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Implementation of Ultrasound-Guided Infraclavicular Subclavian Venous Catheterization During Anesthesia and Elective Surgery: A Prospective Observational Study at a Single Center in Lithuania

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Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: Ultrasound-guided procedures have become more reliable and efficient in daily anesthesiology practice, with increased patient comfort, better antimicrobial pattern, and easier care, and can be used in routine central vein catheterization practice. The infraclavicular subclavian vein approach provides all these advantages and in some clinical scenarios ensures the only appropriate route to central vein access. Therefore, this study of 105 patients aimed to implement and evaluate the use of ultrasound-guided infraclavicular subclavian venous catheterization.





Material/Methods: We enrolled 108 patients who were scheduled for elective major abdominal surgery and had an indication for central venous access. Catheterization was done according to the developed protocol. Anesthesiologists with at least 1 year of experience in regional ultrasound-guided anesthesia participated in this study. Data were collected and compared with the existing literature.

Results: Out of 108 patients enrolled, 3 were excluded due to unfulfilled protocol. The successful catheterization rate was 98.1%. A significant relationship with deeper and narrower vein and failure was noted. On average, the distance between the vein entry point and acoustic shadow of the clavicle was 10.45 mm, at this point the depth was 22.01 mm and the diameter of the vein was 10.74 mm. The length of catheter intratissue passage was 42.06 mm. The angle between the skin and catheter passage was 31.58°. The malposition rate was 8.7%, and no predictive factors were identified. Equations to predict vein diameter and depth were generated. Patient weight more than 119.5 kg predicted procedure failure. There were no complications.

Conclusions: Ultrasound-guided infraclavicular subclavian vein catheterization can be easily and safely integrated into daily clinical practice, with high success rates and low complication rates.

Keywords: **Axillary Vein • Subclavian Vein**

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Background

Despite surgery improvements and less invasive approaches, central venous access remains crucial for advanced hemodynamic monitoring, administration of vasoactive drugs, temporary pacing, and even renal replacement therapy [1]. Even before the ultrasound era, 3 anatomical sites for central line placement were well described and evaluated. Large multi-center trials and meta-analyses showed an almost 3-fold better antimicrobial effect of using an infraclavicular site [2,3], but with a significant increase in catheter malposition and pneumothorax [3]. Use of a jugular site is characterized by high success rates and arterial puncture [2]. Use of a femoral site improves pleural safety but, due to possible vessel valves, guidewire introduction may be complicated. As ultrasound-guided procedures were implemented into clinical practice, some of the sites turned out to be better for ultrasound imaging. Consequently, the standard approach for central venous access during the last 3 decades has moved toward ultrasound-guided internal jugular vein catheterization. Factors such as proximity to the skin, low level of angulation, distance to the pleura, and absence of bony structures make this the easiest site with which to obtain good-quality ultrasound imaging, successful guidewire introduction, and fluent catheter placement. As anesthesiology-intensive care staff members become more familiar with ultrasound-guided procedures, a need emerges to introduce a method with a lower incidence of infection, better patient comfort, and easier nursing care, with a preserved high success rate and low level of procedure-related mechanical complications. The former anatomic landmark technique-based central vein access through the subclavian vein has provided these advantages [4]. However, a moderate success rate (92.5%) and an unacceptably high incidence of mechanical complications (11.9%) [5] make this technique inadequate for modern anesthesia. Even though real-time ultrasound-guided internal jugular vein catheterization has proven to be advantageous, the evidence base for ultrasound-guided infraclavicular approaches is sparse [1]. Initial evaluation of the ultrasound usage for subclavian vein puncture in 1994 failed to prove any advantage [6]. Although a meta-analysis showed clear reduction of mechanical complications, increase in success was found only in the 2D dynamic ultrasound subgroup [7]. Even authors who achieved 100% success describes this method as “technically difficult” [8] To date, only experienced practitioners have managed to achieve a high success rate and low complication incidence [9]. Therefore, this study of 105 patients who underwent anesthesia and elective surgery at a single center in Lithuania aimed to implement and evaluate the use of ultrasound-guided infraclavicular subclavian venous catheterization.

