Original Article

Combining current of injury and P-wave sensing optimized right atrial active-fixation leads implantation

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Background: Pacing parameters may influence pacing lead life and pacemaker life. This study sought to determine whether different right atrial active-fixation lead implantation parameters are associated with chronic pacing performance.

Methods: A retrospective observational study was conducted on all consecutive patients implanted with an active-fixation atrial lead at our institution from July 2014 to October 2016. Atrial leads with a P-wave sensing of ≥2.0 mV, a pacing threshold of ≤1.0 V, and a lead impedance of 300–1,000 ohms were assigned as the optimized group, while atrial leads that did not meet these specifications were assigned as the conventional group. A total of 98 patients who received active-fixation atrial leads (55 patients were male, mean age was 63±12 years old) were studied, and the lead performance of 67 of these patients were optimized in 3 months.

Results: In the multivariate analysis, current of injury [COI; COI_{10min}, odds ratio (OR): 0.296, 95% confidence interval (CI): 0.093–0.939, P=0.039] and P-wave sensing (P_{10min}, OR: 0.449, 95% CI: 0.265–0.762, P=0.003) were recorded at 10 minutes after lead fixation, and were considered predictors of lead optimized performance. The cut-off value of COI_{10min} and P_{10min} was 1.04 mV (sensitivity: 0.58 and specificity: 0.77) and 3.3 mV (sensitivity: 0.67 and specificity: 0.74), respectively, for predicting lead optimized performance after 3 months. COI_{10min} ≥1.04 mV and P_{10min} ≥3.3 mV were combined and considered as the predictable criteria, and the area under the ROC curve was 0.806 (sensitivity =0.70 and specificity =0.77).

Conclusions: Optimized atrial lead performance at 3 months was predictable from COI_{10min} ≥1.04 mV and P_{10min} ≥3.3 mV.

Keywords: Pacemaker; atrium; current of injury (COI); active-fixation lead; pacing performance

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Introduction

The Comprehensive Test of Phonological Processing (CTOPP) extended study revealed that there was a significant reduction in the incidence of atrial fibrillation with the application of physiological pacing (1). A secondary analysis from the mode selection trial (MOST) hypothesized that pacemaker patients with preserved left ventricular ejection fraction (LVEF) may also develop heart failure (HF), depending on the prevalence of right ventricular pacing (2). Accordingly, a number of different pacing algorithms have been developed to reduce the

degree of ventricular pacing in the atrioventricular sequential pacing mode (DDD). These systems have been shown in clinical studies to reduce the risk in developing atrial fibrillation mainly in patients with sinus node disease (3-5). Atrial and ventricular lead stability is a prerequisite for ensuring physical pacing.

Lead implantation is inherently injurious to the focal myocardium, and it changes the electro-activity of the myocardium in a way similar to ischemic injury. This induced electro-activity is called current of injury (COI) (6,7). However, it is difficult to locate the ministry of the right ventricular outflow tract septal electrode. Furthermore, studies have revealed that the right ventricular outflow tract septal electrode can be well located in only 61% of these patients (8). In Saxonhouse *et al.*'s study, COI resolution was observed within a 10 min-recording time (9). Besides, Shali *et al.*'s work revealed that fully rotated leads were associated with the slowest COI recovery, and it also demonstrated that the time course of COI is correlated to acute lead stability in rabbits (10). In addition, recent studies on active-fixation leads have found that the magnitude of COI can predict acute active-fixation lead stability and threshold adequacy (9,11).

Poor P-wave or R-wave sensing would induce competitive cardiac pacing, causing rapid ventricular arrhythmia or rapid atrial arrhythmia, and even death. Low-pacing thresholds extend pacemaker life. In short, good P-wave or R-wave sensing and low-pacing thresholds allow the pacemaker to be used for a longer period. The midterm performance of active-fixation leads can be predicted through the COI recorded at the time of lead implantation, as reported by Haghjoo *et al.* (12).

Good chronic pacing parameters avoid lead replacement and reduce the power consumption of the pacemaker. These leads have a certain life, and good pacing parameters can extend the life of these leads. Compared with atrial lead implantation, ventricular lead implantation technology has become more mature. Due to anatomical differences between the ventricular and atrial myocardium, the fluctuation range of P-wave sensing is smaller than R-wave sensing. Thus, atrial leads are more susceptible to poor perception. Therefore, the present study aimed to investigate the conditions for optimizing right atrial active-fixation lead implantations, in order to obtain optimal chronic pacing parameters.

