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Ultrasound-guided axillary vein puncture for cardiac devices implantation in patients under antithrombotic therapy

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A B S T R A C T

Background: Ultrasound-guided axillary venous puncture (UGAVP) for cardiac devices implantation has been developed because of its rapidity, safety and potential long-term lead protection. Early work excluded defibrillators (ICD), cardiac resynchronization therapy (CRT) and upgrade procedures. Compared to the cephalic approach, in previous studies, there was a greater use of pressure dressings with this technique, suggesting a higher risk of bleeding.
Aims: To assess UGAVP in patients under antithrombotic therapy (ATT) undergoing cardiac devices implantation including CRT/ICD.
Methods: Prospectively, consecutive patients eligible for a pacemaker or ICD implantation were included. All procedures were performed by a single operator, experienced with UGAVP for femoral access, and fluoroscopy-guided axillary vein access. Guidewires insertion time (from lidocaïne administration), and complications were systematically studied.
Results: From 457 cardiac device implantations, 200 patients (77.8 ± 10 y, male 58%) 360 leads were implanted by UGAVP including 36 ICD, 54 CRT and 14 upgrade procedures. A majority (90%) was under ATT: Vitamin K Antagonist or Heparin (n = 58, 29%), direct oral anticoagulant (n = 46, 23%), dual antithrombotic therapy (n = 18, 9%) and single antiplatelet drug (n = 82, 41%). UGAVP was successful in 95.78%. Mean insertion time for 1.8 guidewires per patient was 4.68 ± 3.6 min. No complication (no hematoma) was observed during the follow-up (mean of 45 ± 10 months). Guidewires insertion time reached its plateau after 15 patients.
Conclusion: UGAVP is fast, feasible and safe for patients under ATT undergoing device implantation including CRT/ICD and upgrade procedures, with a short learning curve.

1. 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 (Fig. 1). 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]. Compelling evidence has implicated the infraclavicular musculotendinous complex in mechanical lead failure and occlusion of subclavian catheters [3,4].

Additionally, subclavian access portends the risk of inadvertently accessing the non-compressible subclavian artery and the potential for increased mechanical stress on the lead or indwelling catheter from crossing the subclavius muscle and the clavipectoral fascia. Finally, unlike the jugular system, the use of the axillary

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Abbreviations

ATT	Antithrombotic Therapy
CRT	Cardiac Resynchronization Therapy
ICD	Implantable Cardiac Defibrillator
INR	international normalized ratio
UGAVP	Ultrasound Guided Axillary Vein Puncture
US	Ultrasounds
VKA	Vitamin K Antagonist

system does not require tunneling of the leads over or under the clavicle.

Techniques for accessing the axillary system with the use of fluoroscopic (either with or without venography) or ultrasounds (US) imaging have also been used [5,6]. The landmark (fluoroscopy) approach is associated with a significant risk of arterial puncture, pneumothorax or failed access [7]. In addition, the current trend is to implant under antithrombotic therapy (ATT), because the perioperative bridging of anticoagulation is associated with a higher risk of thromboembolic events [9]. A previous study reported a greater use of pressure dressings with ultrasound-guided axillary vein puncture (UGAVP) [10]. This may suggest a higher risk of bleeding in comparison with the cephalic approach. It is to note that cardiac resynchronization therapy (CRT) with triple leads placement by UGAVP, and upgrade procedures (i.e. in the presence of preexisting leads) have not been described.[4,11]

We aimed to assess the incidence of complications using UGAVP in patients under ATT, including CRT and upgrade procedures. The learning curve of UGAVP use for routine practice will also be assessed in this study.

2. Methods

2.1. Patients selection

Prospectively, all consecutive patients eligible for cardiac devices implantation (i.e. pacemaker, defibrillator, CRT or upgrading) in whom an UGAVP was performed were included in this study, at two centers: Princess Grace Hospital in Monaco between September 2014 and September 2015, and Mohammed VI university hospital in Marrakech Morocco between October 2016 and April 2018. All the patients gave their written consent for the procedure.

