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Follow up observation of permanent epicardial pacing

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ABSTRACT

Objective: To summarize the safety and long-term efficacy of epicardial permanent pacemaker implantation. Methods 69 patients who underwent epicardial permanent pacemaker implantation in Wuhan Asian heart hospital from December 2009 to November 2019 and were followed up at least once after discharge were selected. In 23 children, single chamber pacemakers were implanted through right ventricular epicardium; Among 46 adults, 19 were implanted with pacing electrodes through left ventricular epicardium and 27 through right ventricular epicardium. Follow up the changes of electrode parameters and adverse events within 1 week, 1~3 months, 1~3 years and more than 5 years after operation. **Results:** Right ventricular electrodes were fixed in 50 cases, of which 37 cases were fixed on the right ventricular diaphragmatic surface and 13 cases were fixed on the right ventricular outflow tract; the left ventricular electrodes were fixed in 19 cases, of which 15 were fixed in the lateral wall of the left ventricle, 2 in the posterior wall of the left ventricle, and 2 in the diaphragmatic surface of the left ventricle. The median follow-up was 48.6 months. All 69 patients were discharged smoothly without operation related complications. Two patients with giant left ventricular cardiomyo pathy died of heart failure after cardiac resynchronization therapy (CRT), and one patient with CRT implantation underwent heart transplantation 12 months after operation because of poor efficacy. The pulse generator was replaced in 12 cases because the pacemaker battery was exhausted. Electrode breakage occurred in 4 cases, and bag infection occurred in 1 case. The ventricular thresholds (median) within 1 week, 1~3 months, 1~3 years and more than 5 years after epicardial electrode implantation were 1.0 v/0.4 ms, 0.75 v/0.4 ms, 0.8 v/0.4 ms and 1.0 v/0.4 ms respectively. The left ventricular epicardial electrode threshold was the same as that of the right ventricle, and that of children and adults. Conclusion the parameters of epicardial electrode are stable for a long time, but the safety is not good.

Keywords: cardiology; epicardial pacing; electrode breakage; pacemaker; cardiac resynchronization therapy

1. Introduction

Intravenously implanted endocardial pacemakers are usually the first choice because of their mature technology and small trauma. However, in the case of difficulty in venous implantation (such as venous occlusion, malformation, infants), failure of pacing electrode to cross the tricuspid valve orifice to the right ventricle (such as after tricuspid valve mechanical valve replacement), failure/poor effect of cardiac resynchronization therapy (CRT) implantation through the coronary sinus (CS), simultaneous implantation in cardiac surgery, pacemaker bag infection, etc., surgical placement of epicardial electrode can be a good

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supplementary means for endocardial electrode[1]. Moreover, with the development of manufacturing technology, especially the widespread application of hormone electrodes, the performance of epicardial pacing electrodes has been greatly improved[2,3]. In order to evaluate the long-term safety and stability of epicardial electrode, the authors analyzed the changes of threshold, impedance, perception and the incidence of adverse events after epicardial electrode implantation in our hospital in recent 10 years.

2. Data and methods

2.1. Patient information

Patients who underwent epicardial permanent pacemaker implantation in Asian heart hospital from December 2009 to November 2019 were selected for this study, and they were followed up at least once after discharge. A total of 69 patients, aged from 20 days to 78 years, were included, including 33 males and 36 females. There were 16 cases of cardiomyopathy, 31 cases of congenital heart disease (referred to as congenital heart disease), 18 cases of valvular disease, 2 cases of myocarditis, and 2 cases of epicardial pacing due to bilateral pocket infection after implanting pacemakers for iii degree atrioventricular block (AVB).

23 children, aged from 20 days to 3 years, were implanted with single chamber pacemakers through epicardium due to small vascular lumen. There were 2 cases of viral myocarditis with grade III AVB, 2 cases of congenital grade III AVB, and 2 cases of complex congenital heart disease with grade III AVB after previous surgery. The above 6 cases underwent simple epicardial pacing implantation; one patient with complex congenital heart disease complicated with congenital iii degree AVB underwent epicardial pacing implantation at the same time of cardiac surgery; one child with complex congenital heart disease developed grade III AVB during intraoperative rebound. After re blocking the suture, it turned into atrioventricular 2:1 conduction. Temporary pacemakers were implanted during the operation and permanent epicardial pacing leads were embedded. After the operation, it progressed to grade III AVB and could not recover. The family refused to implant permanent pacemakers and discharged with temporary pacemakers for some reason. After the second admission, permanent epicardial pacemakers were implanted; Fifteen patients with complicated congenital heart disease who developed iii degree AVB after operation were treated with selective epicardial pacing implantation.

