SWI and GWE, suggesting that the longitudinal mechanical synchrony of LBBP group was significantly improved compared with RAV group, and the left ventricular longitudinal systolic function and myocardial work were significantly improved [20]. Wu [21] compared the long-term application of LBBP and HBP in patients with LBBB. The results showed that the echocardiographic rate (LVEF≥50%) was 70.0%vs74.4%, which was better than BVP [22]. The multicenter, randomized controlled study [22] showed that the clinical response rate of LBBP was 72%, the echocardiographic response rate was 73.3%, and 31% showed hyperresponsiveness, which showed that LBBP had a good clinical effect in patients with CRT indications, with shorter QRS pacing time and higher hyperresponsiveness, and could be used as an alternative strategy for BVP pacing.

This paper shows a case of LBBP with ventricular septal perforation, which led to pacing failure. LBBP was successfully completed by

changing the electrode position. Therefore, it is necessary to closely observe the pacing parameters, electrode impedance and screw-in depth of the electrode during LBBP operation, and be alert to ventricular septal perforation [23,24]. At present, many companies have studied new long spiral wires and new supporting sheaths, which greatly improved the success rate and safety of LBBP and significantly shortened the operation time and X-ray exposure time [25,26].

Conclution is this study shows that compared with RVA pacing, LBBP pacing has the same high success rate, stable long-term lead parameters, no significant difference in perioperative complications, and good safety. It is a physiological pacing method worth popularizing.

References

1. Lamas GA，Orav EJ，Stambler BS，et al. Quality of life and clinical outcomes in elderly patients treated with ventricular pacing as compared with dual-chamber pacing. Pacemaker selection in the elderly investigators［J］. N Engl J Med，1998，338（16）：1097- 1104.
2. Lamas GA，Lee KL，Sweeney MO，et al. Ventricular pacing or dual-chamber pacing for sinus-node dysfunction［J］. N Engl J Med，2002，346（24）：1854-1862.
3. Toff WD，Camm AJ，Skehan JD，et al. Single-chamber versus dual-chamber pacing for high-grade atrioventricular block［J］. N Engl J Med，2005，353（2）：145-155.
4. Scherlag BJ，Lau SH，Helfant RH，et al. Catheter technique for recording His bundle activity in man［J］. Circulation，1969，39（1）：13-18.
5. Narula OS，Scherlag BJ，Samet P. Pervenous pacing of the specialized conducting system in man. His bundle and A-V nodal stimulation［J］. Circulation，1970，41（1）：77-87.
6. Deshmukh P，Casavant DA，Romanyshyn M，et al. Permanent，direct His-bundle pacing：a novel approac to cardiac pacing in patients with normal His-Purkinje activation［J］. Circulation，2000，101（8）：869-877.
7. Zanon F，Ellenbogen KA，Dandamudi G，et al. Permanent Hisbundle pacing：a systematic literature review and meta-analysis［J］. Europace，2018，20（11）：1819-1826.
8. Zanon F，Svetlich C，Occhetta E，et al. Safety and performance of a system specifically designed for selective site pacing［J］. Pacing Clin Electrophysiol，2011，34（3）：339-347.
9. Abdelrahman M，Subzposh FA，Beer D，et al. Clinical outcomes of His bundle pacing compared to right ventricular pacing［J］. J Am Coll Cardiol，2018，71（20）：2319-2330.
10. Upadhyay GA，Vijayaraman P，Nayak HM，et al. His corrective pacing or biventricular pacing for cardiac resynchronization in heart failure［J］. J Am Coll Cardiol，2019，74（1）：157-159.
11. Huang W，Su L，Wu S，et al. Benefits of permanent His bundle pacing combined with atrioventricular node ablation in atrial fibrillation patients with heart failure with both preserved and reduced left ventricular ejection fraction［J］. J Am Heart Assoc，2017，6（4）：e005309.
12. Sharma PS，Vijayaraman P，Ellenbogen KA. Permanent His bundle pacing：shaping the future of physiological ventricular pacing［J］. Nat Rev Cardiol，2020，17（1）：22-36.
13. Vijayaraman P，Ellenbogen KA. Approach to permanent His bundle pacing in challenging implants［J］. Heart Rhythm，2018，15（9）：1428-1431.
14. Upadhyay GA，Vijayaraman P，Nayak HM，et al. His corrective pacing or biventricular pacing for cardiac resynchronization in heart failure［J］. J Am Coll Cardiol，2019，74（1）：157-159.
15. Chen X，Jin Q，Li B，et al. Electrophysiological parameters and anatomical evaluation of left bundle branch pacing in an in vivo canine model［J］. J Cardiovasc Electrophysiol，2020，31（1）：214-219.
16. Gaojun Wu，Lan Su，Danhong Fang，et al 。Clinical application of permanent Higgins bundle pacing [J] chinese journal of cardiac arrhythmias。2012，16（4）：302-306.
17. Huang W，Su L，Wu S，et al. A novel pacing strategy with low and stable output：pacing the left bundle branch immediately beyond the conduction block［J］. Can J Cardiol，2017，33（12）：1736.e1-1736.e3.
18. Chen K，Li Y，Dai Y，et al. Comparison of electrocardiogram characteristics and pacing parameters between left bundle branch pacing and right ventricular pacing in patients receiving pacemaker therapy［J］. Europace，2019，21（4）：673-680.
19. Binni Cai, Linlin Li, Fanqi Meng, etc. Evaluation of central electrical characteristics and mid to long term lead parameters in left bundle branch pacing. Chinese Journal of Arrhythmias,2019, 10 , (5)：417-423。
20. Biqin Lin, Binni Cai, Linlin Li, etc. Evaluation of the effects of left bundle branch pacing on left ventricular systolic function and overall myocardial work using two-dimensional speckle layered imaging technology. Chinese Journal of Ultrasound Imaging, 2020,29,(8)：645-648
21. Wu S，Su L，Vijayaraman P，et al. Left bundle branch pacing for cardiac resynchronization therapy：non-randomized on treatment comparison with His bundle pacing and biventricular pacing[J]. Can J Cardiol，2020［2020-05-14］.
22. Huang W，Wu S，Vijayaraman P，et al. Cardiac resynchronization therapy in patients with nonischemic cardiomyopathy using left bundle branch pacing［J］. JACC Clin Electrophysiol，2020，6, (7)：849-858.
23. Huang W，Chen X，Su L，et al. A beginner’s guide to permanent left bundle branch pacing［J］. Heart Rhythm，2019，16（12）：1791-1796.
24. Chen K，Li Y. How to implant left bundle branch pacing lead in routine clinical practice［J］. J Cardiovasc Electrophysiol，2019，30（11）：2569-2577.
25. Mattson AR，Mattson E，Mesich ML，et al. Electrical parameters for physiological His-Purkinje pacing vary by implant location in an ex vivo canine model［J］. Heart Rhythm，2019，16（3）：443- 450.
26. Sharma PS，Huang HD，Trohman RG，et al. Low fluoroscopy permanent His bundle pacing using electroanatomic mapping：a feasibility study［J］. Circ Arrhythm Electrophysiol，2019，12（2）：e006967.