2.2. 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 (Fig. 2).

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 (Figs. 2–3). 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.

No time limit was set. No internal jugular access was used. Puncture time was defined as time between US visualization of the axillary vein to the insertion of the guidewire in the superior vena cava.

All procedures were performed by a single operator, experienced with UGVP for femoral access, and fluoroscopy-guided axillary vein puncture [12].

A learning curve defined as UGAVP time evolution was established. Procedure time, but also complications were systematically studied: hematoma, pneumothorax, hemothorax.

2.3. Management of antithrombotic therapy

ATT (Aspirin, Clopidogrel, Ticagrelor, Dabigatran, Rivaroxaban, Apixaban, low weight molecular heparin and Vitamin K Antagonists [VKA]) were continued until and after the procedure. In VKA

Fig. 1. 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).

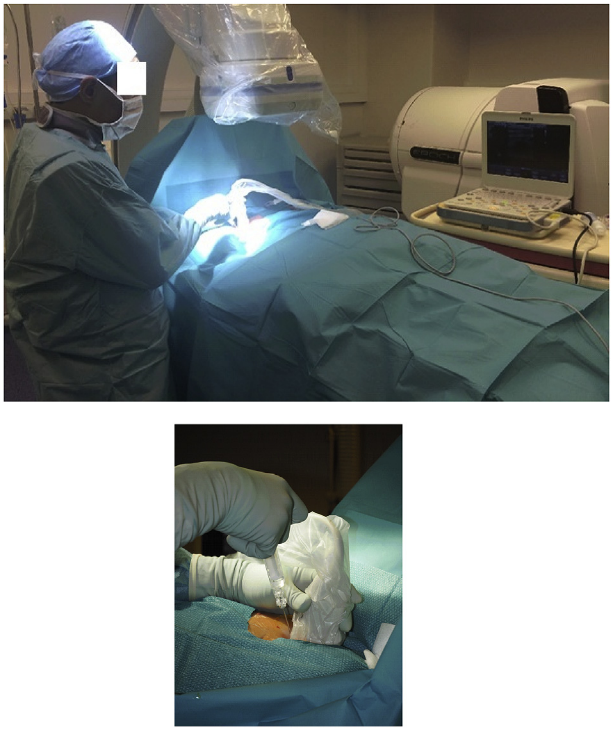

Fig. 2. Patient installation in the catheter laboratory with position of the probe during puncture.

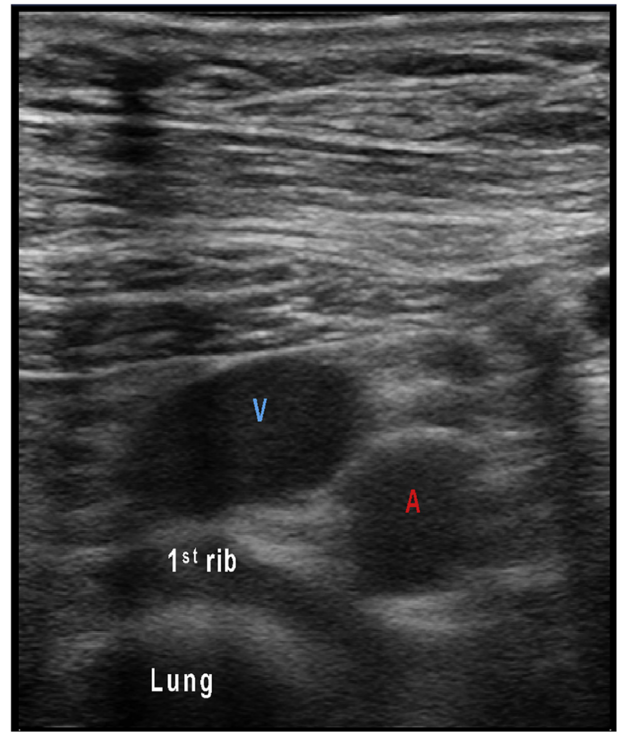

Fig. 3. Ultrasound image of a left axillary vasculature.

