Real-time ultrasound-guided subclavian vein cannulation versus the landmark method in critical care patients: A prospective randomized study*

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Objective: **Subclavian vein catheterization may cause various complications. We compared the real-time ultrasound-guided subclavian vein cannulation vs. the landmark method in critical care patients.**

Design: **Prospective randomized study.**

Setting: **Medical intensive care unit of a tertiary medical center.**

Patients: **Four hundred sixty-three mechanically ventilated patients enrolled in a randomized controlled ISRCTN-registered trial (ISRCTN-61258470).**

Interventions: **We compared the ultrasound-guided subclavian vein cannulation (200 patients) vs. the landmark method (201 patients) using an infraclavicular needle insertion point in all cases. Catheterization was performed under nonemergency conditions in the intensive care unit. Randomization was performed by means of a computer-generated random-numbers table and patients were stratified with regard to age, gender, and body mass index.**

Measurements and Main Results: **No significant differences in the presence of risk factors for difficult cannulation between the two groups of patients were recorded. Subclavian vein cannulation was achieved in 100% of patients in the ultrasound group as compared with 87.5% in the landmark one ($p < .05$). Average access time and number of attempts were significantly reduced in the ultrasound group of patients compared with the landmark group ($p < .05$). In the landmark group, artery puncture and hematoma occurred in 5.4% of patients, respectively, hemothorax in 4.4%, pneumothorax in 4.9%, brachial plexus injury in 2.9%, phrenic nerve injury in 1.5%, and cardiac tamponade in 0.5%, which were all increased compared with the ultrasound group ($p < .05$). Catheter misplacements did not differ between groups. In this study, the real-time ultrasound method was rated on a semiquantitative scale as technically difficult by the participating physicians.**

Conclusions: **The present data suggested that ultrasound-guided cannulation of the subclavian vein in critical care patients is superior to the landmark method and should be the method of choice in these patients. (Crit Care Med 2011; 39:1607–1612)**

KEY WORDS: subclavian vein cannulation; technique; ultrasound; critical care

Central venous catheters play an important role in patient care, especially in the intensive care unit (ICU); however, their use is associated with various complications, even death (1–5). Mechanical complications occur more frequently through the subclavian vein (SCV) route if compared with the internal jugular vein (IJV) and to the femoral vein routes (6, 7). Real-time, ultrasound-guided central venous cannulation results in a lower technical failure rate (overall and on first attempt), faster access, and a reduction in mechanical complications; nevertheless, this has been validated mainly for the IJV in previous reports (8, 9). Ultrasound-assisted location of the vein has been reported to have no effect on the rate of complications or failures of SCV catheterization in previous reports (6). Most ultrasound studies of SCV catheterization used Doppler or "mark and go" techniques and not real-time (two-dimensional) ultrasound guidance (10, 11). Our team has previously demonstrated the superiority of the ultrasound-guided IJV cannulation as compared with the landmark method in critical care patients (9). Furthermore, in our ICU, the overall rate of mechanical complications after "blind" SCV cannulation was approximately 15.8% out of 1000 catheterizations performed annually (unpublished data 2000–2005), which provided a clinical rationale for the present study. Hence, we compared the real-time ultrasound-guided approach with the landmark technique in the routine cannulation of the SCV in mechanically ventilated patients.

***See also p. 1819.**

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MATERIALS AND METHODS

Subjects. The study was prospectively conducted in the ICU from January 2006 to October 2010 and included 463 mechanically ventilated patients. All patients were sedated and mechanically ventilated (Servo-I ventilator; Maquet Inc, Bridgewater, NJ). The end point was to compare the real-time ultrasound method vs. the landmark one in the routine cannulation of the SCV. Randomization was performed by means of a computer-generated random-numbers table and patients were stratified with regard to age, gender, and body mass index (9). Block randomization was used to ensure equal numbers of patients in these groups (12). All physicians who performed the procedures had at least >6 yrs of experience in central venous catheter placement. Family members provided written, informed consent for all patients. The study was in conformation with the principles outlined in the Declaration of Helsinki and was approved by the institutional ethics committee (9).

