Bedside temporary transvenous cardiac pacing lead placement in patients with tricuspid valve surgery without guidance of X-ray: A single-center experience

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Abstract

Background: It is difficult to insert cardiac pacing leads in patient with tricuspid valve surgery (TVS). The aim of this study was to evaluate safety and effectiveness of a novel technique applied for bedside temporary pacemaker placement (TPP) in patients with TVS.

Methods: We investigated patients with TVS who required bedside TPP without X-ray guidance in cardiac intensive care unit between January 2019 and March 2022. They were divided into Novel pre-shaped group (N = 21) and Control group (routine pre-shaped group, N = 26). The ordinary bipolar electrodes were applied in both groups. In Novel pre-shaped group, electrodes were reshaped by a novel technique with three-curve with anterior tip method, while electrodes were shaped by traditional strategy in Control group. We evaluated the operation duration, first-attempt success rate of the lead placement, pacing threshold, success rate of lead placement, the rate of leads displacement, and complications.

Results: Compared with that in Control group, the procedure time was significantly shortened and the first-attempt success rate of lead placement was obviously increased in Novel pre-shaped group (both \( p < 0.05 \)). Although there was a slight reduction in complications in Novel pre-shaped group when compared with that in Control group. However, there were no statistical significance in pacing threshold, the success rate of lead placement, the rate of leads displacement, and complications when compared between two groups.

Conclusions: We propose a novel technique, three-curve with anterior tip method, is a feasible and effective bedside method to insert emergency temporary pacing leads in patients with TVS.

Keywords
bedside, left subclavian vein, temporary pacemaker lead, tricuspid valve replacement
1 | INTRODUCTION

Although tricuspid valve surgery (TVS) is not a common procedure when compared to other valve surgeries, the incidence of third-degree atrioventricular blocks (AVB III) remains high (Herrmann et al., 2021). Sometimes, an emergency bedside temporary pacing lead placement is usually an imperative requirement in patients with TVS to prevent sudden cardiac death in cardiac intensive care unit (Piela et al., 2016; Tancredi et al., 1967). However, it is difficult to insert the bedside temporary pacemaker lead into the right ventricular chamber through deformed tricuspid annulus without the guidance of X-ray. Therefore, it is needed to explore a novel and effective method to improve such situation.

Currently, there are three methods, including X-ray guidance, bedside balloon-tipped floating catheter, and ordinary bipolar electrode placement, applied for the emergency temporary pacing lead placement (Blanco, 2019). However, the patients in cardiac intensive care unit are usually critically ill on a ventilator or on an intra-aortic balloon pump. It is inconvenient to move the patients to the catheter laboratory for the emergency temporary pacing lead placement under the guidance of X-ray. Though the bedside balloon-tipped floating catheter placement is another effective method (Laczika et al., 2000; Piela et al., 2016), however, this method has not been widely applied because of the more expensive fee than ordinary bipolar electrode and sometimes unavailability in the primary hospital of China. Therefore, we proposed a novel strategy modifying the emergency pacing leads at the bedside to improve the procedure in patients with TVS. We expect this novel modification can be widely spread for application in primary hospitals in developing countries.

1.1 | Patient selection

This study was approved by ethics committees of the Second Xiangya Hospital of Central South University. All procedures were performed in accordance with the Helsinki Declaration. We screened the patients from January 2019 to March 2022 according to the following inclusion criteria: (1) Patients who have symptoms or hemodynamic instability associated with bradyarrhythmia. (2) Electrocardiograph (ECG) presented as cardiac arrest or atrioventricular block with the heart rate lower than 40 bpm. (3) The patients had received TVS.

1.2 | Patients exclusion criteria

Patients who did not sign the informed consent were excluded in this study. Patients who received central venous catheters through left subclavian vein were excluded. The patients who have skin infection at left subclavian were excluded. Patients who have surgery of left subclavian vascular or left subclavian venous stenosis were excluded [Figure 1].