Methods

Selection criteria

Between July 2014 and October 2016, 98 consecutive patients, referred to our center for the implantation of dual-chamber pacemakers for symptomatic bradycardia (sick sinus syndrome, atrioventricular block, or both), who were undergoing active-fixation atrial pacing placed at the right atrial appendage, were selected for the present study.

Patients were excluded based on the following criteria: (I) an age <18 years old and a New York Heart Association (NYHA) heart function grade of III or IV; (II) presence of complex congenital heart disease; (III) inability to attend the outpatient device clinic for routine follow-up; (IV) severe liver or kidney damage; (V) presence of atrial fibrillation during the implantation process, in which the pacing threshold could not be measured; (VI) presence of atrial fibrillation during the 3-month pacemaker device follow-up, in which the pacing threshold could not be measured.

The study protocol was approved by the Ethics Committee of Fujian Medical University Union Hospital (No. 2017KY011), and a written informed consent was obtained from all patients.

Implantation technique

Implantation of the right atrial active-fixation pacing leads

The devices were implanted in the Electrophysiology Laboratory using standard implant techniques with local anesthetic and conscious sedation. The leads were inserted through the left or right subclavian vein. The right atrial active-fixation pacing lead was fixed after stable implantation of the ventricular pacing lead. The right atrial active-fixation pacing lead was placed in the right atrial appendage. The active fixed pacing lead model was the St. Judea 1888Tc or Medtronic 5076-52. Once the proper location was fluoroscopically identified, the helix was extended according to the recommendations of the related companies. The intracardiac electrogram was recorded at 25 mm/s from the Bard multi-channel electrophysiology (EP) recording system after the end of the fixed right atrial lead was linked to the V1 lead of EP. The PR-segment elevation (COI) was measured at the 0- and 10-minute point of the atrial lead fixation (*Figure 1*). In order to allow

