International Journal of Cardiology 258 (2018) 121–125

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Could persistency of current of injury forecast successful active-fixation pacing lead implantation?

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ARTICLE INFO

Article history:
Received 10 October 2017
Received in revised form 13 December 2017
Accepted 2 January 2018
Available online 8 February 2018

Keywords:
Current of injury
Active-fixation lead
Pacemaker

ABSTRACT

Background: Presence of adequate current of injury (COI) was recognized as a sign of favorable pacemaker lead outcome. Little is known regarding the value of its dynamic behavior. We sought to test whether persistency of COI could predict active-fixation pacing lead performance.

Methods: COI was monitored up to 10 min after right ventricular (RV) pacing electrode fixation. COI persistency was defined as the percentage of COI magnitude relative to its initial measurement. An unacceptable pacing threshold (≥1.0 V in acute evaluation or ≥2.0 V over 2-year follow-up) with or without lead dislodgement was considered as lead failure.

Results: Lead implantation was attempted for 217 times in 174 patients (age 66.3 ± 7.8 years, 78 female). Acute lead failures occurred 43 times. Independent predictors of acute lead failure were RV enlargement (odds ratio [OR] 1.23, 95% confidential interval [CI] 1.11–2.04, $P = 0.033$), absence of COI (OR 3.13, 95%CI 2.08–9.09, $P = 0.027$), and COI persistency at 5 min (OR 0.32, 95%CI 0.20–0.69, $P = 0.001$) and 10 min (OR 0.41, 95%CI 0.13–0.77, $P = 0.001$). The optimal cutoffs were $COI_{5\ min}$ persistency ≥50% (sensitivity 81.4%; specificity 81.9%) and $COI_{10\ min}$ persistency ≥20% (sensitivity 86%; specificity 88.6%). There were 12 lead failures during 24.0 ± 6.4 months of follow-up. Patients with $COI_{5\ min}$ persistency ≥50% had higher event-free survival compared to those with $COI_{5\ min}$ persistency <50% (hazard ratio 3.54, 95% CI 1.04–12.06, $P = 0.043$).

Conclusions: COI persistency appears to be a valuable indicator for both acute and long-term outcome of active-fixation pacemaker leads. A precipitous decline in COI may require more attention to make sure of the lead performance.

1. Introduction

The frequency of pacing lead dislodgement and unacceptable pacing threshold events were reported as 1.2%–4.8% in previous studies [1,2]. Pacing leads, either tined or screw-in, were attached to the endocardium, resulting in a notable trauma to the focal tissue [3]. This injury could produce current of injury (COI) on the intracardiac electrogram (EGM) characterized as ST-segment elevation from baseline [4]. Presence of adequate COI has been associated with good performance of both active and passive-fixation leads [5–8]. These studies mainly focused on COI magnitude rather than its dynamic properties. Our previous research on experimental rabbit heart models has found that the time course of COI from onset to resolution was positively correlated with acute stability of active-fixation leads; more importantly, initial measurements of COI magnitude might be misleading, whereas continuous monitoring of dynamic COI behavior post fixation may offer benefit in guiding pacemaker lead fixation [9]. Whether these observations will still be true in the real clinical scenario has yet to be elucidated. Besides, the follow-up was only up to 6 months to test the significance of COI on active-fixation lead performance with regard to previous study [8]. It's potential relevance on long-term lead stability and electrical performance remains in question as well.

In this study, we investigated the predictive value of COI persistency on both acute and long-term performance of active-fixation pacing leads in patients with standard pacing indications.

2. Method

2.1. Study subjects

Patients were recruited from a single institution (Zhongshan hospital, Fudan University). Consecutive patients who have conventional indications for right ventricular (RV) pacing

Abbreviation: COI, current of injury; RV, right ventricular; RVA, RV apex; RVOT, RV outflow tract; RA, Right atrium; EGM, electrogram; OR, odds ratio; CI, confidential interval; HR, hazard ratio; ROC, receiver-operating characteristic; AUC, area under curve; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; CKD, chronic kidney disease; BMI, body mass index; SSS, sick sinus syndrome; AVB, atrioventricular block; CIED, cardiac implantable electronic device.

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[1] This author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

https://doi.org/10.1016/j.ijcard.2018.01.005
0167-5273/

were eligible for the study. The exclusion criteria included any of the followings: (1) age ≤18 or ≥85 years, (2) severe tricuspid valve regurgitation, and (3) heart failure patients scheduled for biventricular pacing. The study protocol was approved by the Ethic Committee of Zhongshan Hospital, Fudan University, P. R. China. All subjects have provided written informed consent.

2.2. Pacing lead implantation

Procedures were performed in cardiac catheterization laboratory mainly by Dr. Su YG as previously described [6,7]. Briefly, after local anesthesia, the access was obtained by left subclavian vein puncture. Bipolar, steroid eluting, active-fixation leads with two different electrode designs were used. The fixed screw lead, Model 3830 (Medtronic, Minneapolis, USA) was introduced beyond a guide catheter into either RV apex (RVA) or RV outflow tract (RVOT) at the operator's discretion. The entire lead body was rotated clockwise three to four complete rotations to actively affix the helix into myocardium. In the case of extendable–retractable helix electrode, either Model 1688T/1888T (St Jude Medical, St Paul, USA) or Model 5076 (Medtronic, Minneapolis, USA), the lead was advanced through the peal-away sheath into the right atrium (RA) and then targeted to either RVA or ROVT by using stylet under fluoroscopic guidance. Once proper location was identified fluoroscopically, the helix electrode was extended by rotating the stylet handle clockwise until the tip was completely exposed and embedded in endocardium.

