

ORIGINAL



A randomized clinical trial of ultrasound-guided infra-clavicular cannulation of the subclavian vein in cardiac surgical patients: short-axis versus long-axis approach

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Abstract

Purpose: The aim of this study was to compare the success rate and safety of short-axis versus long-axis approaches to ultrasound-guided subclavian vein cannulation.

Methods: A total of 190 patients requiring central venous cannulation following cardiac surgery were randomized to either short-axis or long-axis ultrasound-guided cannulation of the subclavian vein. Each cannulation was performed by anesthesiologists with at least 3 years' experience of ultrasound-guided central vein cannulation (>150 procedures/year, 50% short-axis and 50% long-axis). Success rate, insertion time, number of needle redirections, number of separate skin or vessel punctures, rate of mechanical complications, catheter misplacements, and incidence of central line-associated bloodstream infection were documented for each procedure.

Results: The subclavian vein was successfully cannulated in all 190 patients. The mean insertion time was significantly shorter ($p = 0.040$) in the short-axis group (69 ± 74 s) than in the long-axis group (98 ± 103 s). The short-axis group was also associated with a higher overall success rate (96 vs. 78%, $p < 0.001$), first-puncture success rate (86 vs. 67%, $p = 0.003$), and first-puncture single-pass success rate (72 vs. 48%, $p = 0.002$), and with fewer needle redirections (0.39 ± 0.88 vs. 0.88 ± 1.15 , $p = 0.001$), skin punctures (1.12 ± 0.38 vs. 1.28 ± 0.54 , $p = 0.019$), and complications (3 vs. 13%, $p = 0.028$).

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Some preliminary results of this study were reported in abstract form at the 34th International Symposium on Intensive Care and Emergency Medicine. [Corradi F, Brusasco C, Cocconcelli F, Agostinelli A, Benassi F, Gherli T, Vezzani A (2014) Real-time ultrasound-guided subclavian vein cannulation in cardiac surgery: comparison between short-axis and long-axis techniques. *Critical Care* 18(Suppl 1): p 132].

Take-home message Central venous cannulation of the subclavian vein is an important tool in the postoperative treatment of cardiac patients, and there is general consensus on the advantage of using ultrasound for vascular access. The short-axis procedure is associated with a higher success rate, shorter procedure time, and fewer needle redirections and complications than the long-axis approach.

Conclusions: The short-axis procedure for ultrasound-guided subclavian cannulation offers advantages over the long-axis approach in cardiac surgery patients.

Keywords: Subclavian vein, Ultrasound, Central venous cannulation, Scanning axis

Introduction

Central venous cannulation is an important tool in the treatment of cardiac surgical patients. The two main access pathways for this purpose are via internal jugular and subclavian veins. Internal jugular cannulation has the advantage of being less frequently associated with mechanical complications, whereas subclavian vein cannulation (SVC) has the advantage of being less frequently associated with central line-associated blood stream infection and thrombosis [1–4]. For these reasons, the former is preferred during surgery but the latter may be required during the postoperative period to reduce the risk of infection and patient discomfort [2], or to obtain a second line for other treatments, e.g., renal replacement therapy. However, SVC has mechanical complications, including pneumothorax, hemothorax and arterial puncture [5, 6]. In order to reduce their incidence, some authors have proposed the use of ultrasound (US) guidance [7–9]. This method has been recommended by all guidelines for venous access, but not specifically for SVC [10, 11].

Two different real-time two-dimensional US techniques can be employed for real-time US-guided venous access, one using a long-axis/in-plane approach, the other a short-axis/out-of-plane approach [12]. It is still unclear whether one of the above techniques is superior to the other [13, 14]. Regarding SVC, the two techniques have been compared in mannequin models with discordant results [15–17]. To our knowledge, only one human study compared landmark versus US-guided SVC using long-axis, but none comparing the long- versus the short-axis technique. The main differences between these two techniques are that the former allows a direct visualization of the needle and vein, whereas the latter only allows visualization of the structures surrounding the vein. Therefore, the present study was designed to compare the success rate and safety of short- and long-axis US-guided post-operative SVC in cardiac surgery patients.