Material and Methods

Ethics Statement

This study is a part of the large “Alternative central vein access in bone marrow transplantation program” study. The study was approved by the Regional Ethical Review Board on 2020.03.02 (registration number BE-2-15) and conducted in accordance with the Declaration of Helsinki. Patients were informed and written consent was obtained on the day of surgery.

Enrollment

This prospective, observational, single-center study was conducted between October 1, 2020, and May 1, 2021, at the Lithuanian University of Health Sciences Hospital Kaunas Clinics. We included 108 patients who were scheduled for elective major abdominal surgery and had an indication for central venous access during the surgery. Exclusion criteria were incomplete adherence or breaches to the catheterization protocol. Six anesthesiologists with at least 1 year of post-training experience in ultrasound-guided regional anesthesia participated in this study.

Study Protocol

A protocol was developed with the goal of creating working conditions comparable to those for internal jugular vein catheterization, as this would ease implementation in routine practice. The aim was to adopt all current evidence-based techniques to facilitate the procedure. Catheterizations were performed under general endotracheal anesthesia.

Patient Positioning

Patients were positioned in the 15-degree Trendelenburg position to increase subclavian [10] and likely axillary vein dilatation and achieve optimal conditions for puncture. A neutral right arm position near the body was used because it remains controversial whether arm abduction is advantageous [11], and most of our operating rooms did not facilitate such positioning. The anesthesiologist’s position was kept the same as when catheterizing the internal jugular vein (over the head of the patient).

Ventilation

Lung-protective ventilation was implemented (tidal volume of 7 ml/kg ideal body weight [12] and PEEP 6 cm H₂O), and ventilation was maintained during the procedure, despite the possible benefit of apnea [13].