1.3 | Procedures

All procedures were performed with local anesthesia with lidocaine. The Seldinger technique was applied for left subclavian vein cannulation. After successful puncture, the guide wire and 6F sheath were placed into the left subclavian vein. Before placement, the temporary pacing lead was reshaped [Figure 2]. In terms of the insertion length, the electrode tip needed to be precisely located at the xiphoid process, and then, a large curve from xiphoid process to proximal vascular sheath was considered as the insertion length. In Control group, a traditional method was used to shape the lead. The lead was manually shaped into a smooth large curve in a single plane (two-dimensional, 2D) over the distal. In Novel pre-shaped group, a novel method was applied with the leads reshaped by three curves and the leads tip toward anteriorly (three-dimensional, 3D). The lead was reshaped by a proximal 15° curve, a second 15° curve, and a distal 45° curve in the same manner as the 2D. For the lead with an additional anterior curve in 3D, a 30° curve was shaped over the distal segment by hand. After lead reshaped, the leads were inserted into right ventricular chamber. The lead was connected to the temporary pacemaker transmitter to test the pacing effect. If the electrode was not successfully inserted, the electrode was pulled out and the process repeated. If the procedure was not successful for a long time, it was necessary to send the patients to the catheter laboratory and implant the lead under the guidance of X-ray. The pacing threshold and sensing threshold were tested in the two groups. The insertion of the electrode to the target position was judged according to the bedside ECG monitoring as previous study described (Liu & Han, 2020; Zhong et al., 2021). After successful implantation, all patients were underwent bedside chest radiograph to the check temporary pacing lead location [Figure 3]. All of the above research plans were approved by the Medical Ethics Committee of the Second Xiangya Hospital of Central South University (2017. No. 26).

![Flowchart of patients enrollment](image-url)
1.4 | Observation indices

(1) Procedure time for the two groups of cases: the duration from successful puncture of left subclavian vein to connection of the temporary pacing lead with the pulse generator, showing a favorable pacing effect; (2) the first-attempt success rate of lead placement: the success rate of placing the electrode in the septum of the right ventricular chamber for the first time identified by ECG; (3) pacing threshold: the lowest pacing voltage measured during the operation; (4) the success rate of the lead placement: the procedure is completed finally and the pacing parameters are favorable despite multiple attempts; (5) complications: mainly including hematoma, pneumothorax, cardiac perforation, and pericardial effusion during the operation; (6) the rate of electrode displacement after the procedure: the condition that required replacement of the pacing electrode due to pacing and sensing abnormalities caused by the post-operative electrode displacement.

1.5 | Data collection and evaluation

During the study, the demographic data, clinical characteristics, the operation duration, the first-attempt success rate of lead placement, pacing threshold, success rate of the lead placement, the rate of electrode displacement, and complications were collected and evaluated.

1.6 | Statistical analysis

The data were analyzed by SPSS 20 (SPSS Inc., Chicago, IL, USA). Numerical data were shown as mean ± standard deviation (SD). The comparison was performed by utilizing the t-test. The enumerative data were analyzed by the chi-squared test, wherein \( p < 0.05 \) denotes a difference that is statistically significant.

2 | RESULTS

2.1 | The clinical characteristics in both groups

Comparison of general clinical data of two groups (Table 1): There were 21 patients in the Novel pre-shaped group, including 11 males (11/21) and 10 females (10/21), with the average age of 57.2 ± 6.7 years old; the Control group covered 26 patients, including 12 males (12/26) and 14 females (14/26), with the average age of
60.5 ± 8.7 years old. By comparing the clinical characteristics of the two groups, there are no statistically significant differences.

### 2.2 Comparison of the observation indices

In Novel pre-shaped group, all patients were successfully implanted into right ventricular septum without the guidance of X-ray; however, there are four patients failed to place the temporary pacing electrode in Control group (detail in Table 2). In those patients, the electrode was successfully placed under X-ray guidance in the catheter center, and the failed four patients were excluded for recording observation indices in the Control group. During the comparison of the observation indices in two groups, the procedure time was significantly shortened in Novel pre-shaped group when compared to Control group (17.0 ± 5.5 vs. 34.8 ± 5.2, \( p < 0.001 \)). However, there are no significant differences in pacing threshold, the rate of electrode displacement, success rate of the lead placement, and complications (all \( p > 0.05 \)). According to the above results, it indicated that the novel method significantly reduced the procedure time and increased first-attempt success rate of lead placement. It is a safe and feasible method for the guidance of bedside temporary pacing lead implantation without X-ray.

