https://doi.org/10.33472/AFJBS.6.6.2024.6182-6190

African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper Open Access

Axillary and Subclavian Vein Puncture in Pacemaker Implantation: A Report from A Vietnam Experience

Giang Song Tran[1], Si Dung Chu[3], Thao Van Phung[3]

[1,3]Vietnam National Heart Institute, Bach Mai Hospital, Hanoi, Vietnam
[2]Hospital of Vietnam National University, Vietnam National University, Hanoi, Vietnam

Article Info

Volume 6, Issue 6, June 2024

Received: 21 April 2024

Accepted: 31 May 2024

Published: 25 June 2024

doi: 10.33472/AFJBS.6.6.2024.6182-6190

ABSTRACT:

Objectives: A study that compared the axillary vein (AV) and subclavian vein (SCV) puncture techniques for permanent pacemaker implantation (PPI).
Methods: A cross-sectional, descriptive, prospective study. Here is a summary of the study's findings in a different way: AV technique is safe and effective for PPI, AV technique may be safer than SCV technique, AV technique resulted in fewer complications than SCV technique at the Vietnam Heart Institute, Bach Mai Hospital from August 2022 to September 2023.
Results: A total of 152 patients undergoing PPI were included in the study. Patients were assigned to either the AV group (n=75) or the ACV group (n=77). The overall success rate was similar between the two groups (89.3% vs 93.5%). The number of vein puncture was lower in the AV group (2.7 ± 1.2 vs 3.2 ± 1.6, $p < 0.05$). The rate of all types of complications was lower in the AV group (9.3%) than in the ACV group (24.7%), $p < 0.05$. There was no significan difference between the two groups in terms of venous access time, X-ray exposure time, or procedure time ($p>0.05$).
Conclusions: The researchers concluded that the AV access technique is a safe and effective altermative to the SCV access technique for PPI.

Keywords: Axillary vein access technique, Subclavian vein access technique, pacemaker implantation, efficacy, safety, Bach mai Hospital.

1. Introduction

In creating vascular access for permanent pacemaker implantation (PPI), the step of venous access is crucial, the choosing the right vein is important for implanting a pacemaker; It affects the outcome as well as the safety of the procedure. There are three main veins used to create this access: the subclavian vein (SCV), the cephalic vein (CV), and the axillary vein (AV). The SCV method might cause complications like puncturing the lung or blood vessel.[1] The CV method requires cutting the skin and dissecting the subcutaneous tissue to reach the vein.[2] The AV method is considered the safest because it avoids puncturing the lung and doesn't require cutting the skin.[1,3] Therefore, accessing the AV has been proposed as a preferred technique in PPI.

Currently, most operators worldwide perform vascular access by either exposing the CV or puncturing the AV to reduce complications. There have been numerous studies on the AV puncture technique when comparing the safety and effectiveness of different venipuncture techniques in PPI, such as the study by Sharma G et al in 2012,[3] Liu P et al in 2016,[1] and Atti V et al in 2020.[2] These studies recorded the superior safety and efficacy of the AV puncture technique compared to the SCV puncture and CV opening techniques. In Vietnam, PPI techniques have developed strongly for more than 3 decades; However, there are still no official reports on experience, evaluation of effectiveness, and safety in intravenous puncture techniques, so we studied the topic of AV and SCV puncture to evaluate the efficacy and safety of 2 these intravenous puncture techniques.

Objectives

A study that compared the AV and SCV techniques for PPI

2. Methods

Research design

A cross-sectional, descriptive, prospective study. Here is a summary of the study's findings in a different way: AV technique is safe and effective for PPI ? AV technique (group 1) may be safer than SCV technique (group 2), AV technique resulted in fewer complications than SCV technique at the Vietnam Heart Institute, Bach Mai Hospital from August 2022 to September 2023.