Materials and methods

Study population

This prospective randomized clinical trial was conducted in the Adult Cardiac Surgery Intensive Care Unit ($n = 9$ beds) of the University Hospital of Parma. The study protocol was approved by the local Ethics Committee (Prot. n.16368 report n.5/13) and registered in ClinicalTrials.gov (ID: NCT01927185) [18]. A

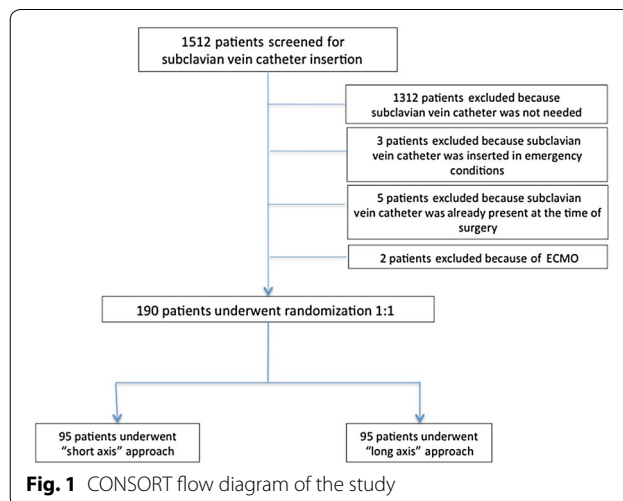


Fig. 1 CONSORT flow diagram of the study

written informed consent to be enrolled in the study was obtained from each of 1,512 patients undergoing cardiac surgery between June 1, 2013 and November 30, 2015. Patients were eventually included if they required the positioning of a second central venous line during the post-operative period for any clinical reason. These were the need of a second line for advanced hemodynamic monitoring ($n = 46$) or hemodialysis ($n = 42$), and the replacement of the internal jugular vein central venous catheter (CVC) for malfunctioning ($n = 67$) or tracheostomy ($n = 35$). Ten patients were not included because they required an emergency central venous line positioning ($n = 3$), or extracorporeal membrane oxygenation ($n = 2$), or because they already had a subclavian vein catheter positioned before surgery ($n = 5$). A flow diagram of the study according to the CONSORT 2010 statement [19] is shown in Fig. 1.

Methods

All SVCs were performed after cardiac surgery when, for clinical reasons (e.g., dialysis, prolonged ventilation, tracheostomy, patient comfort), it was necessary to replace the internal jugular catheter positioned during surgery with a subclavian vein. The decision to perform a SVC and the side of cannulation (right or left) was made by the physician on duty and not involved in the study. Patients were randomized to short- or long-axis approach by means of a computer-generated random-numbers table.

Each cannulation was performed at the patient's bedside by one of two anaesthesiologists (T.M. and A.V.)

with 3- and 6-years' experience in US-guided central vein cannulation, respectively. They had similar experience in short- and long-axis cannulations (>150 procedures/year, 50% short- and 50% long-axis), with >30 SVC/year of which 80% were long-axis. We used non-tunnelled dual-lumen 8F, 20-cm-long CVCs (CS-25802, Arrow Gard Blue®; Teleflex Medical IDA, Business and Technology Park, Athlone, Ireland).

Severe coagulation abnormalities (platelets $\leq 50,000/\mu\text{L}$, or INR ≥ 1.5 , or PTT ≥ 50 s) were corrected before SVC, and anti-coagulant therapy was re-started 2 h after.

US technique

A Philips CX50 system (Philips Healthcare, Eindhoven, Netherlands) equipped with a high-frequency, linear-array probe at 10 MHz was used for all the SVCs. The site of the puncture was prepared using antiseptic solution and protected with sterile drapes, while the probe was covered with a sterile sheath, by using a sterile gel outside

and inside the sheath. A real-time, single-operator, free-hand technique was used. While introducing the needle, the operator held the probe with her/his non-dominant hand, and the needle with dominant hand, to follow the progression of the needle through the tissue into the vein. The vein was approached by scanning the area lateral to the clavicle to view the transition point from the axillary to the subclavian vein, downstream of the joint between the axillary and cephalic veins. The subclavian vein was identified on the lateral border of the first rib anterior to the subclavian artery, in the infra-clavicular fossa [20] (Fig. 2a).