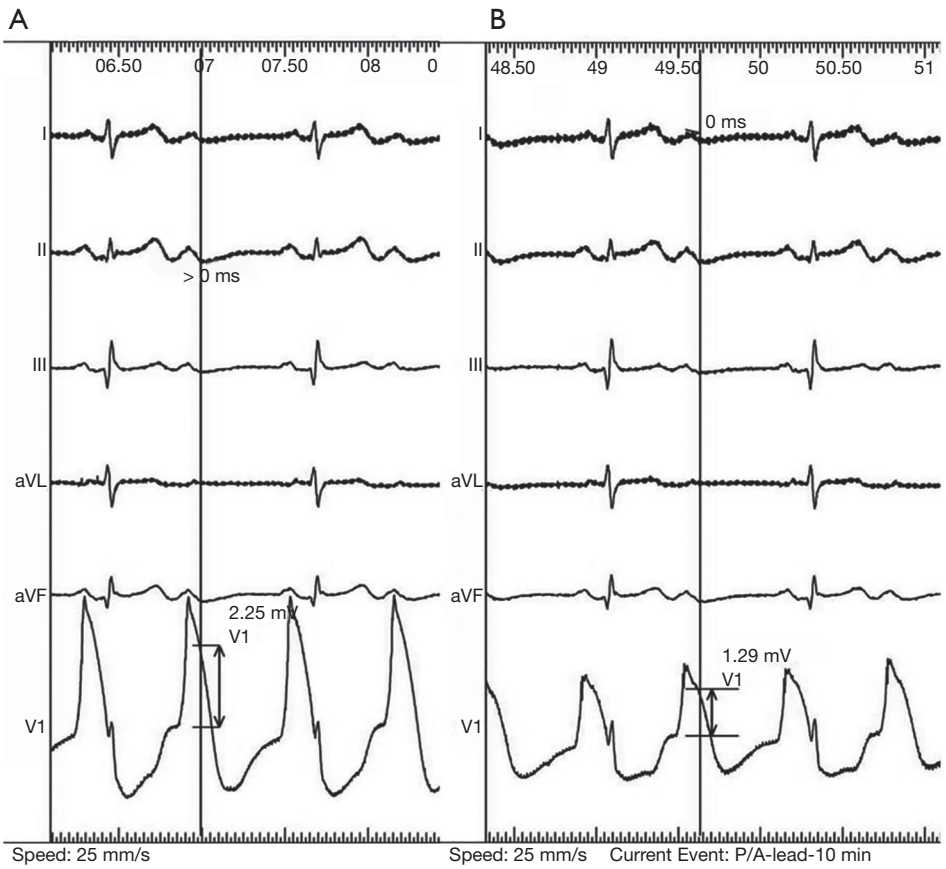

Figure 1 Measurement of COI using the intracardiac electrogram was recorded by the Bard multi-channel electrophysiology recording system in V1 lead. COI was hand-measured PR-segment elevation in mV compared to baseline at 25 mm/s. (A) Shows a COI of 2.25 mV, which was recorded after right atrial lead fixation. (B) Shows a COI of 1.29 mV, which was recorded after 10 minutes of the right atrial lead fixation. At 10 minutes after the lead fixation, the electrogram returned to baseline. After 10 minutes, COI declined compared to that of before. COI, current of injury.

for the decrease in pacing threshold and impedance, pacing parameters were measured at 0 minute and after 10 minutes of atrial lead fixation. The atrial leads were all of the bipolar, steroid-eluting and extendable-retractable type, with an electrically active helix.

Follow-up and data collection

All patients were followed up for at least 3 months. Atrial pacing parameters included P-wave sensing, pacing threshold and lead impedance, and were measured after 3 months. After 3 months of follow-up, the atrial leads were considered as the "optimized group" when these leads had a P-wave sensing of ≥2.0 mV, a pacing threshold of ≤1.0 V, a lead impedance within 300–1,000 ohms, and no dislodgment. Otherwise, the atrial leads were considered as the "conventional group".

The data of all patients including age, gender, preoperative diagnosis and preoperative echocardiography were collected.

Statistical analysis

Statistical analysis was performed using SPSS 19.0 software. Normal distribution data were expressed as mean ± standard deviation (SD), and the two-sample *t*-test was used to compare the data. Otherwise, non-normal distribution data were expressed as median [quartile range (QR)], and were compared using the nonparametric Mann-Whitney U test. Chi-square test was used to compare the count data. A binary logistic regression analysis model was established to identify the predictors of the optimized group. Hosmer-

Table 1 The preoperative baseline characteristics of the included patients

Characteristic	Optimized group	Conventional group	P value
Case	67	31	
Age (years, $\bar{x}$±s)	62±12	65±12	0.306
Male, n (%)	40 (59.7)	15 (48.4)	0.294
AVB, n (%)	25 (37.3)	7 (22.6)	0.148
SSS, n (%)	42 (62.7)	24 (77.4)	
HT, n (%)	30 (44.8)	18 (58.1)	0.221
CAD, n (%)	9 (13.4)	2 (6.5)	0.500
DM, n (%)	11 (16.4)	4 (12.9)	0.883
HPL, n (%)	16 (23.9)	12 (38.7)	0.131
St. Jude 1888Tc, n (%)	65 (97.0)	28 (90.3)	0.161
Medtronic 5076-52, n (%)	2 (3.0)	3 (9.7)	
LVED (mm, $\bar{x}$±s)	49.6±4.1	48.0±3.9	0.070
LVEF, median (QR) (%)	67.0 (10.2)	69.1 (9.4)	0.966
RAE, n (%)	8 (11.9)	6 (19.4)	0.329
RVED (mm, $\bar{x}$±s)	20.5±1.8	20.9±1.9	0.409
BRB, n (%)	23 (34.3)	14 (45.2)	0.304

AVB, atrioventricular block; SSS, sick sinus syndrome; LVED, left ventricular diastolic diameter; CAD, coronary atherosclerotic heart disease; HT, hypertension; HPL, hyperlipidemia; DM, diabetes mellitus; LVEF, left ventricular ejection fraction median; RAE, right atrial enlargement; RVED, right ventricular diastolic diameter; BRB, β receptor blocker.

Lemeshow statistics was used to confirm the model fitness for the data. The sensitivity and specificity of each variable was determined using the receiver-operating characteristic (ROC) curve and the standard formula. Statistical significance was assumed at P<0.05.

Results

Baseline characteristics

All 98 patients implanted with active-fixation atrial leads completed the 3-month follow-up, in which 67 patients were assigned to the optimized group and 31 patients were assigned to the conventional group after 3 months of follow-up. Among these 98 patients, 55 (56%) patients were male and 43 (44%) patients were female. The mean age of these patients at implantation was 63±12 years old. Indications for the pacemaker were atrioventricular block in 32 patients and sick sinus syndrome in 66 patients (*Table 1*).

