Handheld ultrasound device-guided axillary vein access for pacemaker and defibrillator implantation

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Abstract

While ultrasound assistance for accessing the axillary vein has been established as a reliable method for cardiac pacemaker and cardioverter-defibrillator lead implantation, there is a lack of information regarding the utilization of portable handheld ultrasound devices within this context. We describe our experience with the systematic use of a pocket-sized handheld ultrasound device during the implantation of transvenous cardiovascular implantable electronic devices.

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Key words: ultrasound; handheld; axillary vein; pacemaker; Valsalva maneuver.

Contributions: BS, EB, contributions to the conception and design; GS, SV, acquisition, and analysis of data; BS, drafting the original manuscript. All authors have read and approved the final version of the manuscript to be submitted.

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Introduction

Although the implantation of transvenous Cardiovascular Implantable Electronic Devices (CIEDs) is commonly considered a safe procedure, the incidence of early and long-term pacemaker or Cardioverter-Defibrillator (ICD) lead-related complications remains not negligible, being reported as high as 3% in some series, mostly represented by pneumothorax, brachial plexus injury, and lead fracture.[1,2] Most such complications occur as venous access is gained through the direct puncture of the intrathoracic portion of the subclavian vein. Therefore, alternative techniques to access the central venous system throughout extrathoracic veins, such as the cephalic vein and the Axillary Vein (AV), have been increasingly adopted by the operators. However, while being safer than the subclavian vein puncture, the cephalic vein cutdown technique has a lower success rate, longer procedural time, and lower potential to accommodate the placement of multiple leads.[3,4] Over the last years, the AV puncture has been proven to be an alternative approach, both safer and more successful than subclavian vein and cephalic vein, respectively.[5,6] Several techniques for approaching AV during transvenous CIED implantation have been reported. Initially, the venous puncture was performed based on surface anatomic landmarks (blind approach) or guided by fluoroscopy landmarks or contrast venography. More recently, Ultrasound-Guided AV Access (USGAVA) is emerging as effective method for direct visualization of the target vein to be punctured, without the need of either nephrotoxic iodinated contrast medium or ionizing radiation exposure during fluoroscopy. However, despite the United States Agency for Healthcare Research and Quality strongly recommending ultrasound guidance for central venous access,[7] cephalic vein cutdown, and subclavian vein puncture are preferred techniques for CIED lead insertion.[8] Likely, the progressive miniaturization of ultrasound machines with device sizes comparable to current smartphones and the recently reported experiences of intraoperative use of wireless probes and handheld ultrasound devices may prompt widespread acceptance of USGAVA from operators.

Additionally, despite USGAVA having a fast-learning curve with a self-educated success rate of 98%,[9,10] the lack of a comprehensive document providing advice for preferred tools and standardizing the procedure may hinder using the method for CIED implantation. Differences are reported regarding the ultrasound section used to visualize the AV for guiding the puncture, whether it is longitudinal or transverse, and the method of maneuvering the probe for scanning the AV and driving the venipuncture, either transcutaneously (before skin incision) or inside the subcutaneous device pocket.

We recently reported our experience with the intraoperative use of a pocket-sized handheld ultrasound device for pacemaker and cardioverter-defibrillator implantation in 80 consecutive patients.[11] The success rate for venous access was 92.5% with no procedure-related complication. Furthermore, the high percentage

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Technique for ultrasound-guided axillary vein access with a portable handheld system

In our practice, we perform USGAVA using a handheld ultrasound device (GE Healthcare, Waukesha, WI, USA). The procedure involves a single operator, with the non-dominant hand holding the probe (high-frequency 3.3-8 MHz linear array transducer) and the dominant hand performing the venipuncture. Both the display unit and the probe are enclosed within a single sterile, transparent plastic sheath, and sterile gel is applied directly onto the probe inside the sheath (Figure 1). Due to its lightweight design (321 g) and compact dimensions (168×76×22 mm), the display unit can be effortlessly placed above the operating field, on the precordial area of the patient's chest. This positioning allows the operator to observe real-time images while conducting scans of the AV and the surrounding anatomical structures (Figure 2).