With the long-axis approach, a short-axis view of the vein was first obtained and then the probe was rotated, maintaining the vessel in the middle of the screen, until the vein appeared in the longitudinal view. The probe was positioned almost parallel moving away from the clavicle, and the entry point of the needle was in-plane with the probe. With this approach, only the vein was visible on

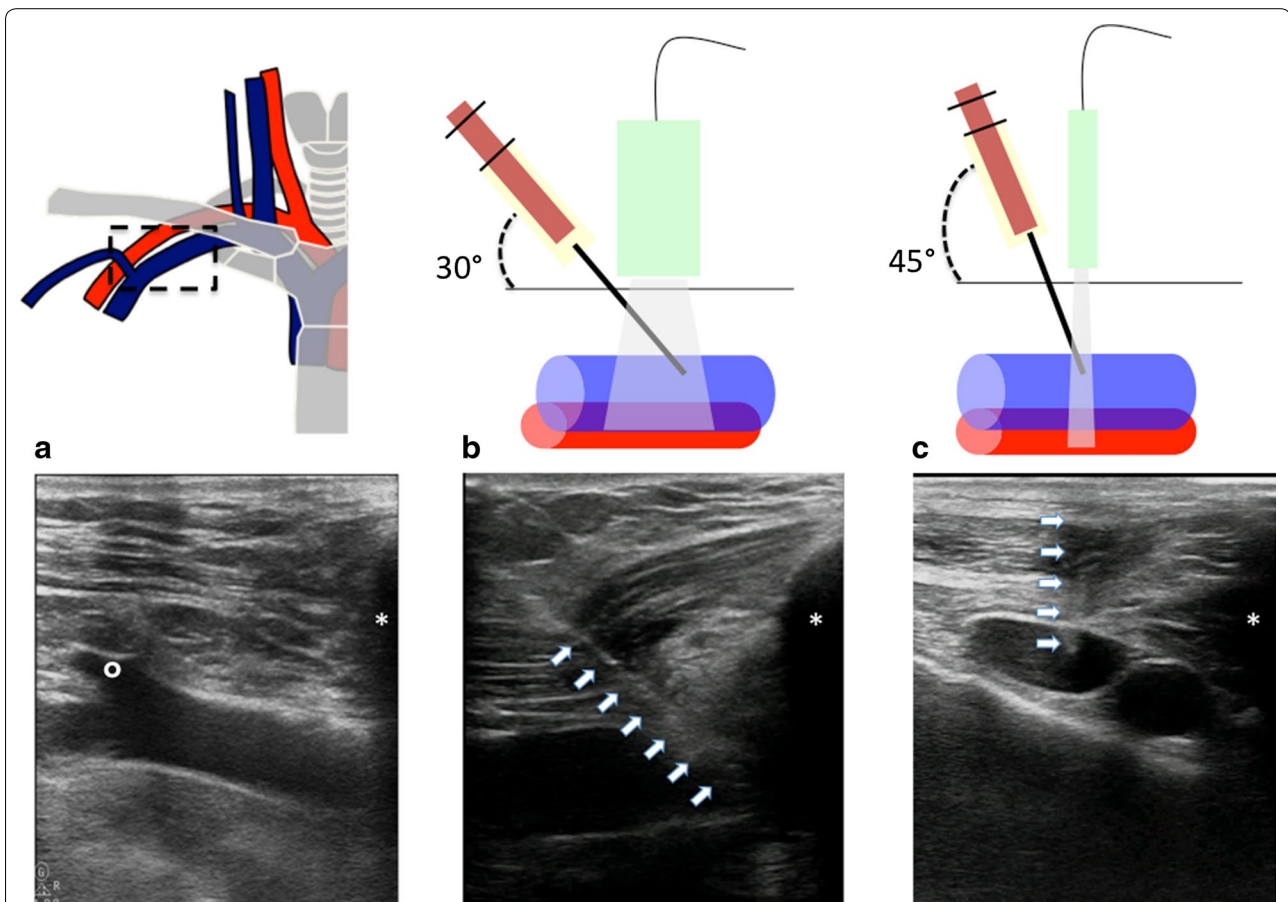


Fig. 2 Upper panels diagrammatic representations of anatomical site (left) and insertion angles for long-axis (middle) and short-axis (right) approaches. Lower panels representative corresponding echo-images. Dashed rectangle shows insertion site, white arrows the needle track. Asterisk clavicle acoustic shadow, white circle cephalic vein

the screen. The needle was held at a 30° angle, oriented in-plane with the transducer, and the skin was punctured at the base of the transducer. The vessel alignment was maintained during the procedure and the entire length of the needle was visible during the progression through the tissues. Entry of the tip into the vessel was confirmed by blood aspiration (Fig. 2b).

