

Optimized Axillary Vein Technique versus Subclavian Vein Technique in Cardiovascular Implantable Electronic Device Implantation: A Randomized Controlled Study

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Abstract

Background: The conventional venous access for cardiovascular implantable electronic device (CIED) is the subclavian vein, which is often accompanied by high complication rate. The aim of this study was to assess the efficacy and safety of optimized axillary vein technique.

Methods: A total of 247 patients undergoing CIED implantation were included and assigned to the axillary vein group or the subclavian vein group randomly. Success rate of puncture and complications in the perioperative period and follow-ups were recorded.

Results: The overall success rate (95.7% vs. 96.0%) and one-time success rate (68.4% vs. 66.1%) of punctures were similar between the two groups. In the subclavian vein group, pneumothorax occurred in three patients. The subclavian gaps of three patients were too tight to allow operation of the electrode lead. In contrast, there were no puncture-associated complications in the axillary vein group. In the patient follow-ups, two patients in the subclavian vein group had subclavian crush syndrome and both of them received lead replacement. The incidence of complications during the perioperative period and follow-ups of the axillary vein group and the subclavian vein group was 1.6% (2/125) and 8.2% (10/122), respectively ($\chi^2 = 5.813$, $P = 0.016$).

Conclusion: Optimized axillary vein technique may be superior to the conventional subclavian vein technique for CIED lead placement.

Trial Registration: www.clinicaltrials.gov, NCT02358551; <https://clinicaltrials.gov/ct2/show/NCT02358551?term=NCT02358551&rank=1>.

Key words: Axillary Vein; Cardiovascular Implantable Electronic Device; Randomized Controlled Trial; Subclavian Vein

INTRODUCTION

The number of cardiovascular implantable electronic device (CIED) implantation has increased over the past few years. The conventional access of lead implantation is the subclavian vein, which is often accompanied by high complication rate, including pneumothorax, hemopneumothorax, inadvertent artery puncture, local hematoma, subclavian crush syndrome, and difficulty in lead operating.^[1,2] Thus, the axillary vein puncture has been proposed as an alternative technique to the conventional subclavian vein access.^[3]

However, the comparison between subclavian and axillary vein access through large-size sampled and randomized clinical trial is still limited. Here, we proposed a randomized, two-armed, open-label study to analyze the efficacy and safety of optimized axillary vein puncture versus conventional subclavian puncture in CIED implantation.

METHODS

Patient enrollment and randomization

Patients aged 18 years or older with the indication of permanent pacemakers, cardiac resynchronization therapy pacemakers/defibrillators (CRT-P/CRT-D), and implantable cardioverter defibrillators (ICD) were included in the study. All eligible patients were asked to sign and date an informed consent document in person before randomized into different groups. Patients undergoing lead replacement were excluded from the study.

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The study was reviewed and approved by the Clinical Research Ethics Board at China-Japan Friendship Hospital and was registered to www.clinicaltrials.gov with trial number NCT02358551.

According to a computer-generated randomization list, patients were randomized to the optimized axillary vein puncture group or the conventional subclavian vein puncture group at a ratio of 1:1 using an 8-sized block. The pulse generators were implanted on the surface of pectoralis major on the same side. Operated chest walls were locally strapped for 24 h and pressed with sandbags for 4 h. Operations in both groups were performed consistently by one skilled electrophysiology physician.

Vein puncture technique

Optimized axillary vein puncture

Ipsilateral cubital vein trocar was retained before the procedure. Pacemaker pocket was created below the clavicle. As the passage of the axillary vein is usually fixed, we used the 21-G needle to search for the axillary vein with X-ray fluoroscopy at the point where the first rib meets the clavicle. The direction of needle was toward the first anterior rib, with an angle of about 45° – 60° between the needle and the skin. After the venous blood was drawn, a 0.018 inch J-shaped guidewire was put into the 21-G needle, and the 5 Fr sheath (Cook Group Incorporated, Bloomington, Indiana, USA) was inserted into the vein [Figure 1]. Subsequently, both the 0.018 inch guidewire and 5 Fr sheath were replaced by the standard 0.035 inch J-shaped guidewire and the peel-away electrode lead sheath (Biotronik, Berlin, Germany). If five attempts of puncture failed, an ipsilateral cubital vein angiography will be performed to observe the passage of axillary vein [Figure 2] and subsequently the same method of vein puncture should be used as stated above.