A normal chest radiography was used to assess the placement of the catheter's tip after the procedure (<2.9 cm caudal to the right tracheobronchial angle to avoid intracardiac placement) as previously described (9, 13). Mechanical complications were defined as artery puncture, hematoma, hemothorax, pneumothorax, injury to the brachial plexus as well as to the phrenic nerve, catheter misplacement, and cardiac tamponade. Subclavian artery puncture was noted by forceful pulsatile expulsion of bright red blood from the needle. All mechanical complications were evaluated clinically, by a chest radiograph, and by means of ultrasonography where appropriate. In most patients in whom the first attempt (one pass of the introducing needle) at catheterization failed, another physician performed the next attempt. If a catheter was misplaced, the position was corrected by manipulation of the catheter under ultrasonographic guidance for patients who were in the ultrasound group or under fluoroscopic guidance for patients in the landmark group. Phrenic nerve injury was assessed by a chest radiograph, fluoroscopy, and ultrasound evaluation as previously described (14). Pneumothorax was treated with tube thoracostomy if it was symptomatic, progressive, or >20% of the interface between the lung and the chest wall was separated.

Landmark Technique. For the landmark technique, the patient was placed in a Trendelenburg position. The ipsilateral anterosuperior region of the chest was shaved if necessary and prepared in a sterile fashion with an appropriate disinfectant (e.g., povidone–iodine or chlorhexidine). Then the area was anesthetized with a 1% lidocaine solution with a 22-gauge needle. The needle was inserted 1 cm inferior and 1 cm lateral to the junction of the middle and medial thirds of the clavicle (infraclavicular approach) (6). The return of venous blood into the syringe attached to the needle confirmed entry into the vessel. The local anesthetic needle was used as the finder needle and a sealed system was used to guide a 19-gauge needle connected to a 10-mL syringe through the same trajectory (Arrow, Howes, PA). Then, the triple lumen catheter was placed by means of the Seldinger's technique as previously described (6–11). Notably, all patients underwent ultrasound scanning of the infraclavicular area to look for the presence of venous thrombosis. Patients in whom cannulation was not possible with the landmark method as a result of thrombosis were excluded from the study and subsequently had the procedure performed with ultrasound on the contralateral side.

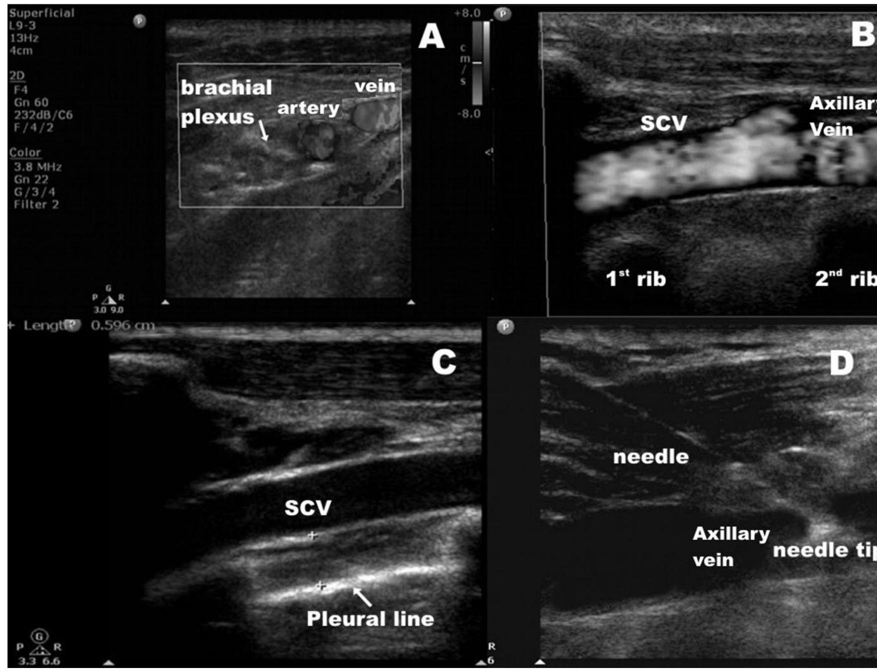

Figure 1. Two-dimensional infraclavicular views depicting the axillary vein and accompanying artery and the brachial plexus (*arrow*) (*A*), the subclavian vein (*SCV*) and the acoustic shadows of the thoracic ribs (*B*), the pleural line (*C*), and the real-time catheterization (*D*)