There were 46 adult patients, aged from 19 to 78 years. Single chamber, double chamber or three chamber pacemakers were selected according to the patient's condition, age, and economic situation. Fifteen patients with chronic heart failure (CHF) with dilated cardiomyopathy and complete left bundle branch block (CLBBB) were implanted with a three chambers pacemaker (crt/crt-d) for left ventricular epicardial electrode implantation. Among them, 14 patients failed to implant the left ventricular electrode through the CS route (abnormal CS opening/abnormal walking/unreasonable target vessel); A case of left subclavian vein occlusion upgraded by CRT-D with dual chamber implantable cardioverter defibrillator (ICD). Nine patients with dual chamber pacemaker implantation were all preoperative patients with sick sinus syndrome (SSS) or (intermittent) high/grade III AVB, including 5 cases of valvular disease. Considering the increased risk of endocardial pacing bag bleeding and infection after anticoagulation after valve replacement, endocardial implantation before cardiac surgery would increase the risk of electrode displacement and falling off, so epicardial pacing implantation was performed at the same time during cardiac surgery; There were 2 cases of complex congenital heart disease and 1 case of hypertrophic cardiomyopathy. Because they were unwilling to tolerate the second operation, epicardial electrodes were implanted during cardiac surgery; The other case had severe tricuspid regurgitation and right heart failure 4 years after the previous III degree AVB pacing through the endocardial right ventricular apex. There was no improvement after 3 months of down-regulation of pacing frequency and drug treatment. The tricuspid valve was repaired surgically and epicardial electrodes were

placed at the same time. 22 cases were implanted with single chamber pacemaker, 2 cases with bilateral pocket infection after pacemaker implantation with III degree AVB in other hospitals, and 1 case with atrial fibrillation and long interval after previous tricuspid valve replacement, all of which were implanted with epicardial pacing alone; There were 11 cases of valvular disease and 8 cases of congenital heart disease, all of which were complicated with atrial fibrillation and long interval/sss/III degree AVB before operation. The epicardial pacing implantation was performed at the same time of cardiac operation.

2.2. Epicardial electrode implantation

Epicardial lead implantation was performed by cardiac surgeons under general anesthesia. All patients used capsureepi-4965 suture unipolar hormone electrode of Medtronic. Different surgical incisions are adopted according to the patient's condition: The (original) median sternal incision is adopted for the patients at the same time/at the selected time of cardiac surgery. Except for the crt/crt-d patients, the left anterolateral fifth intercostal incision is adopted. The other patients with simple epicardial electrode implantation are all adopted the small incision (4~5 cm) under the median xiphoid process of the sternum. The right ventricular electrode was sewn to the right ventricular diaphragmatic surface or epicardium of the right ventricular outflow tract, and the left ventricular electrode was fixed to the left ventricular lateral wall, posterior wall or epicardium of the diaphragmatic surface. The pulse generator was placed in the rectus abdominis bag in all children. In adult patients, the pulse generator was placed in a bag on the rectus abdominis muscle or the fascia of the left subclavian pectoralis major muscle.

2.3. Postoperative program control and follow-up

Collect the program-controlled data within 1 week, 1~3 months, 1~3 years and more than 5 years after operation, including pacing threshold, impedance, R-wave sensing and other electrode parameters, and record the adverse events during follow-up: Electrode breakage, insulation rupture, bag infection, etc.

2.4. Statistical treatment

Continuous variables with normal distribution are expressed as mean ± standard deviation, continuous variables with non normal distribution are expressed as median (interquartile range), and classified variables are expressed as percentage. The normality of the data was tested by the univariate method. The Kruskal Wallis rank sum test was used for the comparison of multiple books, and the dwasssteel Critchlow fligner test was used for the comparison of pairs. The statistical analysis was carried out by sas9.4 software.