Subclavian vein puncture

Ipsilateral cubital vein trocar was retained before the procedure. Pacemaker pocket was created below the clavicle. We used the 18-G needle to search for the subclavian vein with X-ray fluoroscopy at the point of clavicle. The entry point of the needle was a one-third point to the

sternoclavicular joint, and direction of the needle was toward the suprasternal fossa, with an angle of about 15° – 30° between the needle and the skin. After the venous blood was drawn, a standard 0.035 inch J-shaped guidewire and the peel-away electrode lead sheath were inserted into the vein. If five attempts of puncture failed, an ipsilateral cubital vein angiography will be performed to observe the passage of subclavian vein and the same method of vein puncture should be used as stated above.

Outcome measures

Success of puncture was defined as drawing of venous blood and insertion of guidewire and sheath. One-time success was defined as minor adjustment of needle direction and point of puncture, without withdrawing the needle. Number of puncture needed, length of time in puncture and X-ray exposure, parameters of pacemakers including threshold, impedance, and P/R wave amplitude were recorded. Complications and adverse events in the perioperative period were observed and recorded. Patients were followed up at 1, 3, 6, and 12 months after the operation and for every 12 months afterward. Parameters of pacemakers, complications and adverse events during follow-ups were recorded.

Statistical analysis

Continuous variables were used to compare between groups by *t*-test for normally distributed values; otherwise, Mann-Whitney *U*-test should be used. Proportions were compared by Chi-square test. Fisher's exact test was applied when the expected frequency is <5 . Statistical significance was determined at a computed $P < 0.05$. All the analyses were performed on SPSS software version 17.0 (SPSS Inc., Chicago, Illinois, USA).

RESULTS

Clinical characteristics

A total of 247 patients were enrolled in this study between January 2013 and November 2015, with no loss during

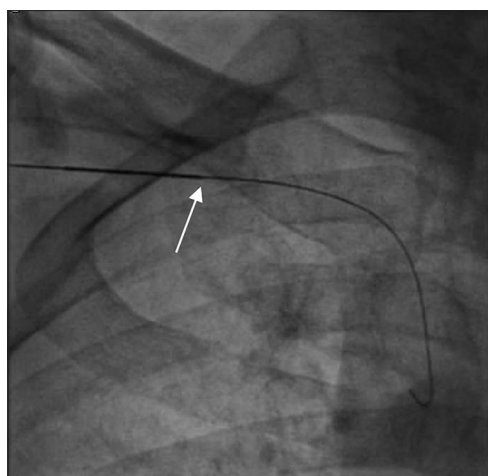


Figure 1: Axillary vein puncture. The arrow indicates the puncture site.

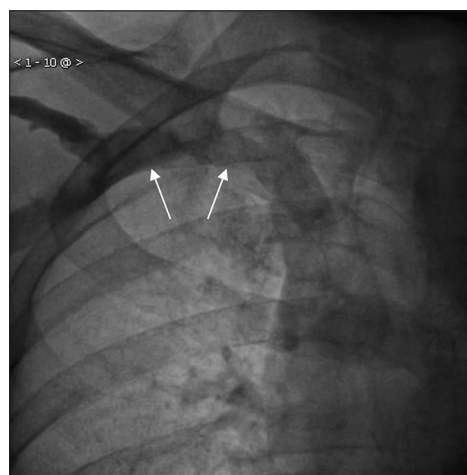


Figure 2: Cubital vein angiography. The passages of axillary vein and subclavian vein can be observed. The left arrow indicates the axillary vein and the right arrow indicates the subclavian vein.

follow-ups. Among all the patients, 125 were randomized into the axillary vein group and 122 were randomized into the subclavian vein group. Clinical characteristics of the two groups were listed. The sex and age distribution, body mass index, and types of CIED were similar between the two groups. No significant difference was observed [Table 1].