Real-Time Ultrasound Guided Method. The area was prepared and draped sterilely as described previously. Furthermore, the ipsilateral IJV area and the contralateral SCV area were sterilized too in case possible catheter misplacements required proper ultrasound-guided repositioning. An HD11 XE ultrasound machine (Philips, Andover, MA) equipped with a high-resolution 7.5-MHz transducer was used. The transducer was covered with ultrasonic gel and wrapped in an intraoperative sterile sheath (Microtek medical intraoperative probe cover, 12 × 244 cm; Microtek Medical, Alpharetta, GA).

The ultrasound method applied for the SCV catheterization was a four-step procedure: 1) preprocedural ultrasound scanning, which obtained both supra- and infraclavicular views, was applied to measure the depth and caliber of the axillary vein and the SCV and evaluate their patency; furthermore, adjacent structures were identified. In anatomic terms, the axillary vein continues medially until it reaches the first rib when it becomes the SCV (Fig. 1); 2) the infraclavicular approach, on the longitudinal axis, was pursued to compare the ultrasound method vs. the landmark one. Although we used a high-frequency transducer, which applies tissue harmonic imaging, depicting two-dimensional views of the vein was difficult. Physicians used sonoanatomic landmarks such as the acoustic shadows of the underlying first thoracic rib and of the sternum to select an area of interest; thereafter, maneuvers of the transducer were performed to depict the axillary vein and its continuation the SCV, on the longitudinal axis, and to achieve an optimum plane of catheterization (Fig. 1). Doppler techniques were additionally utilized to confirm the two-dimensional findings; 3) the needle was advanced slowly so that its trajectory and/or tip could be detected superficially. The needle was advanced in real-time toward the lumen of the vein, on the longitudinal axis, while it was purposefully directed toward the acoustic shadow of the thoracic rib underneath. This was performed to minimize the risk of damaging the pleurae and lung in case that transfixion of the vein was inevitable. Hence, the needle entered the lumen of the vessel either at the level of the axillary vein (Fig. 1*D*) or at the point where the latter continued medially as the SCV (Fig. 2*A*). This is dependent on the angle of penetration and the depth from