With the short-axis approach, the subclavian vein and artery were visualized in transverse scan (cross-sectional image). The pleural line was visible below the vessels. The probe was positioned almost perpendicularly to the clavicle, with its caudal portion over the clavicle, and the point of entry of the needle was out-of-plane with the transducer. The needle was held at an angle of 45° relative to the skin surface and sagittal to the plane of the probe (out-of-plane). During the progression to the vessel, the visualization of the needle was limited to the deformation of tissue and artefacts produced by the needle advancement. When the tip abutted the vein wall, additional pressure produced transient vessel deformation, which disappeared once the wall was penetrated. The presence of the needle in the vein was always confirmed by aspiration of blood into the syringe (Fig. 2c).

In both short- and long-axis approaches, when the tip of the needle was into the vessel, the operator released the transducer, with his/her non-dominant hand stabilizing the needle and with the dominant hand advancing the guide wire into the vessel. The needle was withdrawn and the catheter inserted as usual. An external observer recorded the length of the procedure (access time) from the time when the probe first touched the sterile field of patient's skin to the time when the guide wire was positioned into the subclavian vein. After two failed attempts with the first approach, the procedure was converted to the other approach. If two attempts with the second approach were also unsuccessful, SVC was considered to have failed, and another vein was chosen for cannulation. At the end of the procedure, the position of the catheter and the presence of complications were checked by US as previously described [21]. To complete the procedure, a chest-X-ray was obtained.

Primary and secondary outcomes

The primary outcome was the overall success rate defined as the number of US-guided catheterizations obtained within two attempts. Secondary outcome was assumed by considering the following parameters: (1) insertion time (defined as the time in seconds between the beginning of the procedure and guide-wire insertion); (2) the first puncture with single pass success rate (defined as the first puncture success rate without needle redirections); (3) the number of needle redirections; (4) the number of separate skin punctures; (5) the number of vessel punctures; (6) the

rate of mechanical complications; (7) catheter misplacements; (8) the incidence of central line-associated blood stream infection (CLA-BSI); and (9) the comparisons between the two operators with references with outcome measures.

Statistical analysis

Sample size was calculated assuming a proportion of overall success rate not less than 0.75 in each group. Almost 90 patients per group were required to detect a difference in the proportion of overall success rate between groups not less than 0.15 (alpha = 0.05; power = 0.80; one-tailed test). Data are expressed as mean ± SD, median, range, interquartile range (IQR), count number, or percentages, as indicated. The Shapiro–Wilk test was preliminarily used to evaluate the normal distribution of continuous variables. Unpaired Student's *t*, Mann–Whitney, Chi-squares, or Fischer's exact test were used where appropriate to identify differences between the two groups for continuous or categorical variables. Probability for lack of complications after CVC positioning was calculated with the Kaplan–Meier product-limit estimator. In the Kaplan–Meier plots, the censored/uncensored observations were set for lack/occurrence of complication after CVC positioning. The end of follow-up for censored/uncensored patients corresponded to CVC removal/occurrence of complication. The log-rank (Mantel–Cox) test was applied to evaluate the difference in probability for lack of complications after grouping for short- versus long-axis approach. Statistical significance was assumed with a *p* value <0.05. Statistical analyses were performed by using SPSS (v.20.0; SPSS, Chicago, IL, USA), G*Power (v.3.1.9.2, ©2014, University of Düsseldorf) [22], and R software/environment (v.3.3.2, R Foundation for Statistical Computing, Vienna, Austria).

Results

The positioning of the catheter was possible in all 190 patients with either the short- or long-axis approach. No significant differences were observed in patient characteristics between the two groups (Table 1). The need for subclavian vein catheterization during ICU post-operative stay was within the first 14 days from surgery (mean 7 days). The mean insertion time was significantly shorter in the short-axis group (69 ± 74 s) than in the long-axis group (98 ± 103 s) (Table 2). The short-axis group was also associated with greater overall success rate (96 vs. 78% *p* < 0.001), first puncture success rate (86 vs. 67% *p* = 0.003), and first puncture single-pass success rate (72 vs. 48% *p* = 0.002), as well as fewer needle redirections (0.39 ± 0.88 vs. 0.88 ± 1.15 *p* = 0.001), skin punctures (1.12 ± 0.38 vs. 1.28 ± 0.54 *p* = 0.019), and

