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A long-term, prospective, cohort study on the performance of right ventricular pacing leads: comparison of active-fixation with passive-fixation leads

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Active-fixation pacing leads allow the use of selective pacing sites. We evaluated their long-term performance versus passive-fixation leads in 199 newly implanted patients ($n = 100$ active and $n = 99$ passive). Postoperative pacing thresholds in the active group were higher than in the passive group (0.85 ± 0.31 V vs. 0.53 ± 0.21 V at baseline, $P < 0.001$). The active thresholds fell to 0.72 ± 0.23 V at 5 years with a significant drop at one month (0.68 ± 0.53 V, $P = 0.003$). The passive thresholds slightly increased to 0.72 ± 0.31 V at five years. Differences between groups were significant until three years (all $P < 0.05$). Active impedances were generally lower than passive impedances ($600.44 \pm 94.31\Omega$ vs. $683.14 \pm 110.98\Omega$ at baseline), and both showed significant reductions at one month to $537.96 \pm 147.43\Omega$ in the active group, and after three months to $643.85 \pm 82.40\Omega$ in the passive group (both $P < 0.01$ vs. baseline). Impedance differences between groups were significant until four years (all $P < 0.05$). Adverse events included thresholds over 1 V, 5 of 6 active and 2 of 5 passive leads returned to below 1 V. One active left ventricular lead dislodged. One passive left subclavian lead insulation fracture occurred. Thus Active fixation pacing leads are stable in a five-year long-term follow up. There was no difference between active and passive leads in terms of electrical performance.

For more than half a century, the globe has witnessed great reform of pacemakers and pacing electrodes¹. This started with replacement of epicardial pacing leads with transvenous endocardial ones preventing bradycardiac arrhythmia patients from suffering risks through thoracotomy². Thus, morbidity and mortality of pacemaker implantations decreased drastically. Coaxial bipolar pacing leads are soft, thin, and easy to insert and upgraded the initial endocardial pacing leads in the 1970s³. In the past decades, the progress has continued with smaller diameters, new insulation types, and steroid-eluting electrodes aimed at optimizing the application of cardiac pacing therapy⁴⁻⁶.

Development of fixation technology has also played a role in lead transformation. Stability of fixation to ensure effective long-term pacing is the main principle. The passive alary pacing lead was the first of these and received positive clinical reports⁷. This gives easy fixation to the right ventricular trabecular muscles in the apex and shortens operation time⁸. The right ventricular apex is by far the most common pacing site, but active fixation steroid-eluting leads with a stable performance, low rate of dislodgement, and screwable design have made selecting pacing sites other than the right ventricular apex possible. Active fixation leads also provide the added convenience of possible lead extraction^{9,10}. With an increasing number of pacemaker implantations and senior populations¹¹, active-fixation pacing leads, have played a dominant role in Europe and the U.S. The right ventricular outflow tract (RVOT) is the most widely used pacing site other than the apex. With screwable fixation locating the distal part of the pacing leads, physicians can pace in either the septum or the free wall of the RVOT.

Physiological pacing currently focuses on selective pacing sites like RVOT pacing, His bundle and paraHis bundle area pacing, and biventricular pacing other than traditional apical pacing, especially in those with compensatory left ventricle function¹². Selective right ventricle pacing favors application of active-fixation leads with the flexibility of pacing sites in the right ventricle and the convenience of lead extraction. Physiological



pacing, with the current focus on selective pacing sites, forces the choice of right ventricle pacing leads towards active-fixation leads instead of passive ones¹³.

In western countries, the preference for active-fixation pacing leads over passive ones is common, while in China, active-fixation pacing leads have been introduced but their application is still limited in several senior clinical cardiac centers. Moreover, reports mentioning long-term observation of active-fixation leads and performances compared to passive leads are limited. The present study prospectively evaluates the reliability of active-fixation compared to passive pacing leads by observing lead performances with a total of five-years follow up, and thus, aims to provide physicians in China with evidence for selection of pacing leads.