Atrial leads

Leads in the optimized group had a higher COI at 0 minute [COI_{0min}, 2.06 (1.10) *vs.* 1.29 (1.42) mV, P=0.009] and COI at 10 minutes [COI_{10min}, 1.23 (1.38) *vs.* 0.71 (0.61) mV, P=0.005] in the electrical measurements of the implantation time. P-wave sensing measured at 0 minute [P_{0min}, 4.0 (2.2) *vs.* 2.4 (2.7) mV, P=0.005] and after 10 minutes [P_{10min}, 4.0 (2.7) *vs.* 2.4 (1.7) mV, P<0.001] after lead fixation were also significantly higher in leads in the optimized group than in the conventional group. Pacing threshold measured at 0 minute [T_{0min}, 0.8 (0.6) *vs.* 1.0 (0.4) V, P=0.011] and after 10 minutes [T_{10min}, 0.7 (0.4) *vs.* 0.8 (0.5) V, P=0.014] of lead fixation were significantly lower in leads in the optimized group, compared to the conventional group (*Table 2*).

However, pacing impedance at 0 minute {IMP_{0min}, 640 [160] *vs.* 640 [140] ohms, P=0.833} and after 10 minutes {IMP_{10min}, 640 [120] *vs.* 600 [120] ohms, P=0.221} were similar in leads between the optimized group and conventional group (*Table 2*).

Table 2 COI and pacing parameters recorded during the implantation between the two groups [median (QR)]

Characteristic	Optimized group	Conventional group	P value
0 minute after lead fixation			
Current of injury (mv)	2.06 (1.10)	1.29 (1.42)	0.009
Pacing threshold (v)	0.8 (0.6)	1.0 (0.4)	0.011
P-wave sensing (mv)	4.0 (2.2)	2.4 (2.7)	0.005
Pacing impedance (ohms)	640 [160]	640 [140]	0.833
10 minutes after lead fixation			
Current of injury (mv)	1.23 (1.38)	0.71 (0.61)	0.005
Pacing threshold (v)	0.7 (0.4)	0.8 (0.5)	0.014
P-wave sensing (mv)	4.0 (2.7)	2.4 (1.7)	<0.001
Pacing impedance (ohms)	640 [120]	600 [120]	0.221

Table 3 Predictors of optimized group at 3-month for the active-fixation atrial leads

Characteristic	Odds ratio	95% confidence interval	P value
0 minute after lead fixation			
Current of injury (COI)	1.087	0.528–2.237	0.821
Pacing threshold	1.179	0.361–3.845	0.785
P-wave sensing	1.345	0.856–2.113	0.198
Pacing impedance	1.004	0.997–1.011	0.270
10 minutes after lead fixation			
Current of injury (COI)	0.296	0.093–0.939	0.039
Pacing threshold	2.881	0.304–27.307	0.357
P-wave sensing	0.449	0.265–0.762	0.003
Pacing impedance	0.999	0.991–1.006	0.705

Predictors of outcome for atrial leads in the optimized group

Among multiple implant pacing parameters, active-fixation atrial leads after 3 months in the optimized group was correlated with COI_{10min} [odds ratio (OR): 0.296, 95% confidence interval (CI): 0.093–0.939, P=0.039] and P_{10min} [OR: 0.449, 95% CI: 0.265–0.762, P=0.003] (*Table 3*).

The ROC curve analysis was performed on atrial COI_{10min} and P_{10min} to define the optimal cut-off values for the prediction of the optimized leads. The ROC curve analysis revealed that COI_{10min} ≥1.04 mV predicted for the optimized lead after 3 months with a sensitivity of 0.58 and a specificity of 0.77 (*Figure 2A*). In addition, P_{10min} ≥3.3 mV was identified as the optimal cut-off (sensitivity: 0.67; specificity: 0.74) to predict the optimized lead at 3 months (*Figure 2B*). Moreover, with the combined COI_{10min} ≥1.04 mV and P_{10min} ≥3.3 mV as the predictable criteria, the area under the ROC curve was 0.806 (sensitivity: 0.70; specificity: 0.77) (*Figure 3*).