Table 1 Baseline characteristics of the study population

Characteristics	Short-axis (n = 95)	Long-axis (n = 95)	p
Age (years)	70 ± 12	71 ± 12	0.839
Sex (male/female)	74/21	68/27	0.404
Body mass index (kg/m ²)	26 ± 4	27 ± 5	0.237
INR	1.26 ± 0.19	1.25 ± 0.16	0.462
aPTT (s)	31 ± 5	31 ± 4	0.947
Platelets (× 10 ³ /μL)	162 ± 80	172 ± 108	0.468
Side of catheterization (left/right)	34/61	40/55	0.457
Days after surgery	7 ± 8	8 ± 7	0.543
Reasons for catheterization (n)			0.652
Dysfunctions	29	38	
Monitoring	28	18	
Renal replacement therapy	21	21	
Tracheostomy	17	18	

complications (3 vs. 13% $p = 0.028$). A statistical significant difference ($p = 0.003$) was observed in the Kaplan–Meyer plots for cumulative complications between the two groups (Fig. 3). Specifically, three catheter misplacements occurred in the short-axis group, compared with seven artery punctures, three CLA-BSI, one hematoma,

one subclavian vein thrombosis and one catheter misplacement in the long-axis group. The larger number of complications in the long-axis group was due to the higher incidence of arterial punctures ($p = 0.014$). In these cases, the operators reported difficulties in obtaining a clear two-dimensional infra-clavicular image of the subclavian vein and performing adjustments on the longitudinal axis to visualize the trajectory of the needle. Notably, catheter misplacements did not differ significantly between groups ($p = 0.621$) and were recognized during cannulation, allowing immediate repositioning. The operator with longer experience (A.V.) presented an increased “first puncture success rate” in the short-axis group (94 vs. 77% $p = 0.017$), and a shortest “insertion time” in the long-axis group ($101 ± 88$ s vs. $164 ± 141$ s $p = 0.029$). For both operators, however, the “first puncture success rate” was higher and the “insertion time” was lower in the short-axis (94 vs. 77% and $65 ± 54$ s vs. $84 ± 98$ s, respectively) than in the long-axis (67 vs. 68% and $101 ± 88$ s vs. $164 ± 141$ s, respectively) group. No difference between operators was recorded in the overall success rate, number of needle redirections, skin and vessel punctures or complications using either a technique.