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.

2.4. Follow-up

All patients were monitored in the hospital at least two nights after the implantation. After hospital discharge, patients were followed in our outpatient clinic at 1, 6, and 12 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).

2.5. Statistical analysis

The statistical analysis was made with GraphPad Prism 5 (San Diego, CA, USA). Numerical variables are expressed as mean ± SD.

3. Results

3.1. Patients population

Patients characteristics are summarized in Table 1. 200/457 (43.76%) patients were included: 164 (82%) patients received a pacemaker and 36 patients (18%) received an ICD. The study population was composed by 54 (27%) patients with CRT. Among them, 26 patients (13%) underwent a triple insertion of new leads implanted in the axillary vein. 180 (90%) patients were under ATT (Table 1).

3.2. Ultrasound-guided venous puncture performance

UGAVP was successfully achieved in 182 patients (91%), this rate increased to 95.78% after excluding anatomic variations: non-visualized vein or very small caliber (<2 mm maximal diameter). Axillary vein visualization was obtained in 95% of the cases (Table 2). The vein presented with a very small caliber in 4% of the cases confirmed by angiography during subclavian approach.

Mean puncture time was 4.68 ± 3.64 (0.5–15) minutes. Mean puncture time per guidewire was 2.52 min. Mean puncture duration evolution over the time is illustrated in Fig. 4. The learning curve associated with this technique was estimated to 15 patients, corresponding to the beginning of puncture time plateau (Fig. 4).

3.3. Complications

There was only one minor complication (hematoma: it was the 5th case with failure of UGAVP and conversion to a blind subclavian vein puncture), after a mean follow-up of 45 ± 10 months. This patient (with prosthetic mitral valve) was excluded from analysis because the complication occurred with a subclavian puncture.

4. Discussion

The present study supports a wide and safe use of UGAVP for cardiac devices implantation (pacemakers, ICDs and CRT), especially in patients under ATT. UGAVP resulted in low incidence of complications. This is a fast and short-learning curve technique.

The “blind” or 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.

Table 1
Baseline characteristics and procedural data.

Number of patients	200
Age (y)	77.8 ± 10 [44–94]
Male, n (%)	116 (58)
Body Mass Index (kg/m²), n (%)	<25: 58 (29)
	>25: 148 (74)
Type of procedure (devices), n (%)	VVI: 44 (22)
	PM 36 (18)
	ICD 8 (4)
	CRT/CRT-D: 54 (27)
	CRT-D: 24 (12)
	Upgrade:6 (3)
	3C: 10 (5)
	BiV: 8 (4)
	CRT-P: 30 (15)
	Upgrade: 8 (4)
	3C: 16 (8)
	BiV: 6 (3)
	DDD: 100 (50)
	PM: 98 (49)
	ICD: 2 (1)
	VDD: 2 (1)
	ICD: 1 (1)
	ICD/PM:
	PM: 164 (82)
	ICD: 36 (18)
Side of implantation, n (%)	Left: 174 (87)
	Right: 26 (13)
Major vascular complications, n (%)	0 (0)
Minor vascular complications, n (%)	1 (0.5)
Procedure time (min)	75.13 ± 44.3 [25–205]
Fluoroscopy time (min)	8.46 ± 10.71 [0.5–50]
Antithrombotic therapy, n (%)	No ATT 20 (10)/ATT 180 (90)
	Anticoagulation 104 (52)
	VKA 48 (24)
	DOAC 46 (23)
	Apixaban 14 (7)
	Dabigatran 4 (2)
	Rivaroxaban 28 (14)
	LWMH 10 (5)
	Antiplatelet therapy 82 (41)
	Single APT 74 (37)
	Aspirin 62 (31)
	Clopidogrel 4 (2)
	Prasugrel 2 (1)
	Ticagrelor 2 (1)
	Dual APT 8 (4)
	Anticoagulant + APT 10 (5)
	Dual ATT 18 (9)

APT: antiplatelet therapy; ATT: antithrombotic therapy; BiV: biventricular; DOAC: direct oral anticoagulant; LWMH: low weight molecular heparin; PM: pacemaker; VKA: vitamin K antagonist; 3C: three chambers.