Efficacy analysis of the procedure

The success rate of the two groups was similar. Patients in the axillary vein group were implanted with 231 pacing/defibrillation electrode leads, of which 221 punctures succeeded. The overall success rate was 95.7%. Patients in the subclavian vein group were implanted with 227 pacing/defibrillation electrode leads, of which 218 punctures succeeded. The overall success rate was 96.0%. One-time success rate of both groups was 68.4% (158/231) and 66.1% (150/227), respectively. The mean time spent in puncture of the axillary vein group was 45.9 ± 14.1 s, whereas in the subclavian vein group, it was 28.7 ± 13.9 s ($t = 9.679$, $P < 0.001$). The duration of X-ray exposure was 150.1 ± 33.6 s and 145.5 ± 34.9 s, respectively [Table 2].

The vein punctures failed in 11 patients, who all received cubital vein angiographies to observe the passage of axillary veins or subclavian veins. Among them, three patients in the axillary vein group had total occlusion of veins and two had shifting veins; two patients in the subclavian vein group had total occlusion of veins, one had vein stenosis, and three had shifting veins. We successfully performed the puncture under the guidance of angiography or performed the procedure on the opposite side.

Complications in the perioperative period and follow-ups

In the subclavian vein group, pneumothorax occurred in three patients. Three patients' subclavian gaps were too tight to allow operation of the electrode lead (all of them had puncture repeated once to complete the operation). There were no puncture-associated complications in the axillary vein group. In either group, none had pocket hematoma or other severe complications.

In a mean follow-up of 24.1 ± 7.4 months, lead dislocations occurred in one patient in both groups, both of whom underwent lead replacements. Pocket infection occurred in one patient in both groups, both of whom underwent pocket debridement and later were implanted with the CIEDs in the opposite side. Two patients in the subclavian vein group had subclavian crush syndrome, both of whom underwent lead replacements. The remaining patients had no complications, and threshold, P/R wave amplitude, and impedance of their CIEDs were all in the normal range during the follow-ups. The complication rate in perioperative period and follow-ups of the axillary and subclavian vein group was 1.6% (2/125) and 8.2% (10/122), respectively ($\chi^2 = 5.813$, $P = 0.016$) [Table 3].

DISCUSSION

Common vein access for CIED lead implantation was cephalic, subclavian, and axillary veins. Subclavian vein

puncture has faster learning curve, and the success rate is generally high.^[4] However, due to its anatomic characteristics, complications are relatively common, including pneumothorax, hemopneumothorax, inadvertent subclavian artery puncture, brachial nerve plexus injury, subclavian crush syndrome, and electrode lead fracture.^[1,2] The cephalic vein was proposed to be an alternate access. A large-scale retrospective study found that cephalic vein access was related with lower rate of lead

Table 1: Baseline characteristics of the study population

Variables	Axillary vein group (n = 125)	Subclavian vein group (n = 122)	Statistics	P
Gender (male/female)	74/51	73/49	0.010 [†]	0.919
Age (years)*	63.4 ± 9.7	64.0 ± 8.6	-0.556 [‡]	0.579
Body mass index (kg/m ²)*	25.7 ± 3.1	25.9 ± 2.8	-0.569 [‡]	0.570
Type of CIED				
Single-chamber pacemaker	11	10	0.095 [†]	0.992
Dual-chamber pacemaker	97	94		
CRT-P/CRT-D	4	4		
ICD	13	14		

*Normally distributed continuous variables are presented as mean ± SD. †: χ^2 value; ‡: t value. CIED: Cardiovascular implantable electronic device; CRT-P/CRT-D: Cardiac resynchronization therapy pacemakers/defibrillators; ICD: Implantable cardioverter defibrillator; SD: Standard deviation.