We ensure aseptic conditions by cleaning the infraclavicular area with a 2% chlorhexidine solution. Then, we apply a sterile disposable surgical whole-body drape with a preformed hole to isolate the operation area. Before starting the procedure, we administer local anesthesia (lidocaine hydrochloride 2%) along the planned needle trajectory, carefully avoiding the entry of micro air bubbles into the surrounding tissues to maintain ultrasound image quality. To prepare patients for the procedure, we routinely administer intravenous fluids to increase vein diameter and prevent collapse. The saline infusion begins when the patient is being transferred to the operating room. Furthermore, during ultrasound scanning, we infuse saline wide open through a peripheral vein of the ipsilateral arm to device implantation, and patients are shifted from supine to a Trendelenburg position, tilting the operating table head-down by 5-15°, depending on either AV diameter or patient tolerance. The AV is easily identifiable and distinguishable from the adjacent axillary artery based on specific characteristics such as its superficial position, compressibility under gentle pressure from the probe, lack of pulsation, dynamic inspiratory collapse, visualization of the typical angled entry of the cephalic vein, and the turbulent flow produced by the saline infusion wide open. The puncture is performed freehand, without the use of needle guides, before making a skin incision. This approach is preferred to prevent complexities related to maneuvering the probe inside the pocket and to avoid interference with the image quality due to micro air bubbles that may enter the tissues. While advancing an 18-gauge needle, the ultrasound transducer is tilted to visualize the AV in the longitudinal axis. The longitudinal section of the vessel enables clear visualization of the entire profile of the needle shaft traversing tissues toward the target vessel. Conversely, in the transverse section of the AV (*i.e.*, short axis view), the needle shaft is out of the plane, and the needle tip is visible as a highly echogenic spot with neighboring artifacts caused by ultrasound beam scattering, poorly discernible within the surrounding body tissue. Then, the needle is kept aligned to the centerline marker of the probe and in-plane with the ultrasound beam to visualize the needle tip until it tentatively enters the vessel wall. Once the needle tip-induced vessel indent is confirmed, the needle is advanced with short jabs until it enters the lumen, as confirmed by aspiration of venous blood. In the first attempt, we advance the needle tip toward the portion of the vein running above the body of the second rib (Figure 3). This approach prevents puncturing the lung in case the needle accidentally passes through the posterior wall of the vein. Noteworthy, the limit of such a "second rib approach" is that firm structures (*e.g.*, rib cage, pectoralis muscles) surround the AV in this area, thus hindering its expansion despite maneuvers to increase venous filling (*e.g.*, saline infusion, Trendelemburg position) (Figure 4). In addition, to increase the lumen of the vein and prevent its collapse during respiratory acts, the operator may ask the patient to perform the Valsalva maneuver for a few seconds while puncturing the vein. In our experience, 18% of successful punctures were performed with the assistance of the

Figure 1. Both the pocket-sized display unit and the probe of the handheld ultrasound system are enclosed within a single sterile plastic sheath.

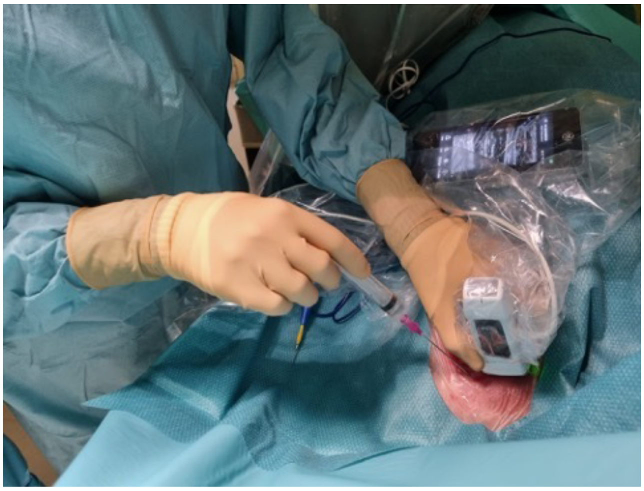

Figure 2. Operating field arrangement during a pacemaker implantation. Thanks to the compact dimensions of the ultrasound device, the operator's visual field is focused on a narrow area that includes the probe during venous scanning and puncturing, as well as the video unit.