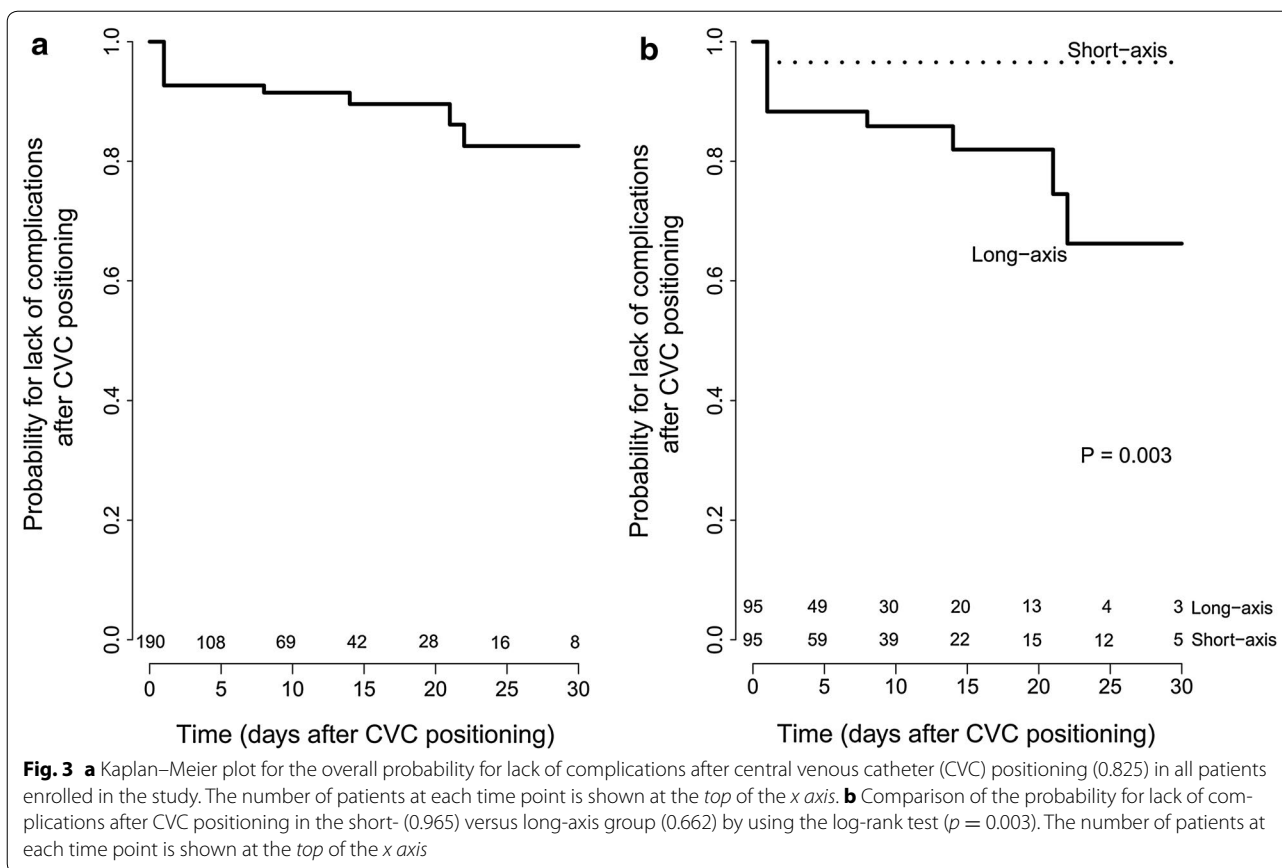
Discussion

This prospective randomized clinical study revealed that the SVC with the infra-clavicular short-axis approach

Table 2 Comparisons between short-axis and long-axis group for primary and secondary outcomes

	Short-axis (n = 95)	Long-axis (n = 95)	p
Primary outcome			
Overall success rate (n and %)	91 (96%)	74 (78%)	<0.001
Secondary outcomes			
Insertion time (s)	69 ± 74	98 ± 103	0.040
First puncture success rate (n and %)	82 (86%)	64 (67%)	0.003
First puncture single pass success rate (n and %)	68 (72%)	46 (48%)	0.002
Average number of needle redirections	0.39 ± 0.88	0.88 ± 1.15	0.001
Average number of skin punctures	1.12 ± 0.38	1.28 ± 0.54	0.019
Average number of vessel punctures	1.01 ± 0.31	0.95 ± 0.47	0.273
Complications (n)	3 (3%)	13 (14%)	0.008
Catheter misplacements (n)	3 (3%)	1 (1%)	0.621
Artery puncture	0	7 (7%)	0.014
CLA-BSI	0	3 (3%)	0.246
Hematoma	0	1 (1%)	0.998
Subclavian vein thrombosis	0	1 (1%)	0.998
Pneumothorax	0	0	–
Hemothorax	0	0	–
Injury of the brachial plexus	0	0	–
Phrenic nerve injury	0	0	–
Cardiac tamponade	0	0	–

CLA-BSI central line-associated blood stream infection



yielded significantly shorter puncture time and higher puncture success rate, along with lower incidence of skin puncture, needle redirections and complications than the infra-clavicular long-axis approach.

Previous research has reported the efficacy and safety of US-guided SVC using the infra-clavicular long-axis approach as compared with the landmark method [8], but, to the best of our knowledge, there are no studies comparing the short- versus long-axis US-guided approaches for SVC in critical care patients.

The present study shows an overall 100% success rate for US-guided SVC combining the short- and long-axis approaches, though the success rate was higher for the short- (96%) than in the long-axis (78%) approach. The difference in the success rate between the two techniques may be in part due to the study design limiting the number of attempts to two for both techniques, in order to limit the complication rate [3, 23].