Table 2: Success rate and duration of the procedure

Variables	Axillary vein group (n = 125)	Subclavian vein group (n = 122)	Statistics	P
Overall success rate (%)	95.7 (221/231)	96.0 (218/227)	0.038 [†]	0.845
One-time success rate (%)	68.4 (158/231)	66.1 (150/227)	0.280 [†]	0.597
Duration of puncture (s)*	45.9 ± 14.1	28.7 ± 13.9	9.679 [‡]	<0.001
Duration of X-ray exposure (s)*	150.1 ± 33.6	145.5 ± 34.9	1.065 [‡]	0.288

*Normally distributed continuous variables are presented as mean ± SD. †: χ^2 value; ‡: t value. SD: Standard deviation.

Table 3: Complications in perioperative period and follow-ups

Variables	Axillary vein group (n = 125)	Subclavian vein group (n = 122)	χ^2	P
Pneumothorax	0	3	3.099	0.119
Difficulty of lead operating	0	3	3.099	0.119
Lead dislocation	1	1	0.000	1.000
Infection	1	1	0.000	1.000
Subclavian crush syndrome	0	2	2.058	0.243
Total	2	10	5.813	0.016

failure.^[5] However, it requires vein incision which renders the operation more complicated and time consuming.^[6] Moreover, the size of the axillary vein is relatively small, thus it often suffers from a high failure rate,^[7,8] especially with multiple leads. The number of implantations of ICDs and CRT-Ps/CRT-Ds has increased in the past few years,^[9,10] and cephalic vein puncture may not be an optimal procedure. Anatomically, the axillary vein terminates at the lateral margin of the first rib and becomes the subclavian vein. Its passage is outside the clavicle and far from the cupula pleurae, and the diameter is larger compared with the cephalic vein with little variation.^[11] Therefore, the axillary vein puncture avoids nerve or pleura injury and subclavian crush syndrome, which ensures a high success rate.

Axillary vein puncture was first reported by Nickalls in 1987.^[12] Afterward, some physicians improved and expanded the technique. Higano *et al.* reported an approach of guiding the puncture pathway using vein angiography and fluoroscopy.^[13] However, these maneuvers are complicated and have steep learning curves, which limit the clinical application.

Belott reported an approach based on anatomic landmark on body surface and radiograph, where the axillary vein terminates and becomes the subclavian vein with little variation.^[3] A few other clinical studies also proposed a maneuver based on this landmark.^[14,15] Overall, axillary vein punctures guided by fluoroscopic landmark, contrast venography, or ultrasound have shown high success rate and low complication rate.^[16-18]

In this trial, the axillary vein puncture can be achieved in most patients, confirming its feasibility. Furthermore, we used the 21-G needle instead of the routine 18-G needle, which reduced tissue injury as well as the risk of artery injury and pneumothorax. In this study, the overall success rate and one-time success rate of axillary and subclavian vein puncture were similar. No pneumothorax or difficulty on lead operating occurred in the operation and no subclavian crush syndrome occurred in the follow-ups, which confirmed the efficacy and safety of this technique. No pocket hematoma or other severe complications occurred in either group, probably due to the operator's experience and the use of electrotome. The duration of procedure in the axillary vein group is longer than the subclavian group, probably because the axillary vein puncture requires more fluoroscopy guidance and searching in local area. In addition, the axillary vein puncture included an extra procedure: exchange of guidewire and sheath, which was time consuming. Moreover, the development of equipment is likely to simplify this additional procedure. The relatively steep learning curve of axillary vein puncture is an issue, and innovations in the axillary vein puncture have been proposed recently, such as using the cephalic vein as anatomic landmark,^[19] introducing guidewire retrogradely from the femoral vein up to the left axillary vein as roadmap,^[20] and utilizing the caudal fluoroscopic view.^[21] These innovations may help optimize the axillary vein puncture technique.

The study has several limitations. First, the relatively short follow-up period is not sufficient to evaluate long-term efficacy. Second, it was a single-centered trial and all the procedures were performed by one operator, thus interpretation and extrapolation of the results should be cautious. A multi-centered trial with larger scale and longer follow-ups is necessary to present more evidence of the advantage of the axillary vein puncture technique.

In conclusion, optimized axillary venous approach may be superior to conventional subclavian vein approach for CIED lead placement.

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Conflicts of interest

There are no conflicts of interest.

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