3. Results

3.1. Distribution of epicardial implanted electrodes and pacemakers

There were 19 patients with epicardial left ventricular electrode implantation, of which 15 cases were fixed to the epicardium of left ventricular lateral wall by CRT, 2 cases were fixed to the epicardium of left ventricular posterior wall, and 2 cases were fixed to the epicardium of left ventricular diaphragmatic surface. Right ventricular epicardial electrodes were implanted in 50 cases, fixed to epicardium of right ventricular outflow tract in 13 cases, and fixed to epicardium of right ventricular diaphragmatic surface in 37 cases. The pulse generator was located in the rectus abdominis saccule in 44 cases and in the left subclavian saccule in 25 cases.

3.2. Follow up

The postoperative follow-up time was (48.6 ± 31.1) months. The shortest follow-up time was 3 months and the longest was 108 months. Two patients with giant left ventricular cardiomyopathy died of heart failure

4 months and 3 months after CRT implantation. One patient with dilated cardiomyopathy had poor curative effect after CRT implantation and underwent heart transplantation outside the hospital 12 months later. 12 patients replaced the pulse generator due to the depletion of pacemaker battery: 1 patient was upgraded to CRT-D with dual chamber ICD, and the service time of pacemaker battery was 60 months; There were 8 patients with single chamber pacemaker implantation, including 4 children, whose average battery life was 78 months, 4 adults, whose average battery life was 102 months, and 3 patients with dual chamber pacemaker implantation, whose average battery life was 80 months; according to the pacing parameters and cardiac function, 7 cases used the original electrode lead, and 5 cases changed to his bundle/left bundle branch pacing. During the follow-up period, there were 5 adverse electrode events: Electrode breakage occurred in 4 cases, of which 1 case was a child (20 days old at the time of epicardial electrode implantation) with single chamber pacemaker implantation, which occurred 5 years after operation, and the electrode and pacemaker were re implanted via venous route; one case was implanted simultaneously during the operation of heart valve disease (mitral valve replacement + tricuspid valve repair), which occurred 3 years after the operation. The electrode was fixed in the right ventricular outflow tract, connected to the left subclavian pacemaker through the subcutaneous tunnel, re implanted the electrode through the vein, and the original pacemaker was used; two patients with CRT implantation occurred at 5 and 7 years after operation, and they all changed to left bundle branch pacing via vein. One case of capsular infection occurred 5 months after operation. There was no improvement after capsular debridement. Pacemaker device and electrode extraction were performed 8 months after operation. One week later, the pacemaker was re implanted through the left subclavian vein. At present, the pacemaker works well.

3.3. Changes of ventricular electrode parameters

The pacing threshold, impedance and R-wave perception of 69 patients were normal during postoperative follow-up and maintained long-term stability. The ventricular threshold in 1 week and >5 years was higher than that in 1~3 months (**Table 1**). There was no significant difference in left and right ventricular electrode thresholds at each follow-up time point (**Table 2**). There was no significant difference in ventricular threshold between children and adults (**Table 3**). One patient with congenital heart disease was implanted with VVI pacemaker. The pacing threshold was high during the operation, but it was still not ideal to repeatedly adjust the electrode position, but the pacing could be normal. The pacing threshold was slightly high during the follow-up after the operation, with a fluctuation of 2.0~2.5 v/0.4 ms. A 58 years old patient with dilated cardiomyopathy (left ventricular diameter 8.7 cm, left ventricular ejection fraction 0.3) complicated with CLBBB and frequent short array ventricular tachycardia underwent CRT-D implantation. The implantation of left ventricular epicardial electrode through left thoracotomy failed through CS approach. The intraoperative parameters were not ideal. The programmed threshold of stroke was 4.5~6.0 v/0.4 ms during postoperative follow-up.

Table 1. Epicardial electrode parameters measured at each time period during follow-up.