Valsalva maneuver. Even in this case, the Valsalva maneuver induces the most significant increase in AV diameter at the portion running out of the body of the second rib (Figure 5). In this case, the operator performs the puncture more proximally, without the protection provided by the bony shield of the second rib. It should be highlighted that, since the Valsalva maneuver requires the patient's cooperation, it may be inadequate or entirely unfeasible in the case of elderly patients or those with cognitive decline. After successful puncture, a 0.035" j-tip guidewire is inserted through the needle into the vein and guided fluoroscopically to the inferior vena cava. For CIEDs requiring multiple leads, additional venous accesses are obtained with the same technique, using one ultrasound-guided puncture per lead by moving the puncture site by 0.5 cm proximally along the AV run. Alternatively, a single-puncture approach with a retained guidewire may be used for multiple lead implantations, depending on the operator's preference. Next, a linear skin incision is made medially to the guidewires using a #11 surgical scalpel. The device pocket is manually created by detaching subcutaneous tissue planes above the pectoralis major muscle fascia. Alternatively, the device pocket can be created using an electrosurgical unit at the discretion of the operator. In this case, to avoid thermal damage to the tissues, the guidewires positioned within the vein are covered with a 5 French dilator introduced transcutaneously and kept in place until the electrical current is delivered (Figure 6). Blunt dissecting scissors are used to reach the guidewires through the subcutaneous tissue and draw them under the skin into the device pocket. Finally, a peel-away dilator/introducer assembly is inserted over the guidewire into the central venous system, and the leads are implanted following standard procedures. In cases where USGAVA fails, we make a skin incision, prepare a device pocket, and attempt an alternative AV approach using fluoroscopic landmarks, mostly without contrast venography, following the standard technique.

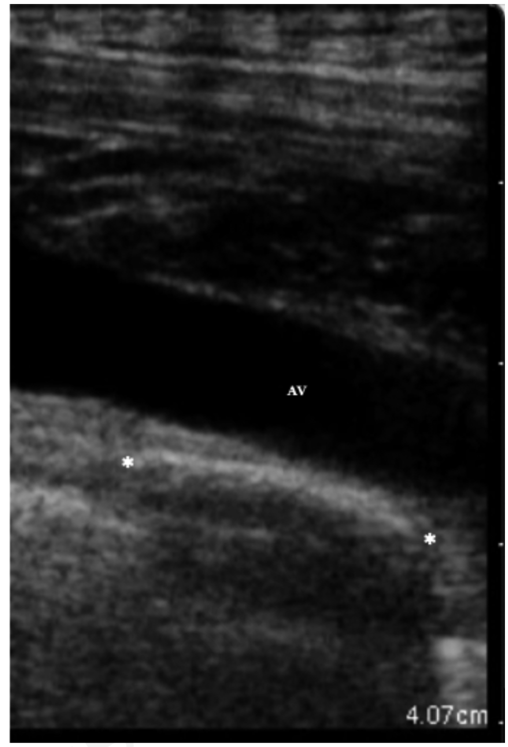

Figure 3. BUltrasound imaging of the target zone for a "second rib approach" during an axillary vein puncture. The asterisks indicate the superior and inferior border of the second rib. Acoustic shadowing produced by the body of the second rib shielding the ultrasound beam is visible. The portion of the vein running above the second rib represents the ideal zone for a safe venipuncture.