Results

199 newly implanted patients of the original 240 patients were studied, as the remaining 41 were elective replacement implants and excluded from the study. 100 patients were in the active group and 99 were in the passive group. All of the pacemaker implantation procedures were successful. No significant differences in gender (68/32 and 52/47 male/female ratio for the active and passive groups, respectively), age (mean 62.0 ± 15.64 years in the active group and 67.04 ± 14.16 years in the passive group), type of bradyarrhythmia (23.0% and 38.4% with atrioventricular block, 70.0% and 61.6% with sick sinus syndrome, 1.0% and 0% with hypertrophic cardiomyopathy, and 6.0% and 0% with dilated cardiomyopathy in the active and passive groups, respectively), or underlying cardiovascular diseases except congenital heart disease and atrial fibrillation (both P values = 0.03) were found between the two groups (16.0% and 15.2% with coronary disease, 43.0% and 38.4% with hypertension, 8.0% and 8.1% with type 2 diabetes, 4.0% and 3.0% with rheumatic heart disease, 4.0% and 0% with congenital heart disease, and 9.0% and 20.2% with atrial fibrillation for the active and passive groups, respectively). More details of the baseline information are presented in Table 1.

R-wave amplitude. The baseline R-wave amplitude of the active group was 11.35 ± 4.35 mV, and 12.40 ± 5.49 mV for the passive group ($P = 0.27$). The R-wave amplitude in the active group was as stable as in the passive group throughout the 5 year follow-up (all $P >$

0.05). Unfortunately the follow-up rate for R-wave amplitude was only 30% because some patients failed to be tested because of syncope or dizziness.

Stimulation thresholds. Stimulation thresholds are shown in Table 2 and were significantly higher in the active than the passive group after implantation, this trend lasted until the third year but diminished in the four and five year follow-ups.

In the active group, the mean pacing thresholds were 0.85 ± 0.31 V at postoperative baseline, there was then a sharp drop to 0.68 ± 0.53 V ($P < 0.01$) within one month. Thereafter, pacing thresholds varied between 0.73 ± 0.67 V and 0.70 ± 0.24 V until 5 years (0.72 ± 0.23 V). Thresholds at each follow-up time point were significantly lower compared to postoperative baseline ($P < 0.05$) after the first month follow up.

Stimulation thresholds in the passive group at baseline were 0.53 ± 0.21 V and fell to 0.50 ± 0.14 V at one month and remaining at 0.50 ± 0.29 V at 3 months. At six months (0.57 ± 0.30 V) there was a steady upward trend until the five year follow up. A significant difference in comparison to the baseline threshold did not emerge until the 2 year follow-up with the highest threshold of 0.72 ± 0.31 V ($P < 0.01$) in the five year follow-up.

Electrode impedance. The electrode impedances in both groups showed a downward trend throughout the whole observation period and are also shown in Table 2. During the time points from baseline to the four year follow up, impedances of the active fixation electrodes were significantly lower ($P < 0.01$) than the passive electrodes.

Impedances in the active group with an average of $600.44 \pm 94.31\Omega$ at baseline decreased to $534.69 \pm 110.34\Omega$ ($P < 0.01$) at the fifth year. The decrease at each time point was significantly different ($P < 0.05$) compared to the baseline impedance excluding the four and five year follow-ups. RV lead impedances at each observation point were significantly different compared to baseline ($P < 0.05$).

Passive lead impedances also showed a downward trend with a mean of $683.14 \pm 110.98\Omega$ at baseline to $561.34 \pm 101.06\Omega$ at five years. Significant differences were observed at all time points after one month.

Table 1 | subjects' characteristics

	Active group n=100		Passive group n=99	P value
Age (years)	62.0 ± 15.64		67.04 ± 14.16	0.77
Gender (Male/female)	68/32	52/47		0.03
Heart rate(beat/min)	50.35 ± 3.16		46.81 ± 2.49	0.98
BMI(kg/m ²)	17.88 ± 1.02		18.62 ± 0.43	0.78
Diagnosis, n (%)				
AVB	23 (23.0)		38 (38.4)	0.88
SSS	70 (70.0)		61 (61.6)	0.21
HCM	1 (1.0)		0 (0.0)	0.63
DCM	6 (6.0)		0 (0.0)	0.02
Underlying other cardiovascular diseases, n (%)				
Coronary Disease	16 (16.0)		15 (15.2)	0.78
Hypertension	43 (43.0)		38 (38.4)	0.42
Type 2 Diabetes	8 (8.0)		8 (8.1)	0.96
Rheumatic heart disease	4 (4.0)		3 (3.0)	0.56
Congenital heart disease	4 (4.0)		0 (0.0)	0.03
Atrial Fibrillation	9 (9.0)		20 (20.2)	0.03
Other Disease	20 (20.0)		31 (31.3)	0.36
RV Lead Position, n (%)				
RVOT	43 (43.0)		0 (0.0)	<0.001
RVA	57 (57.0)		99 (100.0)	<0.001