### 3 DISCUSSION

#### 3.1 Major findings

The aim of the present study was to evaluate the safety and effectiveness of the modified method when implanting temporary
pacing leads into the right ventricular chamber. The significant findings were as follows: (1) The modified method could shorten the procedure time. (2) The modified method is a safe and easy strategy for lead placement. We expect this novel modification can be widely spread for application in primary hospitals in developing countries.

It is necessary to repair or replace tricuspid valve in the patients with severe tricuspid regurgitation. The incidence of permanent pacemaker implantation following tricuspid valve replacement had been reported to be up to 20% (J€okinen et al., 2009; Scully & Armstrong, 1995). Sometimes, an emergency bedside temporary pacing is imperative requirement in patient with TVS and serves as a bridge before implantation of a permanent pacemaker (Suarez & Banchs, 2019). However, the patients in cardiac intensive care unit are usually critically ill with a ventilator or an intra-aortic balloon pump. It is inconvenient to move the patients to the catheter center for emergency temporary pacing lead placement under the guidance of X-ray. Therefore, bedside temporary transvenous cardiac pacing lead placement in patients with TVS without guidance of X-ray is imperatively needed (Gangathimmaiah, 2017). However, due to enlargement of right atrial chambers and mechanical distortion of tricuspid valve after TVS, it is very difficult for the transvenous endocardial ventricular pacing lead to pass through tricuspid valve (Bai et al., 1994; Cooper et al., 1995).

The most challenging part of the placement was traversing the tricuspid valve orifice. There are several causes for the challenges to inserting the lead. Firstly, patients with tricuspid valve replacement commonly accompanied by enlarged atrium and right ventricular chambers. It lacks supportive force for the pacing lead. Secondly, TVS altered the orientation of tricuspid valve. It causes the results that the lead tip would often be directed into cul-de-sacs above and below the valve. Thirdly, TVS following together with the forceful opposition of the tricuspid regurgitant jet. The regurgitation impedes the pacing lead pass through the tricuspid valve. Therefore, the bedside temporary pacing leads implantation procedure is prolonged and difficult (Lee, 1983). In this clinical situation, we developed a novel strategy (shaped the lead) to implant the lead in patients with TVS. The pacing leads were reshaped by three curves with the lead tip toward anteriorly (three-dimensional, 3D). The three curves give a good supportive force for the pacing leads in an enlarged right atrium and ventricular chamber, and an additional anterior curve was shaped with a 30° curve which was compliant with the distorted tricuspid valve (Burr et al., 2012; Kistler et al., 2002). According to our results, the reshaped lead method significantly increased the successful rate of implantation, shortened procedure, and reduced lead complications. Therefore, it is a feasible method.

3.2 | Clinical implications

Fluoroscopy is not a perquisite for patients with tricuspid valve surgery when implanting a temporary pacing lead into right chamber. This novel method of reshaping the leads with 3-D curve is feasible in patients who receive tricuspid valve surgery. It should be recommended for these kinds of patients. It is worth to be widely spread for application in primary hospitals in developing countries.

3.3 | Study limitations

There are several limitations in this study. Firstly, the sample size of this study is relatively small. A much more patients should be enrolled in this study. Secondly, since our center is a tertiary reference center, patients may be more complex than those encountered in real clinical practice. Therefore, multicenter prospective studies with larger numbers of patients are needed.

4 | CONCLUSIONS

We propose a novel technique, three-turn-tip-toward method, which is a feasible and effective method to insert emergency bedside temporary pacing leads in patients with TVS.

AUTHOR CONTRIBUTIONS

MC and ZW had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis, including and especially any adverse effects. ZW, SW, TZ, ZL, QL, and SZ contributed substantially to the study design, data analysis, and interpretation, and the writing of the manuscript. All authors read and approved the final manuscript.

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CONFLICT OF INTEREST

We declare that we have no financial and personal relationships with other people or organizations that can inappropriately influence our work.

DATA AVAILABILITY STATEMENT

Data available on request from the authors.

ETHICS STATEMENT

The ethics review board of Second Xiangya Hospital of Central South University approved the study protocol, and written informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the International Council for Harmonization and good clinical practice principles.
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