Vein puncture technique

There are three main veins used to create this acess: SCV (located below the collabone), CV (located in the uper arm), and AV (located in the armpit). The SCV is located below the collarbone and inside the chest cavity, Puncturing this vein can lead to complications like collapsed lung (pneumothorax) or bleeding in the chest (hemothorax). [1] The CV is located in the upper arm. To use this vein, the technician would need to cut open the skin to reach it. This is a les common approach because it requires more training and has a lower success rate. [2] The AV is located in the armpit. This vein can be reached with a needle without cutting any skin. This approach is becoming more common because it appears to be safe and more effective than the other two techniques. [1,3]

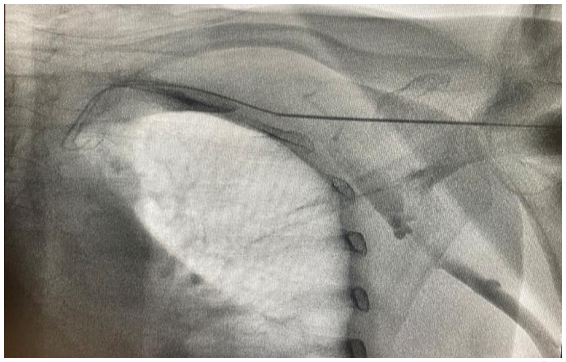

Figure 1: Axillary vein puncture. [4]

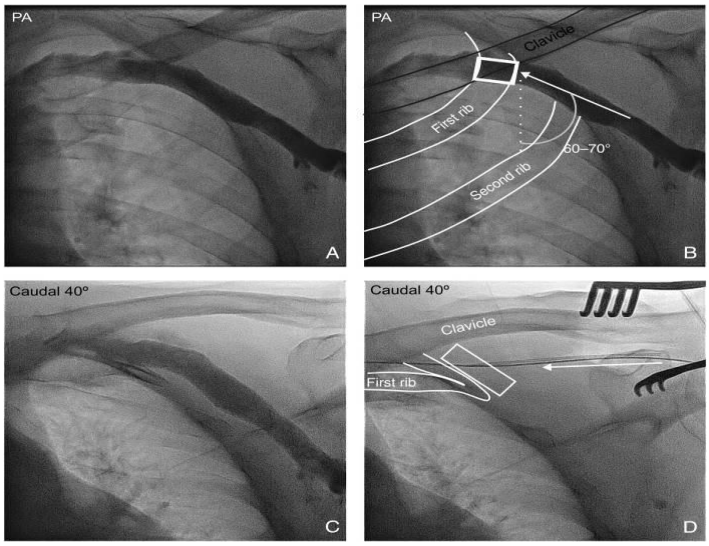

Figure 2: Caudal fluoroscopy to guide axillary vein access. [5]

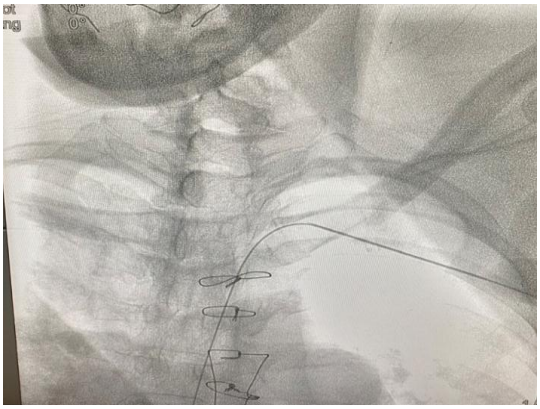

Figure 3: Subclavian vein puncture.[4]

Outcome measure

The study's primary outcome measure was successful insertion of the pacemaker leads. A successful insertion was defined as obtaining venous blood and inserting the guidewwire and sheath. One-time success was defined as a minor adjustment of the needle direction and puncture site without withdrawing the needle. Secondary outcome measures included the number of punctures, puncture time, X-ray exposure, procedure time, pacemaker parameters (including threshold, impedance, and P/R wave ampliture), complications, and adverse events during follow-up. Patients were followed up one month after the procedure.

Major complications: Complications
The table lists major complication that can occur following PPI. These complications can be related to placement of the pacemaker leads (wires), infection at the implantation site, sysmetic infection caused by the pacemaker device, a clollapsed lung puncture (pneumothorax), puncture of the heart (cardiac perforation), need for surgery to revise the pacemaker pocket due to pain, deep vein thrombosis, pulmonary artery embolism, hematoma, a psychological condition that causes a person to fiddle with or manipultate their pacemaker (Twiddler's syndrome), brachial plexus injury, stroke, myocardial infraction, death caused by the surgery.