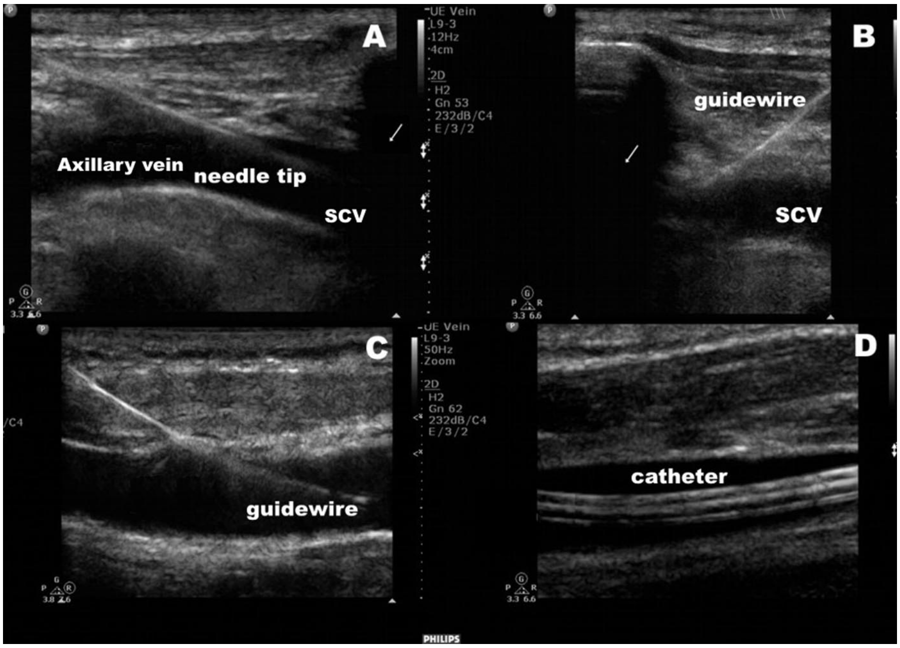

Figure 2. Ultrasound-guided subclavian vein (*SCV*) cannulation (*arrows = sternum). Visualization of the needle (A*), of the guidewire (*B–C*), and of the three-lumen catheter (*D*) during different steps of the procedure.

the skin surface that the vein is located. Also, the course of the needle is dependent on the adjustments performed by the operator to visualize its trajectory on the longitudinal axis. Hence, the angle of penetration and the course of the needle could be modified in each individual catheterization scenario. All of this surely renders the technique largely operator-dependent (Figs. 1 and 2); and 4) the guidewire was advanced according to the Seldinger's technique; thereafter, the ipsilateral IJV and the contralateral SCV were scanned to identify possible misplacements; hence, the catheter could be repositioned under ultrasound guidance.

Data Collection and Analysis. Forms containing patients' characteristics and all the pertinent fields for each technique were filled in timely and data were entered in a customized database. Side of catheterization (either left or right) and the presence of risk factors for difficult venous cannulation such as prior catheterization, limited sites for access attempts (other catheters, pacemaker, prior surgery, or infection), previous difficulties during catheterization (more than three punctures at one site; two sites attempted; failure to gain access), previous mechanical complication, known vascular abnormality, untreated coagulopathy (international normalization ratio >2; activated partial thromboplastin time >1.5; platelets $<50 \times 10^9/L^{-1}$), skeletal deformity, and patients not in the Trendelenburg position were also recorded. The outcomes assessed were the access time, the success of placement, the average number of attempts before successful placement (defined as separate skin punctures), and the rate of mechanical complications.

Access time was defined as the time between penetration of skin and aspiration of venous blood into the syringe. Preparation times for both techniques were not similar, taking into account that in the ultrasound group 118 ± 23 secs were added in as a result of scanning the area before performing the actual penetration. The access time was measured in seconds by a stopwatch by other physicians and the number of attempts and complications was recorded. Every effort has been made to ensure the application of evidence-based catheter insertion practices in both methods. Triple-lumen catheters were used in all cases. All catheterization procedures were performed under controlled nonemergency conditions in the ICU. Consequent to ultrasound-guided catheterization, all physicians were asked to rate the technical difficulty of the task on a semiquantitative scale (0–10), in which 0 equaled a simple procedure and 10 equaled a complex one.

Data were expressed as mean ± SD. The Student's t test for independent means, chi-square analysis, or Fisher's exact test where appropriate were used to identify differences between the two groups. A p value (two-sided in all tests) of $< .05$ was considered significant. SPSS software, version 11.0, was used (SPSS Inc, Chicago, IL).

RESULTS

Baseline characteristics of the study population are presented on Table 1. There were no significant differences in age, gender, body mass index, and in the presence of risk factors for difficult venous cannulation between the two groups (Table 1). Twenty-nine percent of patients in the ultrasound group were not in the Trendelenburg position as a result of increased intracranial pressure; however, catheterization was attempted in these cases. Forty-two patients who were not in the Trendelenburg position, as a result of increased intracranial pressure, and 20 patients in whom cannulation was not possible as a result of thrombosis, in the landmark group, were all converted to the ultrasound group and were excluded from the analysis. Hence, only 401 patients were included in the final analysis (Table 1).