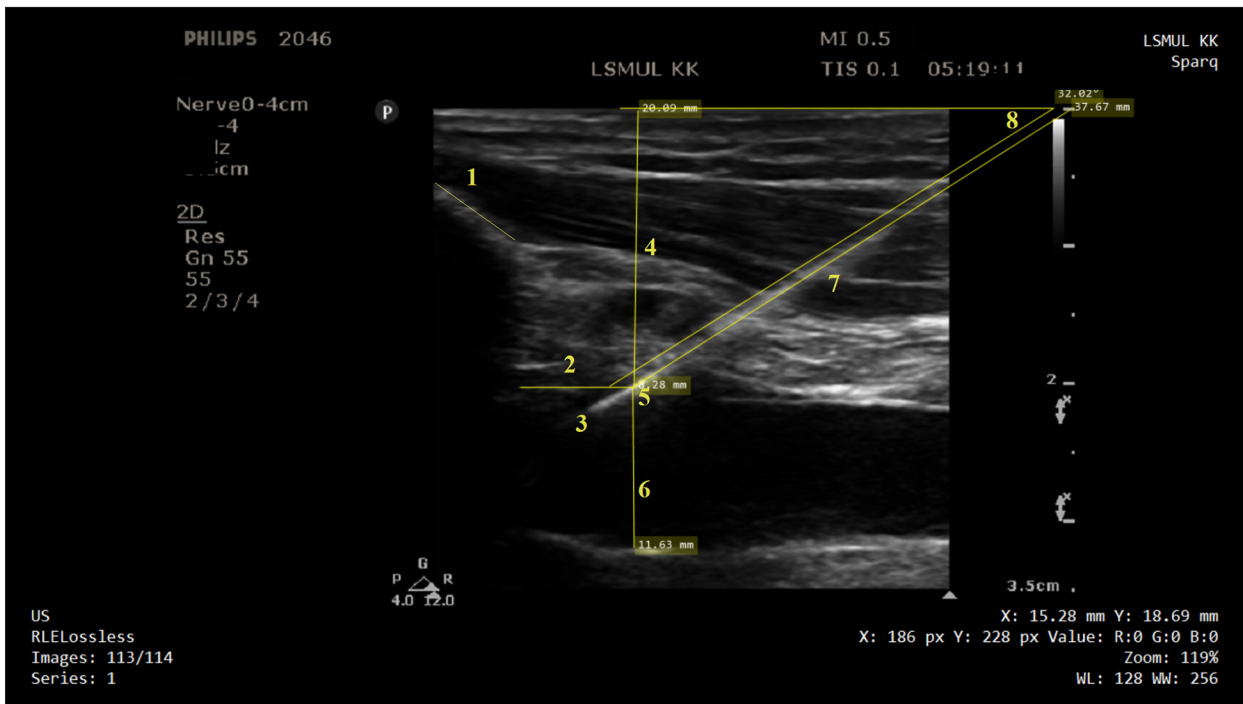


Figure 1. Ultrasound image of infraclavicular area, guidewire, subclavian and axillary veins are displayed in longitudinal view: 1 – clavicular bone; 2 – distance from the clavicle bone shadow and vein penetration point; 3 – guidewire placed in the vein lumen; 4 – vein depth; 5 – vein penetration point; 6 – vein diameter; 7 – intratissue passage; 8 – puncture angle.

Equipment

Identical equipment for all procedures was used: Philips Sparq ultrasound machines with L12-4 Linear Array Vascular probes. Arrow Two-Lumen Central Venous Catheterization Set ref: cv-15802 with blue FlexTip®Catheter Arrow, a nonechogenic introducer needle (18Ga x2-1) preloaded with a guide wire (“J” tip spring – wire guide 0.81 mm/60 cm) was selected for the study. Strict sterile technique was applied, and Pajunk SonoCover 6x80 and Parker Sterile Aquasonic 100 Ultrasound Transmission gel were used. All measurements were performed with MicroDICOM 3.1.4 software.

Catheterization Technique

The subclavian and axillary veins were visualized using a longitudinal approach because it lessens clavicle artifacts and allows the determination of needle-vein relationships in real time. In this way, posterior wall injury, as well as other mechanical complications, can be reduced [14]. The aim was to obtain an image with the medial edge of the transducer overlying the clavicular bone and to ensure that the maximum diameter of the vein was visualized in the longitudinal view (Figure 1). Due to the higher success rate, the most proximal point of the vessel was chosen as the primary puncture site [15]. Needle navigation or guiding techniques (electromagnetic-guided position system) were not used, as evidence for their effectiveness in

humans is insufficient [16]. Venous puncture was performed using a syringe-free, in-plane technique. The introducer needle was advanced until the needle tip was clearly seen in the vein lumen; subsequently, the guidewire was introduced under direct ultrasound observation. The procedure was discontinued if puncture was unsuccessful after 3 needle redirection attempts or lasted more than 15 min. To reduce the incidence of cardiac arrhythmias, guidewire introduction was limited to 20 cm [17]. After confirmation that the posterior vein wall was not penetrated, a 9 Fr 10.2-cm tissue dilator was introduced. The catheter could be advanced up to 20 cm because the puncture site is placed 2-3 cm laterally compared to the anatomical landmark subclavian vein puncture site [18]. The catheter tip position was checked with postoperative chest X-ray and in cases of malposition it was corrected in the Post-Anesthesia Care Unit (PACU) (Figure 2). Catheterization was considered successful if blood from both lumens could be drawn freely. Catheter care was carried out as per the hospital protocol, and in case of dysfunction or premature fall-out, the anesthesiologist was informed.

Statistical Analysis

Statistical analysis was carried out using SPSS v25.0 software. The normality of the data was determined with the Kolmogorov–Smirnov test. Normally distributed data are reported as the mean, and nonnormally distributed data are reported as the median. Binary logistic regression was used to

