Journal of Cardiovascular Diseases & Diagnosis

Bun et al., J Cardiovasc Dis Diagn 2019, 7:5

Research Open Access

Ultrasound-Guided Axillary Vein Puncture Feasibility for Complex Cardiac Devices Implantation

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Received: September 16, 2019; **Accepted:** September 21, 2019; **Published:** September 27, 2019

Abstract

Background: The axillary route use for cardiac devices implantation has recently expanded either with fluoroscopy or ultrasounds guidance. Few studies included defibrillators (ICD), cardiac resynchronization therapy (CRT) and upgrade procedures for ultrasound-guided axillary vein puncture (UGVP).

Aim: To assess the feasibility/safety of UGVP for complex cardiac devices implantation including CRT/ICD.

Methods: Consecutive patients eligible for a pacemaker or ICD implantation were included. All procedures were performed by three operators (one experienced and two fellows) in three different centers. Guidewires insertion time (from local anesthesia injection), and complications were systematically studied. A group of patients implanted with alternative routes (cephalic or subclavian) was used for comparison.

Results: In 176 consecutive patients in whom UGVP was used, a total of 68 complex procedures, including 42 ICD, 48 CRT and 16 upgrade procedures, were analyzed (74 ± 8 y, male 61%) with 138 leads implanted. A majority (83%) were under anti-thrombotic therapy. UGVP was successful in 96.8%. Mean insertion time for a mean number of 1.78 guidewires per patient was 4.4 ± 4.4 min. Guidewires insertion time reached its plateau after 10 patients. One pocket hematoma (1.4%) was drained during a mean follow-up of 12 ± 5 months. The control group included 28 patients (12 subclavian, 16 cephalic; 15 ICD, 18 CRT, 4 upgrade procedures), with a mean insertion time of 10 ± 8 min, for 1.95 guidewires per patient ($p<0.0005$).

Conclusion: UGVP is feasible and safe even for complex device implantations including CRT/ICD and upgrade procedures.

Keywords: Cardiac devices implantation; Vascular complications; Ultrasound guidance; Antithrombotic therapy

Abbreviations: ATT: Antithrombotic Therapy; CRT: Cardiac Resynchronization Therapy; ICD: Implantable Cardiac Defibrillator; INR: International Normalized Ratio; SVC: Superior Vena Cava; UGVP: Ultrasound-Guided Axillary Vein Puncture; US: Ultrasounds; VKA: Vitamin K Antagonist

Introduction

Several anatomical access points and methods to gain central venous access have been described. The axillary, cephalic, and subclavian veins, as well as the internal and external jugular veins, have all been used to insert pacemaker or defibrillator leads.

The axillary vein has become an emerging technique for the placement of pacing and defibrillation leads for several reasons. Unlike the cephalic vein, the main advantage of the axillary vein is that it is almost always large enough to accommodate multiple pacing leads. When compared to the subclavian vein, the properly accessed axillary vein affords a less angulated course. This potentially decreases mechanical stress (subclavian crushing syndrome) on the implanted leads or catheters, hence resulting in a lower incidence of mechanical lead failure or vein occlusion [1,2]. Techniques for accessing the axillary system with the use of fluoroscopic (either with or without venography) or ultrasounds (US) imaging have also been used [3,4].

The landmark (fluoroscopy) approach is associated with a potential risk of arterial puncture, pneumothorax or failed access, but also a higher exposure to radiations, in comparison with US guidance [5]. It is to note that cardiac resynchronization therapy (CRT) with triple leads placement by ultrasound-guided venous puncture (UGVP), and upgrade procedures (i.e., in the presence of preexisting leads) have not been described [4,6]. We aimed to assess the feasibility and safety of UGVP for complex cardiac devices implantations, including CRT/ICD and upgrade procedures.

Methods

Patients selection

All consecutive patients eligible for complex cardiac devices implantation (i.e., defibrillators, CRT or upgrading) in whom an UGVP was performed (group A), at our center (between September 2016 to September 2018 were included in this study. A control group of patients undergoing complex implantations procedures (group B) using other conventional techniques (cephalic cut-down or subclavian puncture) was used for comparison. All the patients gave their written consent for the procedure.