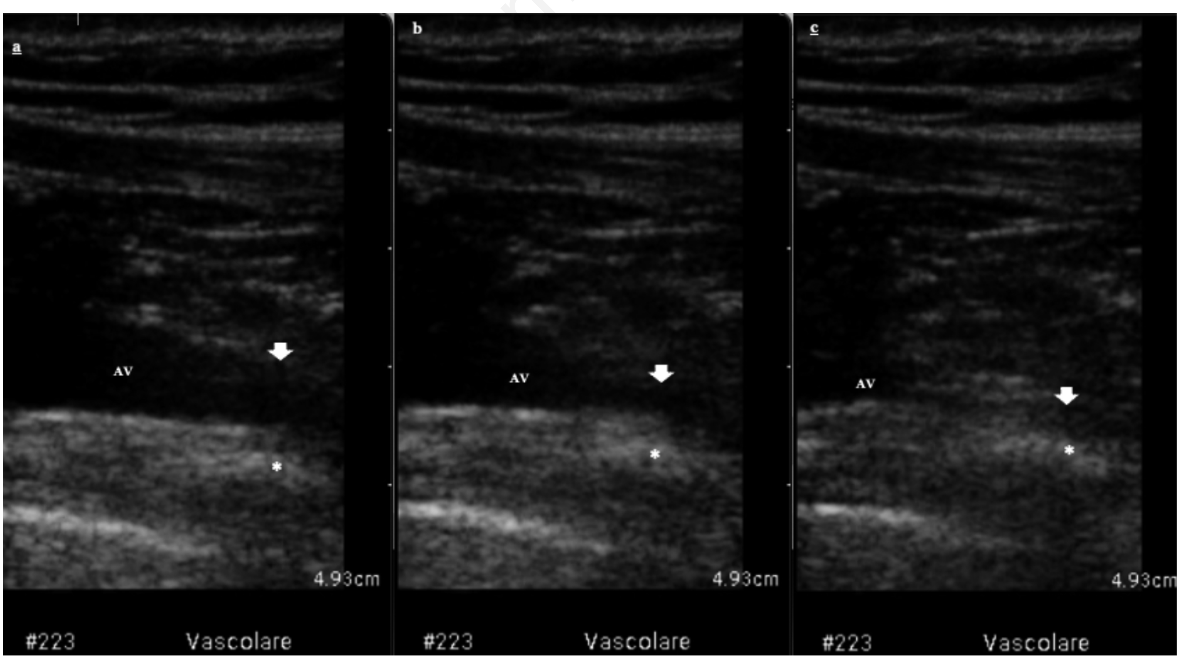

Figure 4. Ultrasound imaging of the axillary vein size variation during the initial (a), mid (b), and final (c) inspiratory phase. The arrows indicate the lumen of the axillary vein portion running over the body of the second rib, the latter is signed by the asterisks. The frame (c), captured at the end of the inspiratory act, shows the complete collapse of the axillary vein over the second rib only. On the contrary, the lumen of the axillary vein exiting the body of the second rib, despite its dynamic nature, remains visible throughout the entire respiratory cycle AV, Axillary Vein

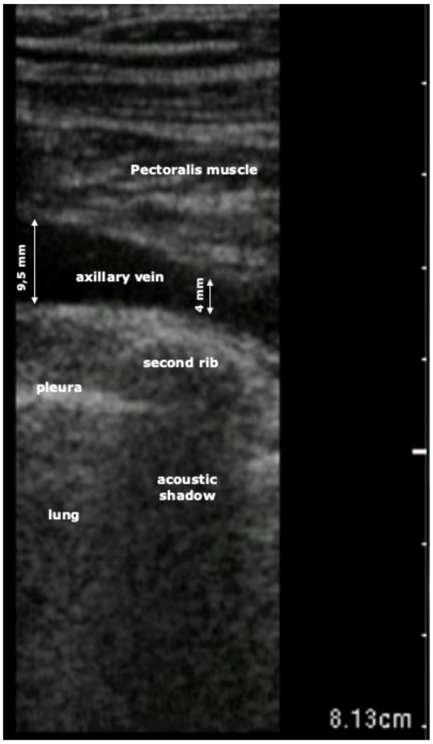

Figure 5. Ultrasound imaging of the same patient in Figure 4 during the Valsalva maneuver. The deeper view allows for better detail of surrounding tissues.

