Efficacy and safety of axillary vein puncture real-time guided by roadmap fluoroscopy in cardiac pacemaker implantation

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Abstract

Objective: Roadmap fluoroscopy has never previously been evaluated for axillary vein puncture in clinical practice. Our retrospective cohort study was performed to investigate the efficacy and safety of axillary vein puncture real-time guided by roadmap fluoroscopy in cardiac pacemaker implantation. **Methods and Results**: A total of 178 patients undergoing axillary vein puncture in permanent pacemaker implantation were included in the present cohort study during a 1-year period at our institution. All procedures were performed by the operators with previous experience in axillary approach. Primary endpoint was defined as axillary vein success rate. Secondary endpoints were venous access site change, time to obtain venous access, procedural time, and complication rate. For the primary outcomes, a higher success rate was observed in the roadmap group compared with the blind puncture group (95.2% vs 78.7%; P<0.001), as well as a lower rate of venous access site change (7.1% vs 35.1%; P <0.001) and shorter time to obtain venous access and procedural time, with lower complications (3.6 % vs 6.4 %; P<0.01). **Conclusion:** The roadmap fluoroscopy real-time guided axillary venous access is safer and has a better success rate and faster execution time compared with the blind axillary puncture in cardiac pacemaker implantation. However, further larger scale prospective randomized controlled trials are required to confirm the findings.

Introduction

Cardiac pacemaker implantation is the mainstay therapy for the patients with bradyarrhythmia as well as those at risk of sudden cardiac death and chronic heart failure. [1-3]Obtaining transvenous access may be achieved by various methods including a cephalic vein cutdown,[4] or using the modified Seldinger technique to access the axillary or subclavian vein. The venous access for endocardial lead placement of cardiac pacemaker is often achieved by blind puncture of the subclavian or axillary vein using anatomical landmarks. [5, 6] However, severe complications can occur in clinical practice, such as pneumothorax, hemothorax, arterial puncture, and brachial plexus injury. [7, 8]

To overcome the inherent limitations, we apply new roadmap fluoroscopy approach to guide the axillary vein puncture. Roadmap real-time guided puncture may overcome this issue, enabling an effective puncture to enhance visualization with a safer procedure. We report the retrospective cohort study during a 1-year period at our institution. To our knowledge, roadmap fluoroscopy has never previously been evaluated for use in cardiac pacemaker implantation. [9-11]

Methods

Subjects and data collection

In our preliminary study, the Judkins catheter was pulled back to the proximal portion of the axillary artery and contrast agent was simultaneously and manually injected through both the axillary artery and the ipsilateral peripheral vein after the transradial coronary angiography in 20 patients with coronary artery

disease. The radiological views of the axillary artery and vein as well as other anatomical structures were recorded to elevate the anatomical relationship at 35^{o} caudal orientation routinely.

The present retrospective study was carried out in Huashan Hospital, Fudan University. A total of 178 patients undergoing axillary vein puncture in cardiac pacemaker implantation were included in our cohort study from July 2020 to June 2021. Eligible patients were all those with an indication of permanent pacemaker implantation including single-chamber and dual-chamber pacemaker. The cardiac pacemaker implantation was approved by the ethics review board of Huashan Hospital, and written informed consent was obtained from all patients in our observational study.

The efficacy and safety of the roadmap real-time guidied puncture strategy was assessed in the consecutive 84 patients and was compared with the standard blind puncture approach in 94 patients preceding pacemaker implantation. Implantation of all cardiac pacemakers was performed in the catheter laboratory by the electrophysiologists with more than 5 years of experience. Anticoagulated patients with low thromboembolic risk were operated after suspension of anticoagulant treatment to minimize bleeding risk. All axillary vein punctures were performed via a right-sided approach under local anesthesia. Antibiotic prophylaxis was administered immediately before the procedure routinely.

Description of vein access techniques

We describe our preferred method of obtaining axillary venous access which is roadmap real-time guidied strategy to allow visualization for improved efficacy and safety. After local anesthesia of the skin and subcutaneous tissue, an incision is made parallel to the groove and a pocket is made medially at the level of the fascial plane. The axillary vein is the continuation of the brachial vein, originating at the lower margin of the teres major muscle and terminating at the lateral margin of the first rib. Roadmap technology characteristics that make the axillary vein puncture easily to enhance visualization with a safer procedure (Figure 1). Roadmap of right axillary vein was used to determine the optimum puncture site and access direction. In the control group, blind axillary vein puncture was performed at the operator's direction.