Ultrasound-guided venous puncture

To access the vein with sonography, the patient was placed in the supine position, without Trendelenburg, and the patient was prepared in the usual sterile manner. A surface vascular US probe was inserted into a sterile plastic sleeve and used to image the axillary vasculature. Real-time US imaging of the spatial relationship of the artery and vein, and of the course of the access needle visually guided the venous puncture. A local anesthesia by lidocaine hydrochloride 2%, under US visualization was made along the course of the puncture needle.

Using an out-of-plane technique, the vein was centered in the middle of the screen with the probe held with the left hand perpendicular to the skin (Figures 1 and 2). An 18-gauge, 7 cm length Cook bevel-tipped needle was introduced and advanced with the right hand below the US probe towards its center while watching for tissue movement on the US screen and maintaining negative pressure on the plunger. Once the needle is seen to enter the vein and blood flashes into the syringe, the syringe was removed, and a guidewire was placed into the lumen. From this point, a sheath and dilator may be placed in the usual fashion.

Puncture time was defined as time between US visualization of the axillary vein to the insertion of the guidewire in the superior vena cava. No time limit was set. In case of failure of UGVP, the cephalic cut-down technique was used as a second option, and at last intention a puncture of the subclavian vein.

All procedures were performed by three operators, (all experienced with UGVP for femoral access) [7] one experienced operator (seven years after having completed his fellowship), and two fellows. A learning curve defined as UGVP time evolution over time was established. Procedure time, but also complications were systematically studied in all groups: hematoma, pneumothorax, hemothorax.

ATT (Aspirin, Clopidogrel, Rivaroxaban, Dabigatran, Apixaban, low weight molecular heparin and Vitamin K Antagonists [VKA]) were continued until and after the procedure. In VKA patients, International Normalized Ratio (INR) target was 2-3 the day of the procedure. The implantation was postponed if the INR was greater than 4.

In group B (cephalic and subclavian puncture), the same puncture time was measured between lidocaine infiltration to the presence of the guidewire in the SVC.

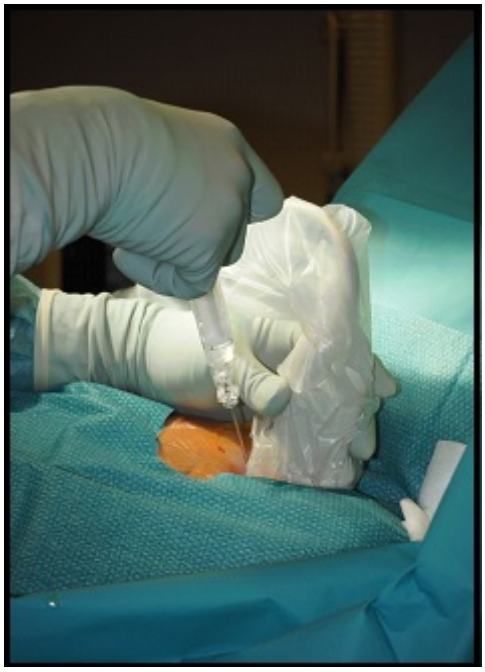

Figure 1: Position of the probe and the hand during ultrasound-guided puncture.