Minor complications
The describes minor complications that can happen during PPI, these include: Arterial puncture of an artery without any bleeding, difficulty placing the pacemaker leads, pain after the device is implanted, swelling or inflammation around the implanted pacemaker, blood clot in a vein near the inplantation site (superficial vein thrombosis), mild brusing around the implantaion site, collapsed lung (pneumothorax) that doesn't require treatment with a chest tube, inflammation of the tissure around the heart (pericarditis) that doesn't require treatment.

Statistical analysis
For continuous data (like age or weight), a t-test is used if the data is normally distributed; If the data isn't normally distributed, a Mann-Whitney U-test is used. For proportions (like the percentage of people who experienced a complication), a chi-square test is used; If the data has small expected frequencies (less than 5), Fisher's exact test is used instead. In all these tests, a p-value less than 0.05 is considered statistically significant; This means there is a less than 5% chance that the observed difference between groups is due to random chance. The software used for this analysis is SPSS 20.0

3. Results

Clinical characteristics
Researchers enrolled 152 patients and assigned them to either the AV group or the SCV group. Neither group had any patients lost to follow-up, there were 247 successful vein punctures out of a total of 448 attempts (55.1% success rate), The table (Table 1) shows that the two groups had similar characteristics, including:

Table 1: Baseline characteristics

Patients characteristics	Axillary vein group	Subclavian vein group	p-value
	n = 75	n = 77	
Mean age	66.6 ± 15.2 [17-97]		
Age (60-69)	51 (68.0%)	60 (77.8%)	0.17
Age ≤ 59	24 (32.0%)	17 (22.1%)	
Gender	61 Male (40.1%), 91 Female(59.9%)		
Female	49(65.3%)	42(54.5%)	0.17
Male	26 (34.7%)	35 (45.5%)	
Body mass index (BMI)	62(82.7%)	65(84.4%)	0.94
Accompanying diseases	Axillary vein group	Subclavian vein group	p-value
Hypertension	34(45.3%)	36(46.8%)	0.87

Diabetes	13(17.3%)	11(14.3%)	0.61
Heart failure	12 (16.0)	16 (20.8%)	0.45
Chronic kidney disease	3(4.0%)	4 (5.2%)	
Chronic obstructive pulmonary disease (COPD)	1 (1.3%)	5 (6.5%)	0.21
Carotid artery disease (CAD)	18 (24.0%)	14 (18.2%)	0.38
History of heart surgery	5 (6.7%)	5 (6.5%)	0.97
Cancer	3 (4.0%)	5 (6.5%)	0.72
Upper limb vascular disease	1 (1.3%)	0 (0.0%)	
Type of pacemaker (two chambers)	62 (82.7%)	69 (90.8)	0.14

The results (table 1) found that the rates of these conditions were similar between the two groups.

The study investigated two techniques for implanting a pacemaker

A total of 151 patients were enrolled and divided into two groups: In one technique (75 patients), the doctor inserts the pacemaker lead through a vein in the armpit (AV). In the other technique (77 patients), the doctor inserts the pacemaker lead through a vein below the collabone (SCV). They found that both methods were successul in placing pacemekers in most people (around 90%), the overall success rate of PPI was similar between the two group (89.3% vs 93.5%) with $p > 0.05$. There were fewer complications in the group that had the pacemaker implanted through the AV, cases of failed AV puncture procedures (8 patients) were converted to SCV puncture technique (6 patients) and 2 patients were switched to right-sided device implantation; Meanwhile, in cases of failed SCV puncture (5 patients), 2 patients were switched to AV puncture and 3 patients were switched to right-sided device PPI.