Time	***N***	**Threshold/(v/0.4 ms)**	**Impedance/Π**	**Perception/mv**
Within 1 week	69	1.0(0.75,1.25)	365(321,418)	10.5(8.0,15.68)
1~3 months	69	0.75(0.75,1.0)	384(330,432)	15.68(8.0,15.68)
1-3 years	67	0.8(0.75,1.0)	367(11,426)	15.68(5.6,15.68)
>5 years	37	1.0(0.75,1.25)	378(31,454)	15.68(5.6,15.68)
P value		<0.0001*	0.46	0.61

Table 2. Epicardial thresholds of left and right ventricle measured at each time period during follow-up/(v/0.4 ms).

Time	*N*	Left ventricle	*N*	Right ventricle	*P* value
		Threshold		Threshold	
Within 1 week	19	1.0(0.75,1.0)	50	1.0(0.75,1.25)	0.13
1~3 months	19	0.75(0.75,1.0)	50	0.75(0.75,1.0)	0.52
1~3 years	17	1.0(0.75,1.0)	48	0.75(0.75,1.0)	0.65
>5 years	10	1.0(0.75,1.0)	27	1.125(0.75,3.0)	0.24

Table 3. Epicardial thresholds of children and adults measured at each time period during follow-up/(v/0.4 ms).

Time	*N*	Children	*N*	Adult	*P* value
		Threshold		Threshold	
Within 1 week	23	1.0(0.75,1.25)	46	1.0(0.75,1.25)	0.8
1~3 months	23	0.75 (0.75 ,1.0)	46	0.75(0.75,1.0)	0.99
1~3 years	23	0.8(0.75,1.25)	44	0.875(0.75,1.0)	0.45
>5 years	12	0.9(0.75,1.25)	25	1.0(0.75,1.25)	0.42

4. Discussions

Paech et al.[4] reported the follow-up results of 158 bipolar hormone eluting epicardial electrodes implanted in 82 children and adults with congenital heart disease. The electrode failure free rates in 2, 5 and 10 years were 98.7%, 93% and 92.4% respectively. At 3.3 years, the average pacing threshold, impedance and R-wave perception of right ventricle were 1.0 v/0.49 ms, 482 Ω and 11.0 mv respectively. Tomaske et al.[5] studied the medium and long-term use of bipolar hormone epicardial electrode in 114 children. The median follow-up was 3.2 years. The right ventricular electrode maintained a good pacing threshold in each period of long-term follow-up. Renchonglei et al.[6] reported that 15 cases of adult cardiac surgery were implanted with epicardial permanent pacing at the same time, and the right ventricular electrode parameters were good in the near and medium term. In this study, 50 cases of right ventricular epicardial electrodes were implanted, all of which were single hormone electrodes, including 13 cases fixed to the epicardium of the right ventricular outflow tract and 37 cases fixed to the epicardium of the right ventricular diaphragm. Consistent with the above research results, the right ventricular epicardial electrode parameters had good medium and long-term effects, and 3 patients with electrodes fixed to the epicardium of the right ventricular outflow tract had mild left ventricular dysfunction. Recently, a Korean study[7] analyzed the relationship between ventricular epicardial pacing at different sites and left ventricular dysfunction in 34 children with congenital atrioventricular block. After a follow-up of 12.3 years, the study showed that right ventricular/left ventricular apical pacing was better than right ventricular free wall, which could provide a reference for the selection of epicardial electrode implantation sites.

Left ventricular epicardial electrode implantation is often used in patients with CRT who fail to implant left ventricular electrode through CS pathway. Garikipati et al.[8] directly compared the improvement of cardiac function in 21 patients with chronic heart failure after CRT implantation in different ways. They were randomly divided into epicardial pathway group (9 cases) and CS pathway group (12 cases). The improvement of left ventricular end systolic volume index, LVEF and clinical cardiac function were similar in the two groups at the follow-up of 6 months. A retrospective study in the United States compared the efficacy of CRT left ventricular electrode implanted through different ways. 96 cases (13.2%) were implanted through surgical

way, and the rest were implanted through traditional CS way. The survival rate and CRT response rate of the two groups were similar at a follow-up of 5.1 years[9]. Marini et al.[10] retrospectively compared the parameters of left ventricular electrodes implanted through video-assisted thoracoscopic epicardial approach and CS approach in 200 patients with chronic heart failure after CRT treatment. After a median follow-up of 24 months, the parameters of left ventricular epicardial electrodes and venous electrodes were good, and the median pacing thresholds were 1.6 v/0.5 ms and 1.2 v/0.5 ms respectively. In addition, there was no significant difference in the improvement of cardiac function, death and instrument complications between the two groups. In this study, the left ventricular electrode epicardial threshold was stable, and the median pacing threshold was about 1.0 v/0.4 ms one year later.