Results using the landmark technique are in contrast to those obtained by the ultrasound method (Table 2). Success rate was significantly higher, whereas the rate of mechanical complications and the number of attempts were significantly lower in the ultrasound group as compared with the landmark group ($p < .05$) (Table 2). In the landmark group, several mechanical complications were recorded. Specifically, eight of ten cases of documented pneumothorax and five of nine cases of documented hemothorax required chest drainage and thoracotomy, respectively. Also, there was one case of cardiac tamponade resulting from perforation of the superior vena cava, whereas two cases of permanent brachial plexus injuries (of the total six) and one case of permanent phrenic nerve injury (of the total three) were recorded. These complications increased the length of time of hospitalization for approximately 49 ± 14 days; nevertheless, no fatalities were recorded during a 3-month follow-up period. Additional risk factor analysis was not performed in the landmark group because this was not an end point of this study. In the landmark group, the occurrence of complications according to the side of cannulation (left/right) was: artery puncture (five/six), hematoma (five/six), pneumothorax (eight/two), hemothorax (four/five), catheter misplacement (six/16), injury of the brachial plexus (four/two), and of the phrenic nerve (two/one) as well as cardiac tamponade (one/zero). Notably, catheter misplacements did not differ significantly between groups (Table 2) and the vast majority occurred into the ipsilateral IJV (95%). However, patients in the ultrasound group were diagnosed during the cannulation procedure, which therefore facilitated immediate repositioning.

Table 1. Baseline characteristics of the study population

Characteristics	Ultrasound Group (n = 200)	Landmark Group (n = 201)
Age (y)	57 ± 12.5	58 ± 11.9
Gender (male/female ratio)	0.52 ± 0.6	0.53 ± 0.5
Acute Physiology and Chronic Health Evaluation score II	20.4 ± 3.5	20.5 ± 3.7
Diagnosis on admission		
Trauma without brain injury	67 (33.5%)	64 (31.8%)
Trauma with brain injury	83 (41.5%)	80 (39.8%)
Burn	5 (2.5%)	8 (3.9%)
Acute respiratory distress syndrome	12 (6%)	11 (5.4%)
Sepsis	20 (10%)	23 (11.4%)
Postsurgical complications	13 (6.5%)	15 (7.4%)
Side of catheterization (left/right)	98/102	104/97
Body mass index (kg/m^2)	25.1 ± 6.1	25.8 ± 6.2
Previous catheterization	48 (24%)	45 (22.4%)
Limited sites for access attempts	39 (19.5%)	36 (17.9%)
Previous difficulties during cannulation	17 (8.5%)	16 (7.9%)
Previous mechanical complications	9 (4.5%)	11 (5.4%)
Known vascular abnormality	2 (1%)	2 (0.9%)
Untreated coagulopathy	2 (1%)	2 (0.9%)
Skeletal deformity	11 (5.5%)	12 (5.9%)
Patients not in Trendelenburg position	58 (29%)[a]	0 (0%)

Comparisons between the ultrasound and the landmark groups. [a]$p < .05$.

Forty-two patients who were not in Trendelenburg position because of increased intracranial pressure in the landmark group were converted to the ultrasound group and were excluded from the statistical analysis. Values are presented either in percentages or as mean ± SD.

Table 2. Outcome measures in the ultrasound group vs. the landmark group of patients

Outcome Measures	Ultrasound Group (n = 200)	Landmark Group (n = 201)[b]
Access time (sec)	26.8 ± 12.5 (16.4–39.2)	44.8 ± 54.9 (30.1–70.4)
Success rate	200 (100%)[a]	176 (87.5%)
Average number of attempts	1.1 ± 0.3 (1.1–1.5)[a]	1.9 ± 0.7 (1.5–2.7)
Artery puncture	1 (0.5%)[a]	11 (5.4%)
Hematoma	3 (1.5%)[a]	11 (5.4%)
Pneumothorax	0 (0%)[a]	10 (4.9%)
Hemothorax	0 (0%)[a]	9 (4.4%)
Catheter misplacement	19 (9.5%)	22 (11%)
Injury of the brachial plexus	0 (0%)[a]	6 (2.9%)
Phrenic nerve injury	0 (0%)[a]	3 (1.5%)
Cardiac tamponade	0 (0%)	1 (0.5%)

Comparisons between the ultrasound and the landmark group of patients. [a]$p < .05$; [b]twenty patients in whom cannulation was not possible with the landmark method because of thrombosis were placed in the ultrasound group and were excluded from the statistical analysis. Access time and average number of attempts are expressed as mean ± SD (95% confidence intervals).