Note: AVB=atrioventricular block; SSS=sick sinus syndrome; HCM=hypertrophic cardiomyopathy; DCM=dilated cardiomyopathy; RV=right ventricle; RVOT=right ventricular outflow tract; RVA=right ventricle apex.



Table 2 | Threshold and impedance through the five-year follow up

Follow-up time	Threshold (V)				Impedance (Ω)			
	n	Active group	n	Passive group	n	Active group	n	Passive group
Baseline	100	0.85 \pm 0.31	99	0.53 \pm 0.21*	100	600.44 \pm 94.31	99	683.14 \pm 110.98*
1 Month	94	0.68 \pm 0.53 Δ	92	0.50 \pm 0.14*	94	537.96 \pm 147.43 Δ	92	660.72 \pm 115.49*
3 Months	95	0.73 \pm 0.67	91	0.50 \pm 0.29*	95	557.22 \pm 132.08 Δ	91	643.85 \pm 82.40 Δ *
6 Months	96	0.71 \pm 0.49 Δ	94	0.57 \pm 0.30*	96	543.21 \pm 133.46 Δ	94	597.45 \pm 130.22 Δ *
1 Year	98	0.73 \pm 0.36 Δ	93	0.55 \pm 0.19*	98	533.33 \pm 145.76 Δ	93	606.94 \pm 103.73 Δ *
2 Years	95	0.73 \pm 0.22 Δ	90	0.64 \pm 0.21 Δ	95	510.9 \pm 142.43 Δ	90	583.43 \pm 89.94 Δ *
3 Years	96	0.70 \pm 0.26 Δ	90	0.63 \pm 0.19 Δ *	96	496.26 \pm 127.59 Δ	90	577.73 \pm 101.78 Δ *
4 Years	98	0.70 \pm 0.24 Δ	92	0.71 \pm 0.26 Δ	98	513.53 \pm 129.19 Δ	92	545.91 \pm 94.64 Δ *
5 Years	94	0.72 \pm 0.23 Δ	90	0.72 \pm 0.31 Δ	94	534.69 \pm 110.34 Δ	90	561.34 \pm 101.06 Δ *

Note: Data are shown as mean \pm standard deviation (SD). * P <0.05, ** P <0.01 vs. Active group. ΔP <0.05 vs. baseline.

Subgroup comparisons. Patients implanted with active-fixation RV electrodes were divided into two subgroups according to the right ventricle pacing sites selected by the preference of the practitioners. No significant differences were discovered in pacing thresholds or lead impedances with pacing sites at the right ventricular apex or the septum of the RVOT throughout the follow-up (Table 3).

Adverse electrode related events. Six patients implanted with active-fixation RV electrodes and five with passive RV electrodes had reported stimulation thresholds that had increased above 1 V during three to six months of device follow-up. Among the six patients in the active group, in five the stimulation thresholds fell back to less than 1 V within one year and the other one remained at 1 V. Of the five patients in the passive group, three pacing thresholds remained above 1 V when observation ended and the rest decreased to normal at two and four years, respectively.

One patient in the active group, diagnosed with dilated cardiomyopathy, experienced left ventricular lead dislodgement nine months after pacemaker implantation and consequently received lead replacement. Another patient in the passive group was found with a left subclavian lead insulation fracture during the fourth year follow up, and underwent RV lead implantation via the left subclavian vein. No lead perforation or other lead related acute or chronic adverse events were recorded in either group.