4.1. Prior experience with ultrasound guidance (Table 3)

Nash et *al* first described the use of two-dimensional US for pacemaker lead implantation in 70 patients in 1998 [8]. 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 [13]. 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. Nevertheless, there was a significant greater use of pressure dressings in comparison with the cephalic approach [7]. In comparison to the subclavian puncture, the absence of pneumothorax can be explained by the extra-thoracic course of the puncture (Fig. 1).

In the present study, no complications were observed with UGAVP. Our series also reported a higher number of leads implanted in comparison with previous studies (139 leads in total), confirming the possibility to implant multiple leads with this technique (including ICD leads), but also the potential benefit in case of upgrade procedures.

4.2. Anatomic variations and role of ultrasounds

In 2003, Galloway and Bodenham published their experience in using US guidance to define the axillary system [14]. The authors examined 50 patients with US. Their data showed that the Trendelenburg position only afforded a 1 mm (12–13 mm) increase in the diameter of the axillary vein and that the arm position did not cause significant differences in the vessel size or US visibility. In this study, it was observed that as the axillary vein coursed laterally, its diameter decreased (from 12.2 mm to 8.5 mm), its depth increased (from 19.5 mm to 32.2 mm), and its proximity to the axillary artery decreased (from 3.4 mm to 8.9 mm). Anatomic variations of the axillary vein and its tributaries were noted in 27.5% with duplicated axillary vein in 5% [15]. Additionally, the variations in branching pattern of the axillary artery were found in 62.5% [16]. Furthermore, the rib cage to vein distance is variable (0.2–2.2 cm) [11].

In cases the BMI > 25 kg/m², there was a significant difference in depth, and a trend to significant differences in diameter. However, age-specific differences in depth and diameter were not observed [17]. These anatomical variations are clinically significant and can increase the risk of vascular complications and pneumothorax with a blind technique. The use of US allows the operator to appreciate anatomic variations in arterial, venous and rib cage spatial relationships, as well as of the vessels themselves. Such imaging provides visualization of the access needle tip course and trajectory.

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 [18,19].

A randomized controlled trial reported a higher first-attempt success rate and fewer needle passes with real-time US guided puncture compared with the anatomic landmark approach [20].

Table 2
Ultrasound-guided axillary vein puncture performance.

Global puncture time (min)	4.68 ± 3.64 [0.5–15]
First puncture time (min)	3.03 ± 2.9 [0.5–15]
Puncture time after 15 first patients	4.46 ± 3.38 [0.5–15]
Puncture time per guidewire (min)	2.52 [0.5–15]
Mean number of guidewires inserted per patient	1.8 ± 0.6 [1–3]
Success rate, n (%)	
Global success	182/200 (91)
After excluding anatomic variations (Non-visualized veins or very small caliber)	182/190 (95.7)
Failure rate, n (%)	8/190 (4.2)

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

	Nash A [5] (1998)	Orihashi K [17] (2005)	Jones DG [8] (2006)	Franco E [22] (2016)	Liccardo M [23] (2018)	Our serie (2019)
Number of patients, n	70	18	60	50	116	200
Number of leads, n	95	32	83	86	304	360
Visibility of axillary vein (favorable anatomy for puncture)	N/A	100%	N/A	100%	98.2%	95%
Success of axillary puncture, n (%)	56 (80)	27	53 (88)	49 (98)	106/116 91%	182/190 (95.7)
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	5 min as time limit (mean time N/A)	4.68 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)	None	None
Pneumothorax	0	0	1 (1.6)	0	0	0
Devices implanted, n (%)						
PM				38 (76)	N/A	164 (82)
VVI	45 (64.3)	4 (22.2)	37 (62)	16 (32)		44 (22)
DDD	25 (35.7)	14 (77.8)	23 (38)	31 (62)		100 (50)
ICD	0	N/A	0	10 (22)		36 (18)
CRT-P, CRT-D	0	0	0	4 (6)		54 (27)
Learning curve, number of patients	after 35	N/A	after 15	After 5-7	Training phase:23	after 15

GW: guidewires; N/A: non-available; PM: pacemakers; SVC: superior vena cava.