The success rate on the first puncture attempt in the AV group was 58.7% and in the SCV group was 46.8%, with no statistically significant difference ($p> 0.05$). There was no difference in success rates between male and female patients ($p> 0.05$). The researchers tracked the number of attempts required to successfully place the pacemaker lead through the chosen vein; They found that the AV group required fewer attempts (2.7 ± 1.2) compared to the SCV group (3.2 ± 1.6), this difference was statistically significant ($p = 0.019$). While the procedure time for both groups was similar (53.4 ± 17.6 minutes for AV vs 55.0 ± 16.0 minutes for SCV), the overall time spent in the operating room (procedural time) was lower for the AV group (222.9 ± 149.8 seconds) compared to the SCV group (286.3 ± 268.0 seconds); However, this difference was not statistatically significant ($p = 0.081$). Importantly, the researchers did not observe any statistically significant differences in fluoroscopy time (time exposed to X-rays) between the two groups (426.2 ± 323.8 seconds for AV vs 478.5 ± 321.4 seconds for SCV group, with $p>0.05$).

Complications in the perioperative period and follow-ups

There were a total of 6 major complications occurring in the study (3.9%). Among them, 2 major complications occurred in the AV puncture group and 4 major complications occurred in the SCV puncture group, the difference was not statistically significant with $p = 0.681$.

There were 20 patients with minor complications in our study (13.2%). In our study, the minor complications included arterial puncture (11 cases) occurring in both study groups: the AV group (4 cases) and the SCV group (7 cases), pericarditis (1 case) occurred in the SV group, sheath kinking and difficulty in lead placement (3 cases) occurred in the SCV group. Prolonged site pain occurred in both study groups: the AV group (1 case) and the SCV group

(4 cases). The rate of minor complications occurring in the SCV puncture group (19,5%) is higher than in the AV puncture group (6,7%), with a statistically significant difference with p-value: 0,019 (< 0.05), OR: 3,39, 95% CI: 1,16-9,85.
The total number of complications in our study was 26 patients (17,1%). In the SCV puncture group, there were 19 patients with various complications, accounting for a rate of 24,7%. On the other hand, the AV puncture group had only 7 cases of complications, accounting for a rate of 9,3%. The difference was statistically significant with p=0,012 (< 0.05), OR: 3,18, 95% CI: 1,25-8,10 (Table 2).

Table 2: Complications in perioperative period and follow-ups

Major complications	Axillary vein group	Subclavian vein group	p-value
Pneumothorax	0	1	
Brachial plexus injury	1	1	
Hematoma	0	2	
Venous thrombosis	1	0	
Minor Complications			
Arterial puncture	4	7	
Pericarditis	0	1	
Sheath kinking and difficulty in lead placement	0	3	
Prolonged pain after device implantation	1	4	
Total	7	19	0,012

4. Discussions

The researchers wanted to find out if the AV technique was as effective and safe as the SCV technique. Overal, the table 1 suggest that the two groups of patients were well-matched for the study. The research found that the AV approach had a lower rate of complications and was more effective in the short term
Common vein access for CIED lead implantation was cephalic, subclavian, and AV. SCV puncture has a faster learning curve, and the success rate is generally high.[6] However, complications are relatively common due to its anatomic characteristics, including pneumothorax, hemopneumothorax, inadvertent subclavian artery puncture, brachial nerve plexus injury, subclavian crush syndrome, and electrode lead fracture.[1,3] The CV was proposed to be an alternate access. Large-scale retrospective study found that CV access was related to a lower rate of lead failure. However, it requires a vein incision, rendering the operation more complicated and time-consuming.[7] Moreover, the size of the AV is relatively small, thus it often suffers from a high failure rate, especially with multiple leads.[8,9] The number of implantations of ICDs and CRT-Ps/ CRT-Ds has increased in the past few years, and CV puncture may not be an optimal procedure.[10,11]
Anatomically, the AV terminates at the lateral margin of the first rib and becomes the SCV. Its passage is outside the clavicle and far from the cupula, and the diameter is larger compared with the CV with little variation. Therefore, the AV puncture avoids nerve or pleura injury and subclavian crush syndrome, AV puncture was first reported by Nickalls RW in 1987.[12] Higano ST reported an approach based on anatomic landmark on body surface and radiograph, where the AV terminates and becomes the SCV with little variation.[13] A few other clinical studies also proposed a maneuver based on this landmark. Overall, AV

punctures guided by fluoroscopy landmark, contrast venography, or ultrasound have shown high success rate and low complication rate.[1]