All operators reported difficulties in depicting a clear two-dimensional infraclavicular image of the SCV and performing adjustments on the longitudinal axis to visualize the trajectory of the needle, because there is a more narrow footprint of the probe compared with a transverse technique. However, they all managed to depict an optimum plane to cannulate the vessel in real-time. Operators reported that an area of interest could be identified, on a two-dimensional image, at the level where the axillary vein continues medially as the SCV (Fig. 1). The actual point of insertion of the needle in the lumen of the vessel and thus the angle of penetration was dependent on the operator and on the anatomic diversities that were encountered in each individual patient (e.g., obese patients). The insertion of the needle in the lumen of the vessel was identified either at the level of the axillary vein (Fig. 1*D*) or at the point where the latter continues medially as the SCV (Fig. 2*A*). The postprocedural evaluation of the ultrasound method for SCV cannulation was performed by means of a semiquantitative scale (0–10) as mentioned previously. Physicians have rated the ultrasound-guided SCV cannulation with an infraclavicular approach as a technically complex task (8 ± 0.2) on this scale.

DISCUSSION

Our group has previously documented the superiority of the real-time ultrasound method vs. the landmark one for the cannulation of the IJV (9). However, the ultrasound-guided SCV cannulation has been reported to be technically demanding, which is in accordance with the present results (6, 10, 11). In this study, a real-time ultrasound-guided technique for the routine cannulation of the SCV was used, under nonemergency conditions, in the ICU. We pursued the longitudinal axis approach to avoid the transfixion of the vein and enable the detailed visualization of the vessel's course as previously described (9). From a technical point of view, if maneuvers of the needle and adjustments of the angle of penetration are necessary to be performed on the longitudinal axis, this may increase the complexity of the procedure taking into account the narrow footprint of the probe as compared with the transverse technique. Alternative ultrasound methods for the SCV cannulation have been described lately; however, these methods do not increase the incidence of the visualization of the trajectory and/or the tip of the needle, no real-time technique is clearly illustrated, and their effect on the rate of mechanical complications has not been evaluated (15, 16). The SCV is 3–4 cm long and lies posterior to the medial third of the clavicle; anterior to the anterior scalene, the brachial plexus, and the subclavian artery; and superior to the first rib (Fig. 1) (17). The vein may stay patent even in hypovolemia presumably as a result of the fact that the vessel is surrounded by connective tissue, which is affixing it to adjacent structures (16). Notably, serious complications occur more commonly with SCV catheterization than with other routes (5, 6).

Using the landmark method, we found a success rate and an incidence of mechanical complications that were both comparable to previous studies (5, 6, 10, 11). Notably, several patients of the landmark group were converted to the ultrasound group and were excluded from the analysis (e.g., patients who were not in the Trendelenburg position as a result of increased intracranial pressure) and surely these are not routine patients. Further analysis of risk factors in the landmark group was not performed because this was not an end point of this study. Risk factors for the SCV cannulation such as a body mass index >30 and

<20 kg/m^2 and two or more needle passes, which are associated with both higher complication and failure rates, are well established in the literature (6). In this series, despite the fact that there were no fatalities, a significant increase of the time of hospitalization was observed as a result of the mechanical complications that were evident in the landmark group. These complications could generate additional ones (e.g., infections) or increase the cost of hospitalization and may even result in the permanent disability of the patient (e.g., permanent phrenic nerve injury) as previously reported (5–11). The present results showed that pneumothorax occurred more frequently on the left side as compared with the right one, which may be the result of the fact that the apex of the right pleura is usually lower than the left (18). In contrast, catheter misplacements into the ipsilateral IJV occurred more commonly on the right side presumably as a result of the more acute angle of the right SCV with the right IJV because they form the right brachiocephalic vein if compared with the less acute angle observed on the left (19, 20). Accordingly, other studies reported a higher complication rate and increased technical difficulty when placing a catheter into the right SCV (20, 21). In the landmark group, we documented three cases of phrenic nerve injury, which may be an underdiagnosed complication of blind SCV cannulation. Phrenic nerve injury may occur because the nerve runs on the anterior scalene, immediately in contact with the posteroinferior side of the SCV at the point of puncture (22). Finally, one case of cardiac tamponade was recorded as a result of perforation of the superior vena cava. Physicians should be aware of this potentially fatal complication, which is likely to be catheter- or guidewire-related and hence not avoidable by using ultrasound guidance, and be diligent when evaluating the catheter's position (6, 9, 13).