4.3. No perioperative bridging for anticoagulation

In our department which is a reference center for atrial fibrillation ablation, ATT is routinely maintained, especially in patients with atrial fibrillation. This may explain that 90% of patients were on anti-thrombotic therapy which is unusually high compared to routine practice. This practice is supported by data from large series, demonstrating that periprocedural continuation of anticoagulation not only confers protection against thromboembolic events but is also safe, as evidenced by the overall low rates of bleeding complications [5,6]. In contrast with previous studies, despite the fact that implantations were performed with uninterrupted ATT, no major bleeding complications were observed, as opposed to previous studies [7].

4.4. UGAVP for ICD, CRT and upgrade procedures

In previous studies concerning UGVAP, ICD, CRT and upgrade procedures were excluded [4]. In contrast, UGVAP was successfully performed for ICD (18 patients), CRT implantation (24 patients) and upgrade procedures (8 patients) in our study. 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 series (11 patients) [21].

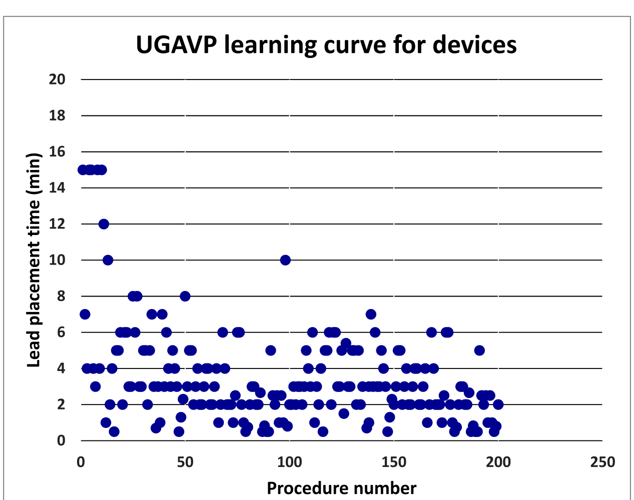

Fig. 4. Ultrasound-guided axillary vein puncture learning curve for devices.

4.5. Limitations

This study is bicentric and not randomized. The lack of a control group is a significant limitation of the study but this does not seem to diminish the quality of this study whose main objective was to verify the feasibility and safety of UGVAP in patients under ATT.

No vascular complication was reported in the present study with UGAVP, but the analysis involved a limited number of patients (n = 200). There have been no randomized trials between the US-guided technique and either the cephalic approach, traditional landmark axillary technique, or fluoroscopic and venogram-guided techniques for pacemaker or ICD placement. However, the limited published literature concerning axillary access with US, including lead placement, has demonstrated a consistent reduction in time to access, number of attempts, and complications. US guidance has plausible benefits in reducing the risk of lead crush, pneumothorax, and hematoma, and may have particular utility 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 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.

5. Conclusion

The present study, as well as the recent literature, support wide use of UGAVP in patients under antithrombotic therapy undergoing cardiac devices implantation including ICD and CRT. The short learning curve should encourage every cardiologist to adopt this technique.

Author's contribution section

Dr Mohammed El Jamili and Dr Sok-Sithikun Bun have equally participated in the preparation of this manuscript.

Mohammed El Jamili: Concept/Design; Data analysis/interpretation; Drafting article; Critical revision of article; Approval of article; Data collection.

Sok-Sithikun Bun: Concept/design; Data analysis/interpretation; Drafting article; Critical revision of article; Approval of article; Data collection.

Decebal Gabriel Latcu: Critical revision of article; Approval of article.

Tahar Delassi: Data collection.

Mustapha Elhattaoui: Critical revision of article; Approval of article.

Nadir Saoudi: Critical revision of article; Approval of article.

Declaration of competing interest

None.

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