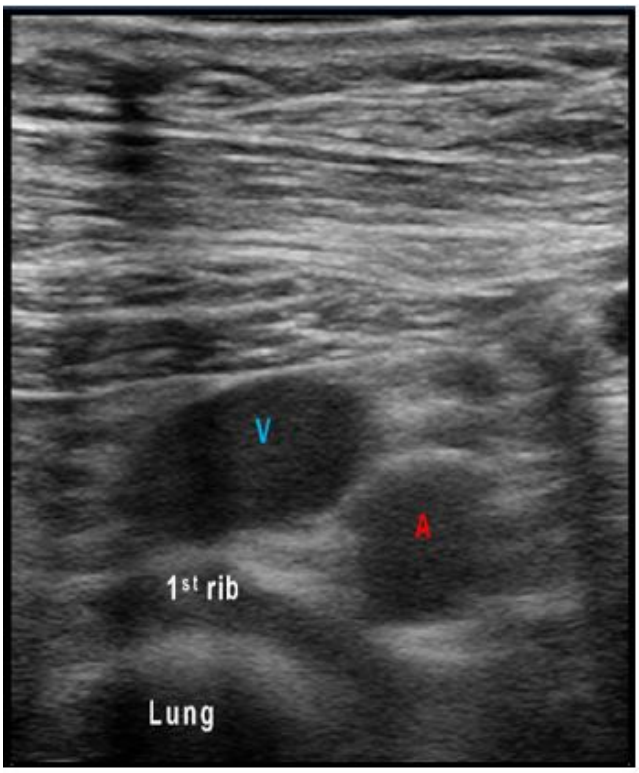

Figure 2: Ultrasound image of a left axillary vasculature.

Follow-up

All patients were monitored in the hospital at least one night after the implantation. After hospital discharge, patients were followed in our outpatient clinic at 1 month, then every 6 months. Axillary access points checks were performed at the end of the procedure, the following day after dressing removal and before discharge. Vascular access complications, including hematomas, were categorized as major if they resulted in prolongation of hospitalization, repeat hospitalization, blood transfusion, or surgical intervention; or minor (hematoma without hospital stay lengthening).

Statistical Analysis

The statistical analysis was made with Excel (San Diego, CA, USA). Categorical variables are described as number (percentage). Continuous variables are described as mean ± SD for variables with normal distributions or as median for variables not normally distributed.

Results

Patients population

Patients characteristics are summarized in Table 1. In 176 consecutive patients in whom UGVP was used, a total of 68 complex procedures were analyzed (74 ± 8 years, male 61%) with 138 leads implanted including 42 ICD, 48 CRT and 16 upgrade procedures (group A). A majority (83%) was under ATT. UGVP was successful in 96.8%. Among them, 30 patients (62% of the patients with CRT) underwent a triple insertion of new leads implanted in the axillary vein. The control group included 28 patients (12 subclavian, 16 cephalic; 15 ICD, 18 CRT, 4 upgrade procedures), with a mean insertion time of 10 ± 8 min, for 1.95 guidewires per patient ($p<0.0005$).

Baseline characteristics	**Procedural data**	
Total number of patients	176	
Complex procedures, n (%)	68 (38.6)	
Age (yr)	74 ± 8	
Male, n (%)	108 (61)	
Body Mass Index (kg/m^2), n (%)	< 25 : 62 (35)	
	> 25 : 114 (65)	
Type of devices, n (%)	Pacemakers: 134 (76)/Defibrillators: 42 (24)	
	One lead (VVI)	44 (25)
	Pacemaker	35
	Defibrillator	7
	VDD Defibrillator	2
	Two leads (DDD)	84 (47)
	Pacemaker: 77	77
	Defibrillator: 7	7
	CRT/CRT-D	48 (27)
	Pacemaker	22
	Upgrade	5
	Three leads	14
	Biventricular	3
	Defibrillator	26
	Upgrade	6
	Three leads	16
	Biventricular	4

Table 1: Baseline characteristics and procedural data.

Ultrasound-guided venous puncture performance

UGVP was successfully achieved in 164 patients out of 176 (93.2%), this rate increased to 96.8% after excluding anatomic variations: non-visualized vein or very small caliber (<2 mm maximal diameter). Axillary vein visualization was obtained in 96.8% of the cases (Table 2). The vein presented with a very small caliber in 3% of the cases.

In the study group (68 complex procedures), the mean puncture time was 4.4 ± 4.4 minutes. Mean puncture time per guidewire was 2.5 ± 2.7 minutes. The learning curve associated with this technique was estimated to 10 patients, corresponding to the beginning of puncture time plateau.