Observing the table above, the success rate in our study is comparable to studies worldwide. Although it is lower than the studies by Sharma G et al (2012),[3] Liu P et al. (2016),[1] Chan NY et al (2016),[14] and Jiménez-Díaz J et al (2019),[15] this could be explained by the fact that all three of these studies used the AV puncture technique under fluoroscopy with conversion to the use of a venous sheath if initial attempts failed. This approach increased the success rate of the procedure. In contrast, our study utilized all three techniques of venous puncture concurrently: landmark-based venous puncture, AV puncture under fluoroscopy, and venous puncture guided by static imaging. However, in our study, patients who failed with AV and SCV puncture techniques were transferred to alternative techniques or the contralateral side, ultimately achieving successful vascular access for device PPI.

The time for venous puncture in our study was defined as the duration from the start of needle penetration through the skin until the guidewire entered the superior vena cava. In our study, the venous puncture time for the AV puncture technique (222.9 ± 149.8 seconds) was lower than that for the SCV puncture technique (286.3 ± 268.0 seconds). However, this difference was not statistically significant with a p-value of 0.081. Based on the results above, the AV puncture technique did not significantly prolong the venous puncture time compared to the SCV puncture technique.

According to the results, the general complication rate in studies in Vietnam and worldwide ranges from 10-18%, while major complications range from 3,9-6,0%. Our study showed a high general complication rate (17,1%), but a low rate of major complications (3,9%). In contrast, other studies by Udo EO et al.[16], and Liu P et al.[1] demonstrated higher rates of major complications while having lower rates of general complications compared to our study. Several factors may explain this difference.

Our study's research design identified minor complications that encompassed a variety of different complication scenarios, such as arterial puncture, pericardial effusion, sheath dissection, or difficulty in lead placement, which were not addressed in other studies.

5. Conclusions

A total of 152 patients undergoing PPI were included in the study. Patients were assigned to either the AV group (75 patients) or the SCV group (77 patients). The overall success rate was similar between the two groups ($p > 0.05$). The number of vein puncture was lower in the AV group ($p < 0.05$). The rate of all types of complications was lower in the AV group than in the SCV group ($p < 0.05$). There was no significan difference between the two groups in terms of venous access time, X-ray exposure time, or procedure time ($p>0.05$). The AV technique is a safe and effective altermative to the SCV technique for PPI.

Limitations

The research is a nonrandomized, Single-center study that looked at early complications only. Absence of long-term follow-up is one of the limitations of the study. A randomized study with a long-term follow-up is required. The choice of technique was left to the discretion of the operator, and therefore bias cannot be ruled out.

Abbreviations

PPI, permanent pacemaker implantation; CI, Confidence Interval; OR: Odd ratio; SPSS, Statistical Product and Services Solution; AV: Axillary vein; CV: Cephalic vein; SCV: Subclavian vein; BMI: Body mass index; COPD: Chronic obstructive pulmonary disease; CAD: Carotid artery disease (CAD).

Date Sharing Statement
The original contributions presented in this study are included in the article, Further inquiries can be directed to the corresponding author.

Ethical Statement
The authors confirmed that the guidelines in the Declaration of Helsinki were followed. Informed consent was obtained from each participant. This study was conducted after the research outline and protocol is approved by the Scientific Council of Hanoi Medical University, and was implemented with the permission of the Vietnam National Heart Institute - Bach Mai Hospital.

Acknowledgment
The authors are grateful to the Hanoi Medical University, and was implemented with the permission of the Vietnam National Heart Institute - Bach Mai Hospital for their approved and their assistance in date collect.