As shown in Figure 2, the target region is outlined with a black box at 35^{o} caudal orientation. To obtain the roadmap real-time guided axillary vein access, ipsilateral contrast venography was performed. The puncture needle enters axillary vein and the J-shaped guidewire has been placed through the axillary vein and advanced down the subclavian vein to inferior vena cava successfully. Our technique of axillary venous access is rapid, requires intravenous contrast, is reproducible and carries minimal risk. Access from a more parallel angle to the vessel may prove beneficial to increase the chance of axillary vein access. The 35o caudal view allows for optimal visualization of the lung border and first rib and therefore should reduce the chance for pneumothorax and hemothorax.

Follow-up protocol

After the cardiac pacemaker implantation and at 24 hours a chest X-ray was made to check lead position, detect pneumothorax, hemothorax, and other complications. Before discharge, all patients and permanent pacemakers were checked to confirm the relevant complications. This evaluation was repeated in the first, third, sixth and twelfth months after the discharge.

Outcome measures

The primary outcomes were the pacemaker implantation efficacy and safety in our study. The implantation efficacy was defined as the success of implant all the pacing leads indicated through the assigned venous access. The implantation safety was defined as the development of complications in or after cardiac pacemaker implantation. Complications were defined as development of pneumothorax, hemothorax, pericardial effusion, cardiac tamponade, venous thrombosis, lead dislodgement, device infection, and lead fracture. Bleeding considered when this required transfusion or pocket surgical revision. Thrombosis was considered when an echo-doppler confirmed it and when the anticoagulant therapy resolved a clinical diagnosis. Primary endpoint was defined as axillary vein success rate. Secondary endpoints were venous access site change, time to obtain venous access, procedural time, and complication rate.

Statistical analysis

Primary and secondary endpoints were analyzed following the intention-to-treat principle. Continuous variables with normal distribution were presented as mean value and standard deviation. Differences in categorical variables were assessed with Fisher's exact two-tailed test. Data analysis were performed with SPSS 12.0 and statistical significance was defined at an alpha level of 0.05.

Results

Between July 2020 and June 2021, a total of 178 patients undergoing axillary vein puncture in cardiac pacemaker implantation were enrolled, of whom 84 were assigned to the roadmap group and 94 to the blind puncture group. There were no significant differences in cardiovascular risk factors in the two groups. The mean ages in the road map group and the blind puncture group were 62.4 years and 64.6 years in the observational study, respectively (Table 1).

Procedure data and associated implantation complications are shown in Table 2. The success rate of venous access was superior in the roadmap group than in the blind puncture group (95.2% vs 78.7%, P<0 .001), as well as a lower rate of venous access site change (7.1% vs 35.1%; P <0.001). Time to access axillary vein was significantly shorter in the roadmap group (6.2 +- 2.2 min vs 11.4 +- 4.5 min, P <0 .001). Meanwhile, implantation duration was significantly shorter in the road map group (36.2 +- 8.2 min vs 43.4 +- 9.8 min, $P < 0.01$). Fluoroscopy duration was comparable in both study groups (5.2 +- 2.1 min vs 6.4 +- 2.8 min,P = 0.28).

In the blind puncture group, there were more implantation complications (n = 6; 6.4%) than in the roadmap group (n = 3; 3.6%), the differences achieved statistical significance ($P < 0.01$). During 12 month follow-up, there was pocket infection in one patient in the blind puncture group, lead dislodgement in one patient in the roadmap group. One patient developed venous thrombosis during follow-up in each group.

Discussion

Features of the roadmap real-time guided approach to the axillary vein access that may result in widespread acceptance are its simplicity and ease. Furthermore, specialized imaging tools are not required nor is a detailed understanding of precise anatomic relationships within this region. [12, 13] There is also an intuitive benefit of documenting patency of the venous system and presence of venous anomalies. The presence of contrast within the axillary vein provides a clear target to guide needle puncture thus avoiding the inherent reluctance of many physicians to perform a blind stick. An additional advantage of this approach is that needle entry can be performed anywhere along the course of the axillary vein. The primary highlight being the use of roadmap to guide venous entry rather than walking the needle laterally along the first rib until venous entry is achieved. [14, 15] Furthermore, the approach has the potential to eliminate the risk of pneumothorax and hemothorax.