Ultrasound-guided axillary vein puncture performance	Procedural data
Mean global puncture time (min)	4.4 ± 4.4
Mean puncture time after 10 first patients	4.0 ± 2.8
Mean puncture time per guidewire (min)	2.5 ± 2.7
Mean number of guidewires inserted per patient	1.78 ± 0.7
Success rate, n (%)	
Global success	164/176 (93.2)
After excluding anatomic variations (Non-visualized veins or very small caliber)	164/170 (96.8)
Failure rate, n (%)	5/176 (3)
Side of implantation, n (%)	Left: 156 (88.6)
	Right: 20 (11.3)
Major vascular complications, n (%)	1 (0.5)
Minor vascular complications, n (%)	0 (0)
Mean procedure time (min)	60 ± 44.4
Mean fluoroscopy time (min)	4 ± 12

Table 2: Ultrasound-guided axillary vein puncture performance and procedural data (total population: n=176).

Complications

One pocket hematoma in group A (1.4%) was drained during a mean follow-up of 12 ± 5 months, and one pocket hematoma occurred in the control group, with hospital stay lengthening, but without need for drainage.

Discussion

The present study supports a wide and safe use of UGVP for cardiac devices implantation (pacemakers, ICDs, CRT and upgrade), especially in patients under ATT. In addition, the current trend is to implant under ATT, because the perioperative bridging of anticoagulation is associated with a higher risk of thromboembolic events [8,9]. A previous study reported a greater use of pressure dressings with UGVP [10]. This may suggest a higher risk of bleeding in comparison with the cephalic approach.

In our department, ATT is routinely maintained for devices implantation. Despite the presence of uninterrupted ATT, UGVP resulted in a very low incidence of bleeding complications. A recent European survey reported a significant incidence of bleeding complications after cardiac devices implantation under ATT, which could raise for example 13% of pocket hematomas in the subgroup of patients under dual-antiplatelet therapy [11]. In contrast with a previous study that reported the use of more pressure dressings, there was no difference in terms of bleeding complications using UGVP [10].

Axillary vein puncture in comparison with other approaches

A recent study reported a comparison of the three techniques for devices implantation (sub-clavicular, axillary and cephalic cutdown), with sub-clavicular vein puncture being more frequently associated with long-term lead failure (5.6%) [12]. The sub-clavicular puncture may also be associated with serious complications including pneumothorax, hemothorax or brachial plexus injury. In comparison to the subclavian puncture, the absence of pneumothorax can be explained by the extra-thoracic course of the puncture (Figure 3). On the other hand, the cephalic cutdown technique is safe, but has a significant failure rate even in experienced operators (78.2%) and is time-consuming [13]. In this study, the learning curve was demonstrated to be short with axillary vein puncture. These reasons may explain why the axillary vein access has become an emerging technique for cardiac devices implantation.

To the best of our knowledge, this is the first study to report the feasibility of routinely using UGVP for ICD (42 patients), CRT implantation (48 patients) and upgrade procedures (14 patients). They were excluded from the previous studies. Recent studies using the fluoroscopy-guided axillary vein puncture included some CRT devices, but this technique was not extended to the three leads, while it was possible in our study [14]. The "blind" (fluoroscopy-guided axillary vein puncture) often implies a collapse of the vein in patients in a fasting state, while US allow direct visualization and can be of a precious help by predicting inter-individual anatomical variations. Furthermore, the fluoroscopy-guided axillary vein puncture implies a higher exposure to radiations in comparison with UGVP for guidewires insertion (53.2 ± 12.5 sec versus zero fluoroscopy using UGVP) [4]. When venography is used, contrast injection may be a major concern in case of renal failure and/or allergy.

Prior experience with ultrasounds guidance

It has been well recognized that the use of real-time US guidance during central line insertion is one of the patient's safety practices with the greatest strength of supporting evidence [15-17]. A randomized controlled trial reported a higher first-attempt success rate and fewer needle passes with real-time UGVP compared with the anatomic landmark approach [18-20] (Table 3).