Figure 6. The operator has encased the metal guidewire used to access the axillary vein with a 5 French introducer dilator, and then advanced it transcutaneously along the wire. This measure aims to prevent potential thermal tissue damage during the utilization of an electrosurgical unit for creating the device pocket, the location of which is demarcated by a superficial linear skin incision performed with the tip of a scalpel.

Discussion

A growing amount of data suggests that using ultrasound guidance for accessing the AV in implanting pacemaker or cardioverter-defibrillator leads is a viable and comparable alternative technique to the conventional approach of AV puncture guided by fluoroscopy landmarks. Previous studies on USGAVA in CIED placement initially employed stationary, high-end ultrasound machines, and more recently, portable laptop ultrasound systems on carts. However, maneuvering these cumbersome ultrasound systems in the operating room, handling transducer wires over the surgical area, and requiring an additional operator at the console for echo imaging adjustment while the primary operator performs the venipuncture could compromise sterility and disrupt the procedure workflow, potentially hindering the adoption of USGAVA in clinical practice. Technological advancements over the years have led to the gradual downsizing of ultrasound machines, with some devices now comparable in size to current smartphones. In 2019, the European Association of Cardiovascular Imaging issued a position statement emphasizing the potential of handheld ultrasound devices in various clinical scenarios, including vascular invasive procedures like central venous catheter insertion.[12] Recent randomized trials have demonstrated comparable imaging quality and procedural success between compact, handheld ultrasound devices and conventional on-cart system ultrasound devices for guiding internal jugular venipuncture, despite some visibility differences due to the relatively lower performance of pocket-sized devices.[13,14] Our experience was the first, notwithstanding the intrinsic technological constraints and diminished functionalities associated with pocket-sized devices, to show comparable effectiveness and safety between a handheld ultrasound device and conventional ultrasound systems with higher technological capabilities.[11] It is worth noting that miniaturized portable devices do come with certain technical constraints, such as lower image resolution and a smaller screen. However, in our experience, these limitations did not adversely impact the operators' performance during AV puncture. We believe that the systematic use of saline infusion wide open from the intervention arm, the Trendelenburg position and, when necessary, the Valsalva maneuver, have contributed to such results. Furthermore, many current handheld ultrasound devices, including the one employed in our study, allow the display to be mirrored onto a larger wireless monitor nearby, similar to a fluoroscopy screen. This feature could prove useful in mitigating some of the technical limitations associated with the device's compact size.

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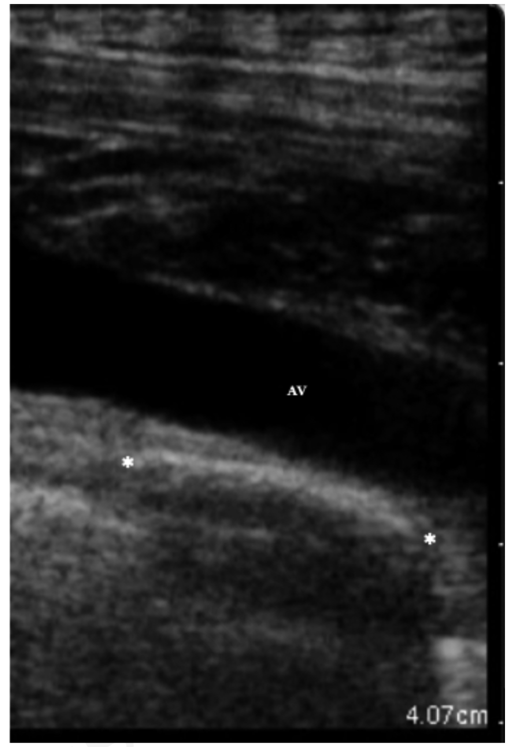