The results of our retrospective cohort study demonstrate significant superiority of the roadmap real-time guided axillary vein approach for cardiac lead implantation. The rationale for this study was based on previous literature data demonstrating high success rate of axillary vein puncture as the route for pacemaker lead insertion, mostly from observational studies. [16-18] The higher axillary success rate guided by road map fluoroscopy was confirmed in our present observational study. Roadmap imaging also allows the possibility of evaluating vein patency before pocket incision, which is especially useful in special patients who previously had undergone thoracic surgery or radiotherapy.

With regard to complication rate, the roadmap real-time guided axillary approach proved to be safer compared with blind axillary vein puncture. Compared to data previously reported in the literature, the incidence of axillary puncture complications in our study was similar to that previously reported. [19-21] The complications occurred in some elderly, malnourished patients. The lower incidence of complications can be explained by our preferred method of obtaining axillary venous access which is roadmap guiding strategy to allow real-time visualization.

Our shorter time to axillary venous access in the roadmap application reinforces the findings of previous study which demonstrated in nonrandomized fashion a shorter time to position the leads in the superior vena cava using the ultrasound -guided axillary approach.[22, 23] From a clinical point of view, longer procedure duration has been associated with increased infection risk, indicating that shorter duration interventions and lower incidence of complications, in addition to enabling quicker operating room turnover, may lead to better infective outcomes.

For the first time we reported roadmap fluoroscopy using for the axillary vein visualized as it approaches the first rib and allows one to clearly see the anterior outline of the lungs at 35o caudal orientation. The puncture needle enters axillary vein guided by roadmap fluoroscopy and guidewire has been placed through the axillary vein and advanced down the subclavian vein to inferior vena cava successfully. By reviewing the literature, we find this to be a novel technique, by means of which we succeed in overcoming the above-mentioned long-standing problem. [24-26] As a newly introduced solution for old challenge, we suggest using roadmap fluoroscopy guided puncture for cardiac pacemaker implantation in clinical practice.

The main limitation of our retrospective cohort study is the lack of a randomized design that makes our findings hypothesis generating only, some caution is needed in the interpretation of the results. In addition, the short follow-up period of this study was not sufficient to allow evaluation of long-term lead-related complications. Moreover, well-designed study with larger sample size and longer follow-up should be conducted to confirm the final results.

In conclusion, roadmap fluoroscopy presented above may prove to be safer and better success in axillary vein puncture for cardiac pacemaker implantation. Our outcomes indicate that roadmap real-time guided puncture was superior to blind puncture in terms of success rate, time to venous access, and procedural time, with lower complication rate. The results of the study would have to encourage electrophysiologists to learn the roadmap guided axillary vein access technique. However, further larger scale randomized controlled trials are required to verify the present findings.

Acknowledgements

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Data access statement

All the data supporting our findings is contained within the manuscript.

Ethics approval and consent to participate

We identified the patient during routine clinical practice and consented to the interventions after elaborate information. The cardiac pacemaker implantation was approved by the ethics review board of Huashan Hospital, and written informed consent was obtained from all patients in our observational study.

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Table 1 Demographic characteristics of patients in pacemaker implantation

	Roadmap group (n=84)	Blind puncture group (n=94)
Age (y)	62.4±7.2	64.6±7.6
Sex (f/m)	40/44	45/49
Hypertention (+/-)	46/38	52/42
Diabetes mellitus (+/-)	22/62	24/70
Coronary artery disease (+/-)	32/52	36/58
Heart failure (+/-)	12/72	14/80
Stroke (+/-)	9/75	12/82
CKD (+/-)	20/64	24/70
COPD (+/-)	14/70	17/77
Obesity (+/-)	22/62	26/68
Smoking (+/-)	20/64	25/69
Hypercholesterolemia (+/-)	24/60	28/66
NT-ProBNP (pg/ml)	676±42	648±38
eGFR (ml/min/1.73m^2)	81.21±7.44	82.08±8.52
LVEF (%)	52.86±3.92	53.50±4.12
Pacemaker indication		
Atrioventricular block	54	58
Sinus node disease	30	36
Type of paccemaker		
Single-chamber	28	32
Dual-chamber	56	62

COPD, chronic obstructive pulmonary disease; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; LVEF, left ventricular ejection fraction; NT-ProBNP, amino-terminal pro-brain natriuretic peptide