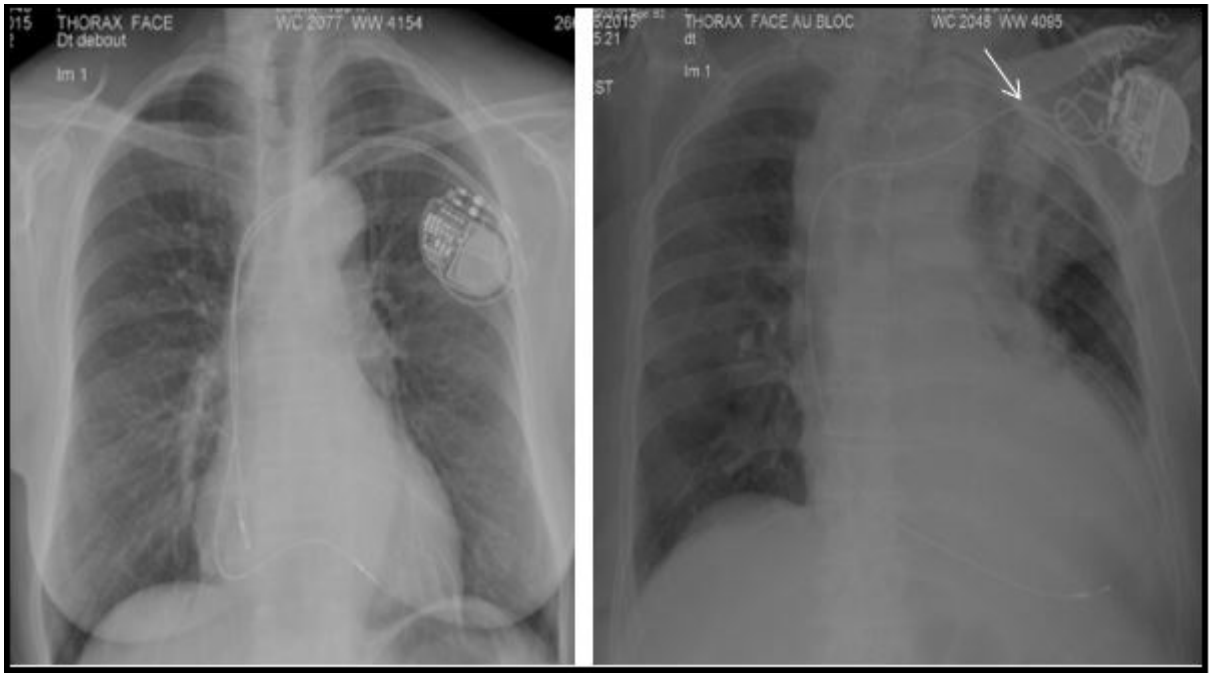

Figure 3: Fluoroscopic comparison of the course of the leads with ultrasound-guided axillary vein puncture (left image), and subclavian puncture (right image). The angulation and potential mechanical stress on the leads are significantly marked with the subclavian access (white arrow).

Variables	Nash A [6]	Orihashi K [18]	Jones DG [10]	Franco E [19]	Esmaiel A [20]	Our series
Number of patients (n)	70	18	60	50	403	176
Number of leads (n)	95	32	83	86	658	314
Number of guidewires, (n)	N/A†	N/A	N/A	85	N/A	314
Visibility of axillary vein (favourable anatomy for puncture)	N/A	100%	N/A	100%	99.75%	97%
Success of axillary puncture, n (%)	56 (80)	27	53 (88)	49 (98)	99.25%	164/170 (97)
Time considerations	31 s time for vein cannulation	82.1 s time for entry in vein	8 min time for lead placement	56 s time for entry in vein	6.9 min visualization of axillary vein - all GW* in SVC‡	4.4 min visualization of axillary vein - all GW* in SVC‡
Vascular complications, n (%)	None	None	Pocket hematomas 2 (3.3) Pressure dressings 26 (43)	Minor pocket hematoma 1 (2)	Pocket hematomas 2 (0.4)	Major pocket hematoma 1 (0.5)
Pneumothorax	0	0	1 (1.6)	0	0	0
Devices implanted, n (%)						
Pacemaker	45 (64.3)	4 (22.2)	37 (62)	38 (76)	403 (100)	134 (76)
VVI	25 (35.7)	14 (77.8)	23 (38)	16 (32)	255 (63)	44 (25)
DDD	0	N/A†	0	31 (62)	143 (37)	84 (47)

ICD	0	0	0	10 (22)		42 (24)
CRT-P, CRT-D				4 (6)		48 (27)
Learning curve, number of patients	After 35	N/A	After 15	After 5-7	N/A	After 10
Note: *GW: Guidewires; †N/A: Non-Available; ‡SVC: Superior Vena Cava.						