In the study of Tomaske et al.[5], 6 electrodes were broken, with an incidence of 4.5%. Cho et al.[11] followed up 44 newborns and infants implanted with epicardial electrodes for 9.1 years. Five of them had broken electrodes (11.4%), and the intact rate of electrodes at 5 years was 75.7%. A domestic retrospective study with a follow-up of 10 years showed that the incidence of epicardial electrode breakage was significantly higher than that of endocardium. Among 92 cases of epicardial electrode breakage, 8 cases (8.7%), while none of the endocardial electrode breakage (0/51 cases), but the latter had higher bag infection and pericardial perforation than the former[12]. In this study, 4 (5.8%) electrodes were broken, with an average of 4.9 years after operation. One of them was implanted 20 days after birth. Five years after operation, the program-controlled electrode was broken. The imaging examination showed that the broken part was the middle bend of the electrode lead, and the pacemaker had fallen to the middle and lower abdomen. It was considered that the abdominal wall of the affected child was weak, and the falling of the pacemaker caused the angle of the winding electrode lead to become smaller, and the local tension was too large, resulting in the breakage.

The other 3 cases were all electrode leads connected to the left subclavian pacemaker through the subcutaneous tunnel. Considering that the possible reason was that the lead tension was large, which was caused by repeated friction between the lead and the ribs with the heartbeat and respiration, it was suggested that the electrode lead should be avoided from passing through the rib space during surgical epicardial electrode implantation. If it could not be avoided (such as the left ventricular electrode in CRT patients), the electrode sleeve could be used to protect the lead from passing through the rib space to reduce the occurrence of electrode breakage[13].

Among the 15 patients treated with CRT in this study, 2 (13.3%) patients with huge left ventricle died of heart failure after operation, which occurred at 3 and 4 months after operation. The end diastolic diameter of left ventricle before operation was 9.8cm and 9.0CM respectively. One patient underwent heart transplantation in an external hospital 12 months after operation due to poor effect of CRT. Li et al.[14] in China evaluated the long-term efficacy of 28 patients who failed to implant left ventricular epicardial electrodes via CS. They were followed up for an average of 44.6 months, and 3 patients (10.7%) died in the long term. Kamath et al.[15] followed up 78 patients with epicardial left ventricular electrode implantation assisted by robot for an average of 44 months. The results showed that 8 cases died in the short-term follow-up, 12 cases died in the long-term follow-up, and the long-term mortality was 26%. The high mortality rate of the study was related to the older age of the enrolled patients [(77 ± 11) years] and the lower LVEF value (0.17 ± 0.10).

With the increasing number of patients undergoing complex congenital heart disease surgery in large cardiovascular centers, the obvious improvement of the performance of epicardial electrodes, and the development of modern surgical technology, such as thoracoscopy and robot assistance, the demand for epicardial pacing electrodes will increase day by day. Epicardial pacing has certain or even absolute advantages in newborns, infants and cardiac surgery. However, with the rise of Hippo system pacing and the development of leadless pacing, there are more choices of pacing modes in the cases of failure of CRT left ventricular

electrode through CS, bag infection, tricuspid valve replacement, subclavian vein occlusion, etc. Epicardial pacing is not the only alternative. This study shows that although epicardial pacing parameters are stable for a long time, their safety needs to be improved. As a supplement to endocardial pacing electrodes, epicardial pacing parameters are only applicable to situations that are not suitable for endocardial pacing.

There are many deficiencies in this study: a) retrospective study; b) small number of samples; c) the left ventricular epicardial electrode in CRT patients had no control group, and the clinical cardiac function indexes were missing. Therefore, the research conclusion may be insufficient, which needs to be verified by large-scale, multi center randomized controlled clinical trials.

Conflict of interest

The authors declare no conflict of interest.

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