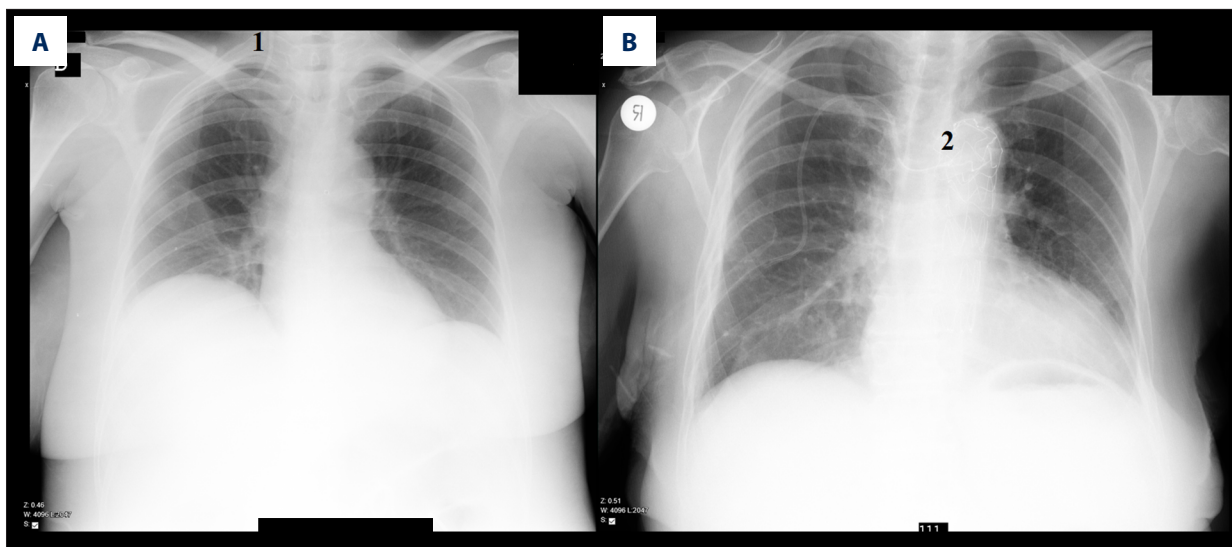


Figure 2. Catheter tip confirmation, chest X-ray obtained after catheterization. (A) Image 1, showing catheter’s tip is located in right jugular vein. (B) Image 2, showing catheter’s tip is located in a left brachiocephalic vein.

Table 1. Demographic and anatomic parameters of patients enrolled into the research. Weight is expressed in kilograms, SAPS in points, distances in millimeters.

	Kolmogorov-Smirnov Test of Normality	Mean	Std. error	Std. dev	Median
Age	0.200	61.36 years	1.72	17.72	
Weight	0.82	72.55 kg	1.55	15.95	
SAPS	<0.001			12.12	22.0 points
Distance between the acoustic shadow and vein penetration point	0.121	10.45 mm	0.43	4.45	
Vein diameter	0.200	10.74 mm	0.29	3.03	
Vein depth	0.200	22.01 mm	0.54	5.54	
Intratissue passage	0.200	42.06 mm	0.79	8.11	
Angle	0.200	31.5 degrees	0.59	6.05	

determine factors affecting malposition and failure rate. Linear regression was used to determine factors affecting vein diameter and depth. Normally distributed data were compared with the *t* test. Comparison with prespecified data was carried out using a one-sample binomial test. The discrimination threshold was determined with a receiver operating characteristic (ROC) curve.

Results

In total, 108 cases were enrolled in the study. Three were eliminated due to incomplete fulfillment of the protocol. The proportion of men and women was almost equal: 49.5% and 50.5%, respectively. Age, weight, vein diameter, vein depth, vein

entry distance, puncture path, and angle fulfilled the normal distribution criteria. However, the SAPSII score did not. Our achieved distance between the vein entry point and acoustic shadow of the clavicle on average was 10.45 mm (SD 4.45 mm). At this point, the depth and diameter of the vein were 22.01 mm (SD 5.54 mm) and 10.74 mm (SD 3.03 mm), respectively. The length of catheter intratissue passage was 42.06 mm (SD 0.79 mm). The angle between the skin and catheter passage was 31.58° (SD 6.05°) (Table 1).

Success Rate and Complications

In all cases our used probes produced satisfactory images; both ventral and dorsal vessel’s walls can be identified. We achieved

Table 2. Independent factors for prediction of vein diameter and depth. Age, weight, and male gender are significant independent prediction factors for large vein. Single independent contributor weight reliably predicts deeper vein location.