Discussion

The main finding of the present study was that COI and P-wave sensing recorded after 10 minutes of the lead fixation may predict the optimized lead for active-fixation atrial leads after 3 months. Kashiwase *et al.*'s study suggested that the threshold descends and approaches a 5-minute

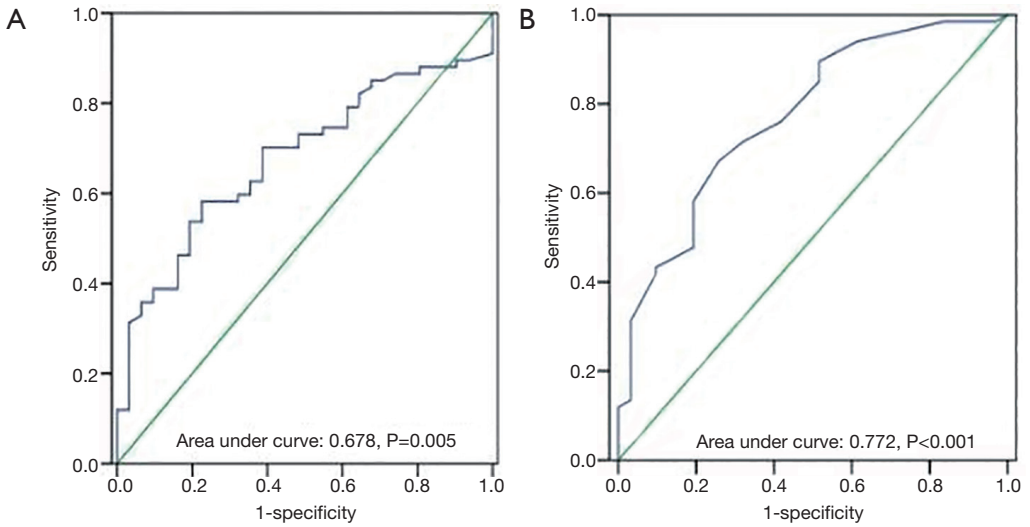

Figure 2 Receiver-operating characteristic curve (ROC) for COI and P-wave sensing after 10 minutes of atrial lead implantation to predict the 3-month optimized lead performance. (A) The area under the curve (AUC) of 0.678 indicated that COI_{10min} ≥1.04 mV predicted for optimized lead at 3 months with a sensitivity of 0.58 and a specificity of 0.77. (B) The AUC of 0.772 indicated that P_{10min} ≥3.3 mV was identified as the optimal cutoff (sensitivity: 0.67; specificity: 0.74) to predict the optimized lead at 3 months. The diagonal line (AUC =0.5) corresponds to the random guess.

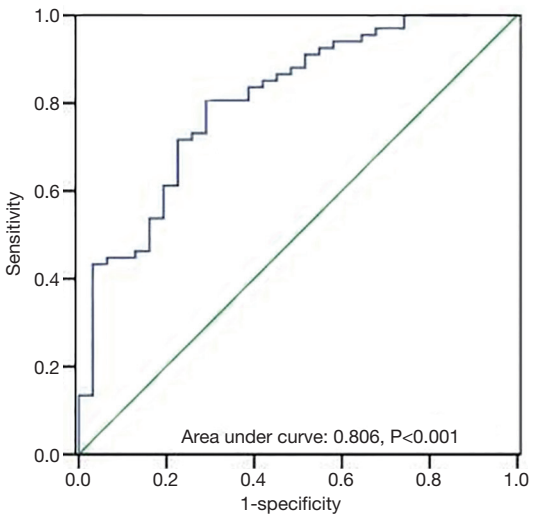

Figure 3 Receiver-operating characteristic curve (ROC) for the combined COI and P-wave sensing after 10 minutes of atrial lead implantation to predict the lead optimized performance after 3 months. With the combined COI_{10min} ≥1.04 mV and P_{10min} ≥3.3 mV as the predictable criteria, the area under the ROC curve was 0.806 (sensitivity: 0.70; specificity: 0.77). COI, current of injury.

stable plateau after implantation with active-fixation (13). The ROC curve analysis revealed that COI_{10min} of ≥1.04 mV indicated the optimized lead after 3 months with a sensitivity of 0.58 and a specificity of 0.77, and the area under the ROC curve was 0.678. The predictive optimized lead after 3 months with COI_{10min} had low sensitivity, and was not recommended to be used alone. In addition, the optimized lead after 3 months could be predicted by P_{10min} of ≥3.3 mV (sensitivity: 0.67; specificity: 0.74), and the area under the ROC curve was 0.772. The sensitivity of P_{10min} was higher, when compared to the sensitivity of $COI_{10min,}$ and the specificity of these two was similar.