Table 3: Comparison to prior experience with ultrasound-guidance for axillary vein.

Nash et al. first described the use of two-dimensional US for pacemaker lead implantation in 70 patients in 1998 [6]. The authors found that the use of US for placement of pacemaker leads was a safe technique but needed a significant "learning curve" in that nearly all of the unsuccessful cases were in the first half of the series. No major complications were reported. Orihashi et al. described their experience in 18 patients and found a 90% success rate within two attempts using longitudinal imaging within the pacer pocket and a freehand technique [18]. The authors observed the ease of compressibility of the vein by the needle, and the utility of short jabbing motions to image the needle tip and facilitate venipuncture. Finally, Jones et al. demonstrated in 60 patients that the learning curve for US access was short, and that US guidance led to a reduction in lead placement time (8 min versus 12 min) and fluoroscopy time compared with the cephalic approach even after inclusion of training [10]. Nevertheless, there was a significant greater use of pressure dressings in comparison with the cephalic approach. Franco et al. were the first to report the use of a wireless US device for cardiac devices implantation [19].

The most recent experience was reported in a data collection from a single operator with a success rate of 99.25% in a large series of 403 patients (pacemakers only), and a 0.5% of complications [20]. In our study, a very low rate of complications was also observed with UGVP (0.5% as well). Our total time for access was 4.4 ± 4.4 min (measured in 176 patients) in comparison with 6.9 ± 2.41 min (measured in 59 patients), in the previous experience. The other major difference in the fact that the puncture was performed percutaneously, while it was performed within the incision in their study (pocket open).

Our series also reported a high number of ICD leads (42) implanted and upgrade (16) procedures using UGVP in comparison with previous studies, confirming the possibility to implant multiple leads with this technique (30 patients with triple lead insertion).

The additional cost associated with this technique has been approximated to 18.85€/procedure (cost of the sterile plastic sleeve). This cost may be added to the initial cost of a dedicated vascular probe, if not present in the catheter laboratory/operating room. In large series, this over-cost will probably be offset by the reduction of complications with this technique.

Conclusion and Limitations

This study is monocentric and not randomized. A previous study reported a significantly shorter lead insertion time with UGVP, in comparison with the cephalic technique (8 min versus 12 min), which is obvious when comparing a percutaneous puncture to a cut-down technique approach.10 In our study, guidewires insertion time using UGVAP (4.4 ± 4.4 min) was compared to a mixed control group of cephalic/subclavian approaches with a significantly longer insertion time. We believe that US guidance has plausible benefits in reducing the risk of lead crush, pneumothorax, and hematoma, and may be useful in patients with preexisting leads. With advances in US imaging technology, increasing emphasis on patient safety, and trainees who are more familiar with US-guided access, the use of US in device implantation is likely to expand.

The present study, as well as the recent literature, support safety and wider use of UGVP in patients undergoing cardiac devices implantation including ICD and CRT.

Conflicts of Interest

There are no conflicts of interest for the present study.