Discussion

Despite the preference for active-fixation pacing leads in western countries their use in China has been less common. The aim of this study was to evaluate the reliability of active-fixation pacing leads in comparison with passive leads by observing lead performances with a total of five-years follow up. This information should provide physicians in China with evidence for pacing lead selection.

This study showed a convincing performance of active-fixation RV leads in a Chinese population. Stimulation thresholds of the active leads varied steadily except for a sharp drop at one month postoperatively. The sharp decline in pacing thresholds in active-fixation electrodes was also found by Kistler et al.¹⁴. The pacing thresholds of the active pacing leads were stable throughout our five-year observation period. This also supported a former study of 100 patients who underwent pacemaker implantation and were followed-up for 24 months¹⁵. In the passive group in our study, the RV lead thresholds were generally lower than in the active fixation leads, but showed an increasing trend throughout the observation period. We assume that clinical differences between active-fixation and passive electrodes could become distinct if a longer observation period was investigated. Differences in impedance between the groups were found to be significant, but not clinically. This was also in accordance with a study by Luria et al. who compared straight and J shape screw-in leads also with a five-year follow up¹⁶. No adverse events involving perforation and dislocation related to RV pacing electrodes were reported in either group. This long-term event free lead implantation was due to the work of well-trained senior physicians as well as the established long-term survival of modern active-fixation leads^{17,18}.

This long-term, prospective, randomized, cohort study investigating the five-year performance of both active-fixation and passive pacing leads was characterized by a considerable sample size and long term follow-up. The RV leads in both groups performed stably in terms of stimulation thresholds, and lead impedances. The findings of this study present a favorable result for active fixation pacing leads and support the reliability and safety of pacing when it is performed at selected sites in the right ventricle. In addition, it provides Asian countries with convincing evidence for the widespread use of active pacing leads, which performed as well as the passive leads in this study.

Table 3 | Comparison between two subgroups according to the right ventricle pacing sites in the patients implanted with active-fixation RV electrodes

Follow-up time	Threshold (V)				Impedance (Ω)			
	n	RVOT	n	RVA	n	RVOT	n	RVA
Baseline	43	0.82 \pm 0.29	57	0.88 \pm 0.33	43	604.88 \pm 94.65	57	596.67 \pm 94.55
1 Month	40	0.85 \pm 0.66	54	0.59 \pm 0.50	40	523.33 \pm 136.43	54	571.08 \pm 135.04
3 Months	41	1.02 \pm 1.09	54	0.52 \pm 0.21	41	556.10 \pm 127.99	54	562.71 \pm 136.16
6 Months	39	0.90 \pm 1.05	57	0.62 \pm 0.16	39	534.61 \pm 134.87	57	549.63 \pm 137.90
1 Year	42	0.95 \pm 0.57	56	0.82 \pm 0.19	42	504.52 \pm 153.93	56	533.30 \pm 140.08
2 Years	41	0.78 \pm 0.24	54	0.67 \pm 0.22	41	460.43 \pm 135.96	54	554.70 \pm 134.93
3 Years	43	0.90 \pm 0.28	53	0.75 \pm 0.20	43	498.07 \pm 157.51	53	499.93 \pm 124.80
4 Years	42	0.70 \pm 0.21	56	0.65 \pm 0.20	42	464.20 \pm 193.31	56	544.77 \pm 110.57
5 Years	40	0.65 \pm 0.14	54	0.70 \pm 0.22	40	532.50 \pm 166.17	54	548.81 \pm 105.13

Note: Data are shown as mean \pm SD. RV = right ventricle; RVOT = right ventricular outflow tract; RVA = right ventricle apex.



Table 4 | RV leads used in the study

RV lead	Manufacturer	Steroid-elution	Polarity	Active/Passive
5076	Medtronic	Yes	Bipolar	Active
1888tc	St. Jude Medical	Yes	Bipolar	Active
4074	Medtronic	Yes	Bipolar	Passive

The main limitation of this study was that it concentrated on the function of the pacemaker. We made no measurements of the clinical outcomes of the patients to evaluate whether the active fixation ability allowed better patient outcomes because of the ability to select RVOT pacing sites. In addition, the study population was not large enough to fully address the safety aspects and complication rates in both groups; much larger numbers are required to fully evaluate these. Another limitation was the lead positions were not equally distributed between the groups leading to the potential for bias in these results.