2.3. Intracardiac EGM measurement

A pacing system analyzer (Medtronic2290, Minneapolis, USA) was applied for real-time bipolar intracardiac EGM tracing up to 10 min (Fig. 1). Three or four representative beats were recorded at a speed of 200 mm/s at 0 min, 5 min and 10 min after the electrode fixation. The maximum amplitude of ST-segment elevation from baseline was measured manually by two individuals who were blinded to the study design, and then averaged. ST-segment elevation ≥5.0 mV was defined as adequate COI[6]. COI persistency was defined as the percentage of COI magnitude recorded at 5 min or 10 min after fixation relative to its initial measurement.

2.4. Assessment of acute lead performance

After 10-min complete acquisition of intracardiac EGM, standard measurements of pacing parameters were performed if the electrode remained in position. Stable leads with a pacing threshold ≤1.0 V at 0.4 ms pulse width were considered satisfactory based on previous reports [8,10], and the pacemaker implantation was continued according to the standard procedures. Otherwise leads were considered as failed, and repositioning was required with repeated measurements in the same manner.

2.5. Follow-up

Patients were scheduled for pacing parameter testing at day 1, and X-ray examination before hospital discharge. Routine out-patient follow-up was conducted at 1, 3, 6, 12, 18 and 24 months after the procedure. Lead failure was specified as capture threshold ≥2.0 V, with or without a visible change in the lead position on chest X-ray.

2.6. Statistical methods

The sample size is estimated aiming an 80% power (two-sided alpha, 0.025) to detect a difference of 2 mV in ST-segment elevation. Continuous variables were presented as means ± standard deviations. *t*-Test and Pearson Chi-square test were used to compare the quantitative and categorical variables between groups, respectively. Logistic Regression analysis was used to identify independent predictors of acute lead performance. The receiver-operating characteristic (ROC) curves were built to verify the optimal cutoffs for each independent predictable variable regarding COI to predict successful lead fixation in acute phase. The area under curve (AUC) with its 95% confidence interval (CI) were calculated, and were compared between those variables using a Hanley-McNeil test [11]. Kaplan-Meier analysis was performed to compare the time-to-event rates between groups. A p value <0.05 was considered statistically significant.

3. Results

3.1. Patient demographics and baseline characteristics

A total of 174 consecutive patients undergoing ventricular active-fixation pacing lead placement were enrolled from August 2010 to September 2013. The average age of the study cohort was 66.3 ± 7.8 years, and 44.8% of them were female. Heart failure symptoms (defined as New York Heart Association class above II) were present in

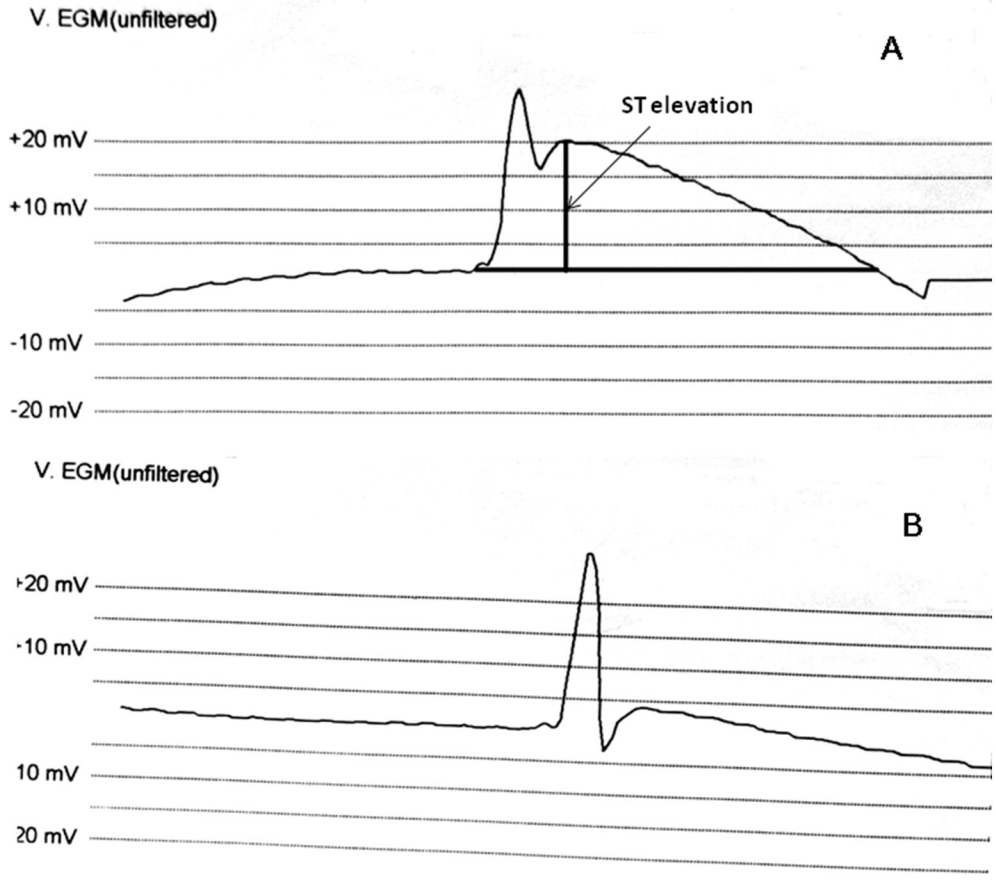

Fig. 1. Bipolar intracardiac electrogram tracing at a speed of 200 mm/s by a Medtronic model2290 pacing system analyzer. Panel A. Current of injury (COI) was measured manually as the maximum amplitude of ST-segment elevation from baseline at the time of electrode fixation. Panel B. COI resolution after 10 min of electrode fixation.