References

1. Roelke M, O'Nunain SS, Osswald S, Garan H, Harthorne JW, et al. (1995) Subclavian crush syndrome complicating transvenous cardioverter defibrillator systems. Pacing Clin Electrophysiol 18: 973-980.
2. Migliore F, Curnis A, Bertaglia E (2016) Axillary vein technique for pacemaker and implantable defibrillator leads implantation: A safe and alternative approach?. J Cardiovasc Med 17: 309-313.
3. Migliore F, Siciliano M, De Lazzari M, Ferretto S, Dalla Valle C, et al. (2015) Axillary vein puncture using fluoroscopic landmarks: A safe and effective approach for implantable cardioverter defibrillator leads. J Interv Card Electrophysiol 43: 263-267.
4. Mehrotra S, Rohit MK (2015) Prospective study to develop surface landmarks for blind axillary vein puncture for permanent pacemaker and defibrillator lead implantation and compare it to available contrast venography guided technique. Indian Heart J 67: 136-140.
5. Seto AH, Jolly A, Salcedo J (2013) Ultrasound-guided venous access for pacemakers and defibrillators. J Cardiovasc Electrophysiol 24: 370-374.
6. Nash A, Bureell CJ, Ring NJ, Marshall AJ (1998) Evaluation of an ultrasonically guided venepuncture technique for the placement of permanent pacing electrodes. Pacing Clin Electrophysiol 21: 452-455.
7. Errahmouni A, Bun SS, Latcu DG, Saoudi N (2014) Ultrasound-guided venous puncture in electrophysiological procedures: A safe method, rapidly learned. Pacing Clin Electrophysiol 37: 1023-1028.
8. Dutta S, Cohn SL, Pfeifer KJ, Slawski BA, Smetana GW, et al. (2016) Updates in perioperative medicine. J Hosp Med 11: 231-236.
9. Douketis JD, Spyropoulos AC, Kaatz S, Becker RC, Caprini JA, et al. (2015) Perioperative bridging anticoagulation in patients with atrial fibrillation. N Engl J Med 373: 823-833.
10. Jones DG, Stiles MK, Stewart JT, Armstrong GP (2006) Ultrasound-guided venous access for permanent pacemaker leads. Pacing Clin Electrophysiol 29: 852-857.
11. Deharo JC, Sciaraffia E, Leclercq C, Amara W, Doering M, et al. (2016) Perioperative management of antithrombotic treatment during implantation or revision of cardiac implantable electronic devices: The European Snapshot Survey on Procedural Routines for Electronic Device Implantation (ESS-PREDI). Europace 18: 778-784.
12. Chan NY, Kwong NP, Cheong AP (2016) Venous access and long-term pacemaker lead failure: Comparing contrast-guided axillary vein

puncture with subclavian puncture and cephalic cutdown. Europace 19: 1193-1197.

13. Squara F, Tomi J, Scarlatti D, Theodore G, Moceri P, et al. (2017) Self-taught axillary vein access without venography for pacemaker implantation: prospective randomized comparison with the cephalic vein access. Europace 19: 2001-2006.
14. Hettiarachchi EM, Arsene C, Fares S, Faraj A, Saulitis E, et al. (2014) Fluoroscopy-guided axillary vein puncture, a reliable method to prevent acute complications associated with pacemaker, defibrillator and cardiac resynchronization therapy leads insertion. J Cardiovasc Dis Diagn 2:136.
15. Rothschild JM (2001) Making health care safer: A critical analysis of patient safety practices. Evidence Report/Technology Assessment No. 43. Rockville, MD: Agency for healthcare research and quality 245-253.
16. Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ (2001) Making health care safer: A critical analysis of patient safety practices. Evid Rep Technol Assess (Summ) 43: 668.
17. Rupp SM, Apfelbaum JL, Blitt C, Caplan RA, Connis RT, et al. (2012) Practice guidelines for central venous access: A report by the American society of anesthesiologists task force on central venous access. Anesthesiology 116: 539-573.
18. Orihashi K, Imai K, Sato K, Hamamoto M, Okada K, et al. (2005) Extrathoracic subclavian venipuncture under ultrasound guidance. Circ J 69: 1111-1115.
19. Franco E, Munoz RD, Matia R, Hernandez-Madrid AN, Román CSAL, et al. (2016) Wireless ultrasound-guided axillary vein cannulation for the implantation of cardiovascular implantable electric devices. J Cardiovasc Electrophysiol 27: 482-487.
20. Esmaiel A, Hassan J, Blenkhorn FA, Mardigyan V (2016) The use of ultrasound to improve axillary vein access and minimize complications during pacemaker implantation. Pacing Clin Electrophysiol 39: 478-482.