However, with the combined COI_{10min} ≥1.04 mV and P_{10min} ≥3.3 mV as the predictable criteria, the area under the ROC curve was 0.806 (sensitivity: 0.70; specificity: 0.77). Compared with the respective prediction, the sensitivity and specificity of the combined prediction were enhanced.

In Mond *et al.*'s study, the pacemaker threshold peak appeared at 1 month after the operation (14). The study conducted by Haghjoo *et al.* (12) demonstrated that lead performance at 6 months can be predicted through an adequate amount of COI recorded at the time of lead implantation. The adequate amount of COI was defined as an increase in PR-segment elevation of ≥2.0 mV for atrial leads. The conclusion of the above study was different from that in the present study.

The main differences between the study of Haghjoo *et al.* (12) and the present study were as follows: the study of Haghjoo *et al.* (12) defined "good performer at 6 months

of follow-up" as that having a P-wave sensing of ≥1.5 mV, a pacing threshold of <1.5 V, and no dislodgment, while in the present study patients were followed up for only 3 months. The study of Kistler *et al.* (15) demonstrated that the active-fixation leads maintained stable long-term pacing parameters after 3 months following implantation. The data from the follow-ups were kept stable during the 12 months post-implant (16). J-shaped and straight atrial leads with active (screw-in) fixation mechanism demonstrated favorable lead performance throughout follow-up (17). Therefore, pacing parameters at 3 and 6 months following implantation can both represent the chronic pacing performance. The present study defined "optimized performer after 3 months of follow-up" as those having a P-wave sensing of ≥2.0 mV, a pacing threshold of ≤1.0 V, a lead impedance within 300–1,000 ohms, and no dislodgment. The present study requires a higher standard of pacing threshold and a P-wave sensing level, as both are important for prolonging the service life of pacemakers and pacing electrodes. High P-wave sensing can reduce the incidence of competitive cardiac pacing, and ensure that the pacemaker works better (2). The present study did not record COI_{10min}. The study conducted by Chen *et al.* (18) demonstrated that a low level of COI_{0min} and COI_{10min} suggest a poor lead fixation, which shows the importance of COI within 10 minutes after lead fixation. The study conducted by Redfearn *et al.* (11) revealed that the continuous monitoring of lead parameters within 10 minutes of fixation is useful for predicting acute lead stability, and the adequacy COI can predict for acute lead stability and acute pacing thresholds. Hence, it is necessary to dynamically monitor these pacing parameters during lead implantation.

In the study conducted by Chen *et al.* (19), the optimized placement of a right ventricular lead was identified by COI_{0min} >4.77 mV and R-wave sensing >7.25 mV recorded after 10 minutes of lead fixation. The optimized ventricular lead was defined as an R-wave sensing of >5.0 mV, a pacing threshold of <1.4 V, and a lead impedance of within 300–1,500 ohms after 10 minutes of lead fixation. Similarly, it was found that high chronic P-wave sensing was correlated to high P_{10min}.

The results of the present study should be interpreted in light of certain limitations. First, the sample size of the study was relatively small. Second, the present study had a retrospective design, which selects the case of past patients in our center; hence, there is a certain choice bias.

Conclusion and clinical implications

The present study suggests that right atrial lead implantation parameters might be associated with lead optimized performance after 3 months of follow-up. The chronic performance of right atrial active-fixation leads may be predictable using the COI and P-wave sensing recorded at 10 minutes after lead fixation. COI ≥1.04 mV and P-wave sensing ≥3.3 mV recorded at 10 minutes after atrial lead fixation are recommended to possibly optimize lead performance after 3 months.

For young patients who need to be implanted with permanent pacemakers, they may have to replace the pacemaker several times due to energy depletion. In addition, lead stability and good pacing parameters can extend the life of the lead and pacemaker. Therefore, the pacing lead implantation is particularly important.

In order to obtain long-term good pacing parameters and lead stability after lead implantation, the results of the present study need to be considered.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study protocol was approved by the Ethics Committee of Fujian Medical University Union Hospital (No. 2017KY011), and a written informed consent was obtained from all patients.

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