Using the ultrasound method, we found a higher success rate and a decreased incidence of mechanical complications as compared with the landmark one ($p < .05$). Previous studies have not used real-time ultrasound-guided techniques for the SCV catheterization (5, 6, 10, 11). However, a great variability in terms of physicians' expertise, ultrasound protocols, and patients' characteristics is evident in published reports (5, 6, 10, 11, 23–25). Other authors favored the infraclavicular approach in the past (26). In this study, the infraclavicular approach was used to facilitate the technical comparison between the ultrasound method and the landmark one. However, the point of skin penetration differs between the two methods. Specific details concerning the point of the insertion of the needle in the lumen of the vein were presented in the previous paragraphs. Hereby, let us underline that if the skin puncture point is located in close proximity to the axillary region, this may increase the risk of damaging the artery and/or the brachial plexus. On the other hand, catheterization in close proximity to the sternum is technically difficult because the clavipectoral fascia may become a barrier to cannulation with the larger introducers. The triple-lumen catheters, which were used in this study, have less difficulty with the proximal approach, but introducers may be trapped and inhibited as the insertion point moves proximally toward the sternum. Despite the mentioned technical considerations, the present ultrasound method offers the following advantages: 1) identification of the adjacent structures; 2) careful penetration strategy by identifying the needle superficially and thereafter catheterization of the vein on the longitudinal axis; and 3) purposeful targeting of the underlying thoracic rib as the needle advances deeper to minimize the risk of damaging the pleurae and the lung if transfixion of the vein is inevitable. Finally, the major advantage is the inherent one of a real-time ultrasound technique. It is worth mentioning that in this study, patients positioned at 30° dorsal elevation, although excluded from the statistical analysis, were all successfully catheterized by means of the ultrasound method. This is in agreement with a previous study of IJV catheterization performed in critical care patients positioned in 30° dorsal elevation (27). Hence, potential deleterious position changes can be avoided in high-risk patients (e.g., patients with brain injury), a phenomenon that is commonly observed in the ICU.

This study exhibits several limitations. Patients of the landmark group who were not in the Trendelenburg position as well as those in whom cannulation was not possible as a result of thrombosis were converted to the ultrasound group; furthermore, they were all excluded from the final analysis. This might have caused selection bias between the groups, which may have reduced the numeric benefit in the ultrasound arm when compared with the landmark one. A possible disadvantage of the suggested ultrasound method is its complexity because the experienced physicians who participated in this study have rated the method as technically difficult. The benefits of the ultrasound method may not accrue until after a significant learning period and its learning curve may be highly operator-dependent (28); however, this was not an end point of this study. It is of note that we have recorded complications in the ultrasound group (e.g., hematoma resulting from inadvertent arterial damage either to the adjacent main artery or some of the many branches in this area) as others have previously reported (29). Despite the mentioned limitations, we provided evidence that ultrasound guidance should be used for the routine catheterization of the SCV because the latter, even in experienced hands, may cause various complications (5, 6, 10, 11, 23–25). Finally, let us underline that previously established guidelines have already characterized ultrasound-guided vascular access as one of the top 11 evidence-based practices (4, 30, 31).

CONCLUSION

We demonstrated the superiority of the real-time ultrasound method over the landmark method for the SCV cannulation in critical care patients. The former results in a significantly higher success rate and in a lower incidence of mechanical complications compared with the latter.

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