		Unstandardized B	Coefficient std. error	Standardized coefficients beta	Sig.
Vein diameter	Constant	3.513	1.587	–	0.29
	Age	0.071	0.16	0.412	<0.001
	Weight	0.048	0.017	0.251	0.006
	Sex (Female)	-1.137	0.566	-0.188	0.047
Vein depth	Constant	7.578	2.085	–	<0.001
	Weight	1.99	0.028	0.573	<0.001

Table 3. Relationship between procedure's success and body weight, vein diameter, and depth. Weight is expressed in kilograms, distances in millimeters.

Successful procedure	Mean difference	Std. error difference	Two-sided p value
Weight	-44.80 kg	10.56	<0.001
Vein diameter	4.46 mm	2.13	0.039
Vein depth	-10.29 mm	3.846	0.009

a success rate of 98.1% (n=103). No pneumothorax, arterial puncture, or hematoma formation was observed. Catheter position was confirmed using postoperative chest X-rays. In 94 (91.3%) cases, correct placement was confirmed: 66 (64.1%) were positioned in the superior vena cava and 28 (27.2%) in right atrium. Malposition was observed in 9 (8.7%) patients: 5 (4.8%) in right jugular vein and 4 (3.9%) in left brachiocephalic vein. We were not able to distinguish any predicting factors (eg, age, weight, vein diameter, puncture angle, puncture proximity) for catheter tip malposition in any location (right internal jugular vein, contralateral brachiocephalic vein). One premature catheter fall-out was observed; however, it was due to an accidental infusion line pull.

Predictors of Vein Diameter and Depth and Successful Catheterization

Using linear regression analysis, an equation predicting vein diameter was generated. Age, weight, and sex were identified as independent contributing factors:

Vein diameter prediction equation [mm]= $3.513+0.071 \times \text{Age}[\text{years}] + 0.048 \times \text{Weight}[\text{kg}] - 1.137 \text{ Female}$. R Square -0.240. Durbin-Watson - 1.850, Std Residual - 2.619; +2.166.

However, by predicting vein depth, these demographic parameters showed interdependency, therefore only weight can be identified as reliable and significant predictor for vein depth.

Vein depth prediction equation [mm]= $7.578+0.199 \times \text{Weight}[\text{kg}]$ R Square -0.328. Durbin-Watson - 2.287, Std Residual - 2.761; +2.656 (Table 2).

Binary logistic regression due to the low failure rate was not able to determine factors related to procedure failure (2 cases). However, an independent sample t test showed statistically significant smaller (4.46 mm) vein diameter and deeper (10.29 mm) vein location compared to the success group (Table 3).

With only 2 procedure failures, it is difficult to make strong conclusions, but ROC still identified a cut-off value of more than 119.5 kg as a predictor for unsuccessful catheterization, with AUC (area under the curve) - 0.995 (a sensitivity 99.1% and a specificity 100%) (Figure 3).

Discussion

Long-term vein access through the subclavian vein provides less restriction of neck mobility and a lower incidence of thrombosis [19]. In addition, Niccolo Buettiet al [20] reported an increased risk for catheter-related blood stream infections associated with jugular and femoral central catheters placed with ultrasound guidance. Interestingly, this is not the case for catheters placed in the infraclavicular area using ultrasound guidance. Furthermore, subclavian or axillary vein catheterization could be more convenient in several clinical scenarios, such as