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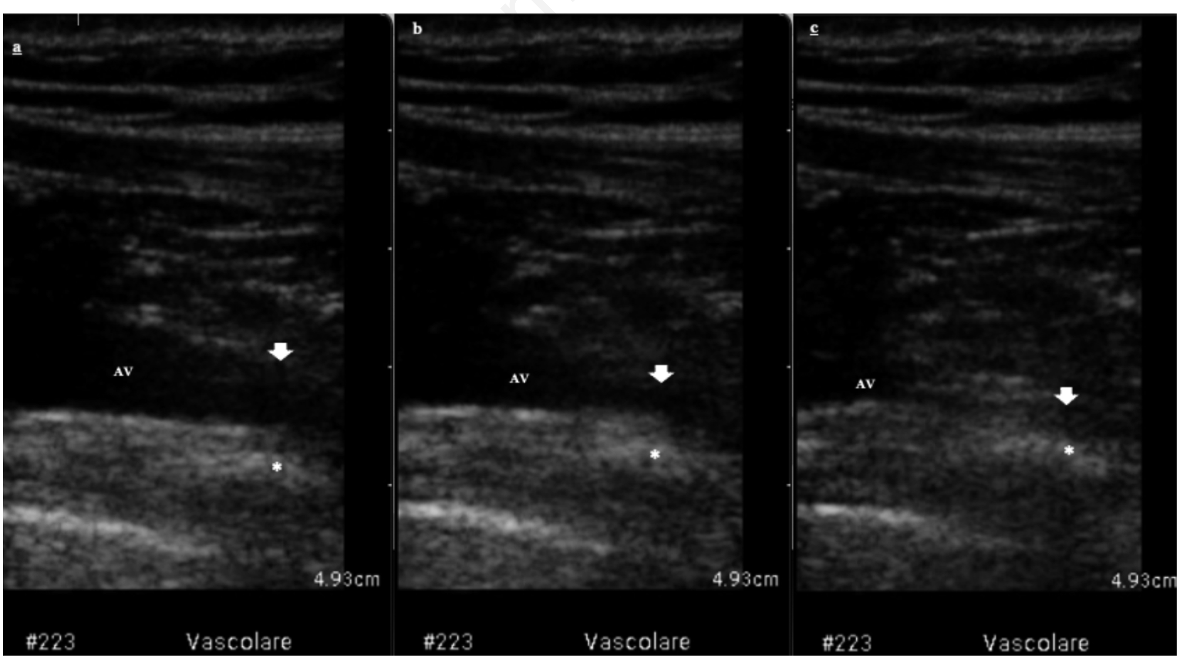

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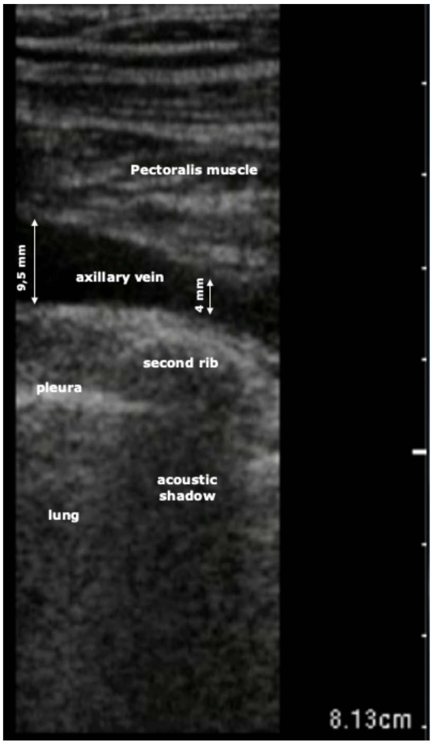

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