Table 2 Outcomes and complications of patients in pacemaker implantation

	Roadmap group (n=84)	Blind puncture group (n=94)
Axillary vein success rate (%)	95.2	78.7
Venous access site change (%)	7.1	35.1
Time to venous access (min)	6.2±2.2	11.4±4.5
Procedural time (min)	36.2±8.2	43.4±9.8
Fluoroscopy time (min)	5.2±2.1	6.4±2.8
Complication rate (%)	3.6	6.4
Pocket hamotoma	1	1

	Roadmap group (n=84)	Blind puncture group (n=94)
Pneumothorax	0	2
Hemothorax	0	1
Venous thrombosis	1	1
Lead dislodgement	1	0
Cardiac tamponade	0	0
Device infection	0	1
Lead fracture	0	0

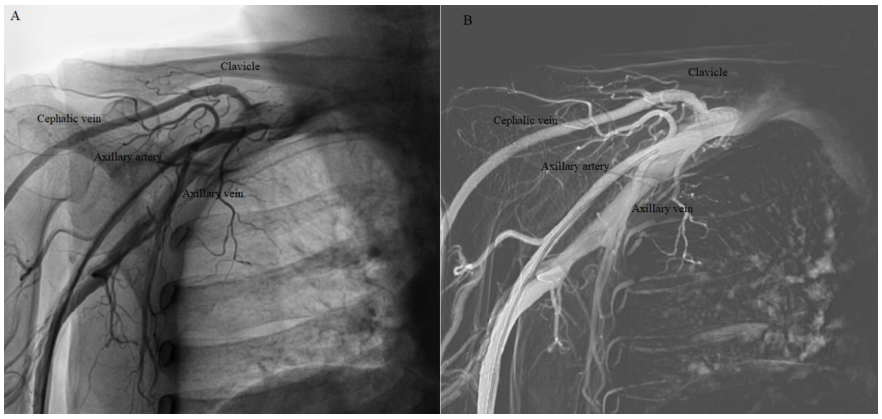

Figure 1 Fluoroscopy showing the anatomical relationship between the axillary artery and axillary vein visualized at 35º caudal orientation. (A) Angiography shows the anatomy of axillary vein and axillary artery. (B) Roadmap fluoroscopy shows the anatomy of axillary vein and axillary artery.

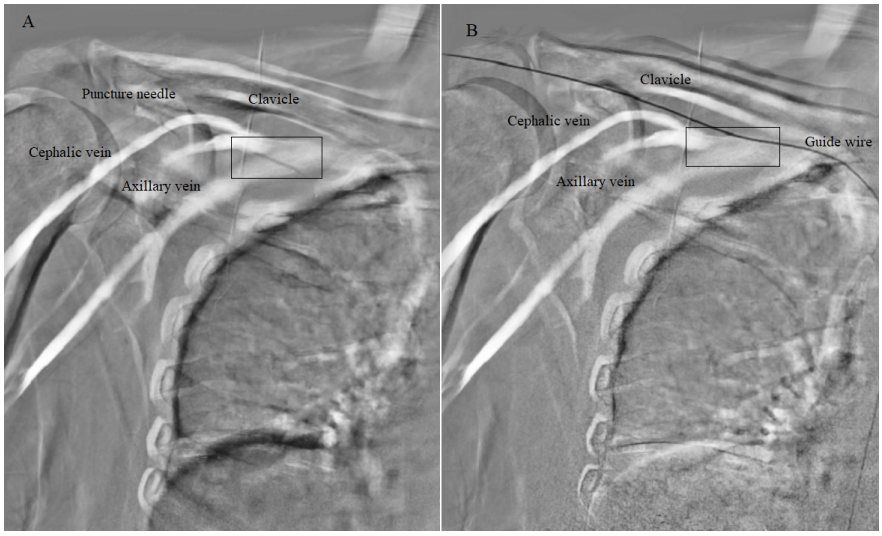

Figure 2 Axillary vein puncture guided by roadmap fluoroscopy in pacemaker implantation. The target region is outlined with a black box at 35º caudal orientation. (A) The grey line demonstrates the location of puncture needle to entry axillary vein guided by roadmap fluoroscopy. (B) The J-shaped guidewire has been placed through the axillary vein and advanced down the subclavian vein to inferior vena cava successfully.