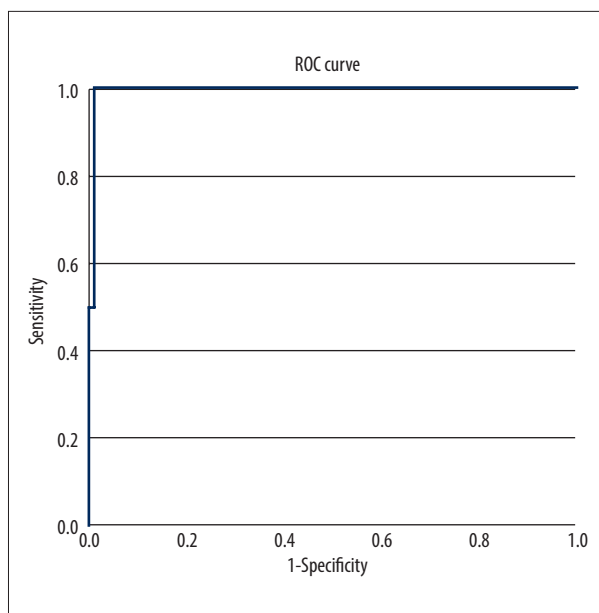


Figure 3. ROC with AUC of 0.995, predicting successful catheterization based on weight cut-off value 119.5 kg, with sensitivity 99.1% and specificity 100%. ROC – receiver operating characteristic; AUC – area under the curve.

neck immobilization due to trauma, major larynx or neck surgery, and noninvasive ventilation with a helmet, which makes jugular access troublesome. Femoral access could potentially delay the start of surgery because of its proximity to the abdomen in urgent laparotomy, and pelvic ring application in trauma makes femoral catheterization impossible. The infraclavicular area in these cases would be the most convenient route; therefore, mastering US-guided catheterization techniques to guarantee patient safety and central access is necessary.

The subclavian vein is defined as a continuation of the axillary vein proximal to the lateral border of the first rib and is located dorsally at the medial third of the clavicle. Using the landmark technique, the puncture point is a short and narrow gap between the clavicle and the costoclavicular ligament [21]. Consequently, ultrasound imaging of the point is limited by clavicular bone. However, distal vessel images are still available, resulting in more lateral vein penetration, likely out of the intrathoracic space. The relationship of the vein with the first rib in practical ultrasound imaging is not certain. Other studies have used more lateral and steeper puncture techniques than those described in our study [22]. Therefore, some sources state that the “infraclavicular axillary vein” could be a more appropriate term [21]. In our future work, we plan to incorporate 3D CT reconstructions of the upper thorax to describe the catheter’s relationship with anatomical structures, which will allow us to name the puncture site more accurately.

Regarding the visualization technique, we completely agree with the recommendation of Franco-Sadud R et al [23] that routine subclavian vein catheterization should be performed under direct real-time ultrasound observation. Since the out-of-plane technique cannot guarantee appropriate needle tip visualization, as shown by Andrea Farina et al [24], we are certain that the in-plane approach should become routine. Moreover, this is advantageous in the teaching process because it increases successful first-attempt catheterizations from 37% to 69% and reduces redirections from 2.7 to 1.8 ($P=0.0002$) when compared with the out-of-plane technique [25]. Initially, the medial edge of the ultrasound transducer was placed over the clavicle for proximal approach documentation. Recently, we found an additional benefit to this technique. Because the proposed Microconvex transducers [26] become irrelevant, a wider area for needle insertion and the desired puncture angle can be achieved just overlying the clavicle with the medial edge of the transducer.

When compared with anatomical landmark technique-based subclavian vein catheterization, the ultrasound-guided catheter exit site is 2-3 cm more lateral, near the deltopectoral groove. Whereas arm abduction in the landmark technique decreased the success of catheterization by the second attempt from 96.2% to 84.4%, it increased pneumothorax risk from 1.9% to 9.4% and the artery puncture risk from 2.5% to 8.8% [27]. Therefore, we decided to keep the patient’s right arm parallel to the body. However, arm abduction reduced catheter tip malposition from 3.9% to 0.4% without affecting the success rate (98.8% vs 97.1%), as shown by Ahn Hand and colleagues [28].

The rate of malposition of the axillary vein catheter tip into the ipsilateral internal jugular vein or contralateral brachiocephalic vein is reported to be as high as 15% [29]. Our observed malposition incidence (8.7%) does not significantly differ from the landmark technique-based subclavian vein catheterization malposition rate reported in the literature. Ultrasound-guided subclavian vein catheterization has shown similar results (9.5%), with the ipsilateral jugular vein being the most common site of malposition (95%) [30]. In our study, malposition in the internal jugular vein and left brachiocephalic vein was similar (4.8% and 3.8%, respectively).