Conclusion

Active-fixation pacing leads presented no adverse lead related events, in this limited population, and performed as stably as passive leads over five-years of observation. There was no difference in the electrical performance of the leads. Active-fixation pacing leads can be used for physical pacing.

Methods

Study design. A total of 240 consecutive patients received permanent pacemaker implantations in the department of Cardiology of Guang dong Cardiovascular Disease Institute during Jul. 2007 and Dec. 2008. The inclusion criteria were Class I or IIa indications as given by the American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) and the Heart Rhythm Society (HRS) updated guidelines for device-based therapy of cardiac rhythm abnormalities¹⁹, those who could walk and were capable of finishing the follow-up period. Exclusion criteria included replacement of a former pacemaker without newly implanted right ventricle leads and patients with severe liver or kidney dysfunction. The recruited patients were randomized to either the active group with active fixation electrodes as right ventricle (RV) electrodes, or the passive group with passive electrodes as RV electrodes. The selection was by random number generated by computer.

The study was approved by the ethics committee of Guang dong Cardiovascular Institute, Guang zhou 510000, China. Patient records/information was anonymized and de-identified prior to analysis. The methods were carried out in accordance with the approved guidelines.

Permanent pacemaker procedures. Permanent pacemaker procedures under local anesthesia were performed in standardized intervention rooms and preventive antibiotics were given half an hour preoperatively. Pacing leads were transvenously inserted via the left or right subclavian vein. A J-shaped stylet was used to guide the leads through the tricuspid valve. Then, RV leads were placed to the right ventricle apex by a straight stylet. Synchronized movement with the heart beat of the distal part of the RV leads determined good stability. Two fluoroscopy assessments including anterior-posterior and left lateral fluoroscopy were used to determine the apex lead, and one more left anterior oblique (LAO) 45° view was used to determine the position of the septum of the RVOT²⁰.

In the active group, two types of right ventricle leads model 5076 (Medtronic Inc., Minneapolis, MN, USA) or 1888TC (St. Jude Medical, St Paul, MN, USA) were selected, and placed in either the RVOT septum or the right ventricle apex depending on the physician's preference. Model 4074 (Medtronic Inc., Minneapolis, MN, USA) RV leads in the passive group were all placed in the right ventricular apex²⁰. More details on the types of pacing leads used are listed in Table 4. Exact positions of the pacing leads were identified by multiple fluoroscopic views and electrocardiography (ECG). Fixation of the distal electrode with the endocardium was confirmed by the helix being screwed-up and synchronized motion with regular cardiac systole during the procedure.

Atrial leads of both groups were placed in the right atrial appendage. While in seven cases that had been diagnosed with dilated cardiomyopathy, left ventricle leads were placed in the posterior-lateral coronary vein via the coronary sinus.

Follow-up. Basic pacing parameters referring to pacing threshold and lead impedance were analyzed intraoperatively under a pulse width of 0.48 ms. Lead related parameters including pacing thresholds and impedances were tested at 1, 3, and 6 months, and 1, 2, 3, 4, and 5 years during follow up.

Statistical analysis. All statistical analyses were conducted using SPSS version 12.0 (SPSS Inc., Chicago, IL, USA). Continuous data were described as mean \pm standard

deviation (SD). Differences between groups and subgroups were observed by independent-samples Student's *t* test, and parameters in the same group of different time points were analyzed by repeated measures of ANOVA. Comparison of proportion was analyzed by Chi square test or Fisher test where appropriate. All of the analysis was done in a two-tailed power of test with a *P* value of less than 0.05 defined as a statistical difference, and a *P* value less than 0.01 as a significant difference.

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Author contributions

L.L. carried out the study design, data collection and analysis, wrote the manuscript. J.J.T. also carried out the study design, clinical study and approved the final version of the



manuscript. H.P., S.L.W., C.Y.L., D.L.C., Q.H.Z., Y.H.L., S.L.C., Y.C. and H.Q.W. participated in the clinical study and help to perform the statistical analysis.

Additional information

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