The higher number of complications in the long-axis approach was mainly due to artery punctures (7%). This is explained by the fact that the long-axis approach cannot simultaneously visualize the subclavian artery and vein, unlike the short-axis approach. In the long-axis approach, veins and arteries can appear similar, particularly when

they are in an uncompressible area. Moreover, the operator needs to line up the thin ultrasound beam with the whole length of the needle, and both of them with the midline axis of the vessel longitudinal plane. During the entire SVC positioning the operator's hand can slide a few millimeters and the three axes can move out of alignment with each other, thus visualizing the artery. In this context, the information regarding the location of the subclavian artery relative to subclavian vein is lost, and the continuous display of the needle (tip and shaft) leads to a misleading sense of safety that may ultimately lead to arterial puncture. Conversely, the short-axis approach requires the alignment of only two axes by positioning the probe perpendicular to the course of the vessel, and allows the visualization of the target vessel and surrounding structures. Both artery and vein can be simultaneously visualized and, even if minimal probe adjustments are required, this offers the operator a good midline orientation. With this technique, the needle tip cannot be seen directly but its progression can be inferred from the movements of surrounding tissues. These are probably the reasons why, in the present study, a higher rate of first-puncture success and a lower insertion time in the short- than in the long-axis approach was achieved.

Our results are consistent with those of Chittoodan et al. [24], who evaluated the short-axis and long-axis approaches to internal jugular vein cannulation in 99 patients by experienced sonographers by finding a higher first pass success rate and fewer carotid artery punctures when a short-axis approach was employed. Similarly, Mahler et al. [25] reported that the success rate was higher in the short-axis group with a lower insertion time in patients undergoing peripheral vein cannulation. In a simulated vascular model, Stone et al. [14] and Blaiwas et al. [15] found that novice US users obtain vascular access faster with a short-axis approach. One reason why the procedure time was found consistently shorter with the short- rather than the long-axis technique is that the latter requires a first short-axis assessment of the vessels followed by probe rotation [24, 26].

Finally, in a large cohort of international experts regarding recommendations for the use of ultrasound in the Intensive Care Unit, Frankel et al. [10] recommended that the short-axis view should be used during insertion of intravascular catheters to improve the success rate, although there are benefits to visualizing the vasculature in both short- and long-axis images. In a phantom-model study, the long-axis technique appeared to be superior because less frequently associated with inadvertent punctures of surrounding structures [14]. However, three studies using human torso mannequin models returned inconsistent results: one showing that the short-axis approach allowed more rapid cannulation but produced accidental penetration of the posterior vessel wall [15], and two showing that the long-axis approach decreased the time to cannulation, and the numbers of redirections and posterior wall penetrations [16, 17]. These studies were limited by the use of phantoms/mannequins and certainly there are differences between models and the human body. First, anatomy varies between people and the interaction with patients is different from that with the vascular phantom. Second, although a pleural line could be noted in a phantom, it is unclear how pleural puncture and subsequent pneumothorax would be appreciated. Third, the authors did not evaluate the placement of the catheter into the venous access sites they investigated. And, fourth, the mannequin does not take into account the collapsibility of the vessel, which will be particularly important in situations such as hypovolemia.

Limitations of the study

The results of this study were obtained by just two experienced operators, and thus cannot be directly extrapolated to physicians with more or less experience with one or other type of US-guided approach. A further study is needed to assess the training necessary to achieve similar results by operators without prior experience. Moreover,

a landmark control group was not included in the study. This was because US has been used with success in our Department for more than 10 years so not using it in all patients was considered unethical. Finally, no patient had massive obesity, which may hamper US visualization of the subclavian vein, thus making internal jugular cannulation preferable.

Conclusion

In conclusion, in cardiac surgery patients, the US-guided infra-clavicular short-axis approach, when performed by an experienced operator, shows some clinical advantages, namely, a higher success rate and fewer complications. Moreover, the catheter insertion time was shorter than with the long-axis approach.

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Acknowledgement

We thank Professor Vito Brusasco for help in the final editing of the manuscript.

Author contributions

Drs Vezzani, Corradi, and Brusasco contributed to study design, data collection and analysis, and the writing of the manuscript, and are the guarantors of the paper; Dr Ramelli contributed to data collection, data analysis, and reading and checking of the manuscript; Drs Santori, Cantadori, and Gonzi contributed to data analysis, statistical revision, and reading and checking of the manuscript; Drs Nicolini and Manca contributed to organization of the study, patient selection, and data collection; Dr Gherli contributed to data analysis and reading and checking of the manuscript.

Compliance with ethical standards

Conflicts of interest

None for all authors.

Received: 25 October 2016 Accepted: 2 March 2017

Published online: 13 March 2017

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