Our achieved overall success ratio of 98.1% is a significant improvement in comparison with the anatomic landmark technique, which is highly related to operator experience and varies from 89.3% to 95.1% (overall success rate 92.5%, $P=0.023$) [5]. Our results are comparable to Hyun-Jung Shin et al’s [31] reported success ratio of 95.5% when using an in-plane infraclavicular catheterization approach. The rate of catheter malposition (8.6%) did not differ significantly from that reported in the literature (9.3%, $P=0.489$) [32].

BMI >30 kg/m² is associated with aggravated subclavian vein visualization, as shown by Stachura MR et al [19]. Obesity impedes successful catheterization using an US-guided infraclavicular approach. We believe this is not due to inability to distinctly visualize the vessel, as the ultrasound probes we used provided an acceptable vessel view. However, deeper vein location leads to a steeper puncture angle and, consequently, an inability to adequately visualize the tip of the needle and to recognize ventral wall penetration. Use of a Microconvex transducer does not seem to help much. A study in Japan in which the extrathoracic ultrasound-guided subclavian route was tested for pacemaker/defibrillator leads implantation concluded that further modifications of the needle are needed for better visualization. Vein depth was comparable to that in our study (22.7 mm) but with a very large entry angle (mean, 52.4°) [33]. In comparison to the Hai-Yan Wang et al [15] study, we found a slightly wider maximum diameter (10.74 mm [SD 3.0 mm] vs 8 mm [SD 3.3 mm]) and deeper location of the vein (22.01 mm [SD 5.5 mm] vs 19.3 [SD 4.5 mm]). This could be explained by the pronounced Trendelenburg position, positive-pressure ventilation, and different population.

The complication rate reported in the literature varies from 1.4% to 18.8% and is the highest when using the landmark technique [5]. This discrepancy may be due to different levels of experience of the operators and lack of standardized definitions of mechanical complications [34].

Since with an ultrasound-guided approach, the catheterization site is more lateral and closer to the shoulder, we were concerned that it would result in premature fall-out or excessive looping in subcutaneous tissue. However, the only premature fall-out occurred due to accidental pulling of an infusion line attached to the catheter. An additional benefit of more lateral puncture sites could be a lower risk of pinch-off syndrome, since the catheter is not inserted through the costoclavicular ligament.

The ultrasound-guided supraclavicular subclavian vein approach shows promising results, with shorter puncture time 29.8 s, 4% fewer attempts needed, and less guidewire misplacement – 0% in comparison to the ultrasound-guided infraclavicular approach (46.9 s, 22.2%, and 8.9%, respectively) [35]. Moreover, it has a higher success rate (98.4%), shorter

insertion time (43.9 s), fewer needle redirection attempts (0.69), and less guidewire advancing difficulties – 2.4% in comparison to ultrasound-guided jugular vein (96.8%, 53.1 s, 1.17, 27.4%, respectively) [36]. The ultrasound-guided supraclavicular subclavian vein approach could potentially be identified as the simplest route to the central vein, but the advantageous antimicrobial pattern and patient comfort still need to be proven.

Limitations

All 6 anesthesiologists who participated in the study had completed residency and had at least 1 year of constant practice in ultrasound-guided regional anesthesia. Therefore, how the results of this study can be extrapolated to trainees or less experienced practitioners remains uncertain. We were not able to randomize who would perform the procedure. In addition, all catheterizations were performed in almost ideal conditions, which contributes to a higher success rate and might not be achievable in every clinical scenario of anesthesia practice. Another limitation is our sample size; it was clearly too small to detect mechanical complications, but still enough to update our own hospital protocols. A low possibility exists that late-onset pneumothorax could have been undetected; however, there were no patients with subsequent clinical signs of pneumothorax.

Conclusions

Ultrasound-guided infraclavicular subclavian venous access can be safely and effectively used into routine clinical practice without any additional changes in preparation protocols. Procedure failure is mainly associated with increasing vessel depth. Body weight above 120 kg could be a predictor of procedure failure. The incidence of catheter tip malposition in our study is similar to those reported when using the anatomical landmark technique. We could not find factors associated with malposition.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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