Author Contributions
All authors contributed to data analysis, revised the manuscripts, drafting or revised the article during the review process, agreed on the journal to which the manuscript will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Funding
There is no funding to report

Disclosure
The authors report no conflicts of interest in this work

ORCID iDs
Tran Song Giang: https://orcid.org/0009-0002-5633-482X
Chu Dung Si: https://orcid.org/0000-0001-7723-5893

6. Rererences

1. Liu P, Zhou YF, Yang P, et al. Optimized Axillary Vein Technique versus Subclavian Vein Technique in Cardiovascular Implantable Electronic Device Implantation: A Randomized Controlled Study. Chin Med J (Engl). 2016; 129 (22): 2647-2651.
2. Atti V, Turagam MK, Garg J, et al. Subclavian and Axillary Vein Access Versus Cephalic Vein Cutdown for Cardiac Implantable Electronic Device Implantation: A Meta-Analysis. JACC Clin Electrophysiol. 2020; 6 (6): 661-671.
3. Sharma G, Senguttuvan NB, Thachil A, et al. A comparison of lead placement through the subclavian vein technique with fluoroscopy-guided axillary vein technique for permanent pacemaker insertion. Can J Cardiol. 2012; 28 (5): 542-546.
4. Squara F, Tomi J, Scarlatti D, Theodore G, Moceri P, Ferrari E. Self-taught axillary vein access without venography for pacemaker implantation: prospective randomized comparison with the cephalic vein access. Europace. 2017; 19 (12): 2001-2006.
5. Patel HC, Hayward C, Nanayakkara S, Broughton A, Mariani JA. Caudal fluoroscopy to guide venous access for pacemaker device implantation: should this now be standard practice? Heart Asia. 2017; 9 (1): 68-69.

6. Luo GH, Li WJ, Zhong SZ, Li ZH, Fang J. Modification of the right subclavian vein catheterization and its anatomic basis and techniques. Chin Med J (Engl). 2005; 118 (8): 645-653.
7. Nocito A, Wildi S, Rufibach K, Clavien PA, Weber M. Randomized clinical trial comparing venous cutdown with the Seldinger technique for placement of implantable venous access ports. The British Journal of Surgery. 2009; 96 (10): 1129-1134.
8. Knight BP, Curlett K, Oral H, Pelosi F, Morady F, Strickberger SA. Clinical predictors of successful cephalic vein access for implantation of endocardial leads. Journal of interventional cardiac electrophysiology: an international journal of arrhythmias and pacing. 2002;7(2):177-180.
9. Calkins H, Ramza BM, Brinker J, et al. Prospective randomized comparison of the safety and effectiveness of placement of endocardial pacemaker and defibrillator leads using the extrathoracic subclavian vein guided by contrast venography versus the cephalic approach. Pacing and clinical electrophysiology: PACE. 2001; 24 (4 Pt 1): 456-464.
10. Starck CT, Caliskan E, Klein H, Steffel J, Schoenrath F, Falk V. Results of transvenous lead extraction of coronary sinus leads in patients with cardiac 4,703 resynchronization therapy. Chin Med J (Engl). 2013; 126 (24): 4703-4706.
11. Hua W, Ding LG, Fan XH, et al. Initial Experience with MultiPoint Pacing Cardiac Resynchronization Therapy in China. Chin Med J (Engl). 2016; 129 (10): 1241-1243.
12. Nickalls RW. A new percutaneous infraclavicular approach to the axillary vein. Anaesthesia. 1987; 42 (2): 151-154.
13. Higano ST, Hayes DL, Spittell PC. Facilitation of the subclavian-introducer technique with contrast venography. Pacing and clinical electrophysiology: PACE. 1990; 13 (5): 681-684.
14. Chan NY, Kwong NP, Cheong AP. Venous access and long-term pacemaker lead failure: comparing contrast-guided axillary vein puncture with subclavian puncture and cephalic cutdown. Europace. 2017; 19 (7): 1193-1197.
15. Jiménez-Díaz J, Higuera-Sobrino F, Piqueras-Flores J, Pérez-Díaz P, González-Marín MA. Fluoroscopy-guided axillary vein access vs cephalic vein access in pacemaker and defibrillator implantation: Randomized clinical trial of efficacy and safety. Journal of cardiovascular electrophysiology. 2019; 30 (9): 1588-1593.
16. Udo EO, Zuithoff NP, Van Hemel NM, et al. Incidence and predictors of short- and long-term complications in pacemaker therapy: the FOLLOWPACE study. Heart rhythm. 2012; 9 (5): 728-735.