Clinical Trial Protocol

The Journal of Vascular Access

The Journal of Vascular Access I-8

© The Author(s) 2023 Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/11297298231152631 journals.sagepub.com/home/jva

(S)SAGE

Saranya Nagalingam, Sivashanmugam T, Charulatha Ravindran and Rani Ponnusamy

Influence of arm position on the first

pass success rates of ultrasound-guided

infraclavicular axillary vein cannulation

in spontaneously breathing patients: A

randomised clinical trial

Abstract

Background: Significant collapsibility during spontaneous respiration, deeper location, and smaller vein size are key challenging factors to safe infraclavicular axillary vein cannulation. Arm abduction reduces collapsibility, but interventional data supporting this observation is lacking. This study investigates the effect of neutral and abducted arm position on the first pass success rate of infraclavicular axillary vein cannulation in spontaneously breathing patients.

Methods: One hundred and twelve patients were randomly assigned to two arm positions, neutral or abducted by 90° at the shoulder joint. Under ultrasound guidance, the infraclavicular axillary vein was cannulated using an in-plane approach. The primary outcome was the first pass success rate of guidewire placement in the infraclavicular axillary vein. The secondary outcome measures were the number of attempts for successful cannulation, failure rate, and catheter tip malposition.

Results: Fifty-two patients in the neutral arm and fifty-six patients in the arm abduction group were compared according to the intention to treat analysis. The abducted arm position was associated with a higher first pass success rate (RR = 3.39, 95% CI = 1.47 - 7.85; p = 0.004) with fewer attempts (p = 0.005), lower failure rate (RR = 1.37, 95\% CI = 1.16-1.61; p = 0.000) and lower catheter tip malposition (1.5 vs 15.8%; p = 0.012) when compared to the neutral arm position. Conclusion: Abducted arm position resulted in a significantly higher first pass success rate with a lower failure rate and catheter tip malposition during ultrasound-guided infraclavicular axillary vein cannulation in spontaneously breathing patients.

Keywords

Arm position, cannulation, collapsibility, infraclavicular axillary vein, ultrasound

Date received: 30 September 2022; accepted: 7 January 2023

Introduction

Infraclavicular axillary vein (IAV) is the preferred site for short-term central venous access in patients with tracheostomies, cervical spine injuries, the neurosurgical cohort, and long-term access in patients with subcutaneous ports and implanted catheters.^{1,2} However, the key factors hindering safe cannulation are significant collapsibility of the vein during spontaneous breathing, deeper location, and smaller vein size.^{3,4}Attempts to cannulate the vein with marked collapsibility can increase the number of needle punctures and result in serious complications such as

pneumothorax and arterial puncture in a non-compressible region. The Trendelenburg position,5 retracted shoulder

Department of Anaesthesiology, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth University (Deemed to be), Puducherry, India

Corresponding author:

Charulatha Ravindran, Department of Anaesthesiology, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth University (Deemed to be), Pondicherry Cuddalore ECR, Pillayarkuppam, Puducherry 607402, India. Email: ravindrancharulatha@gmail.com

position⁶ and arm abduction^{7–9} have been evaluated for their ability to improve venous diameter and decrease collapsibility. Among these, arm abduction was shown to significantly decrease the collapsibility index and increase the cross-sectional area and circumference of the vein during spontaneous breathing.⁸ This observation can have important implications in reducing the number of needle passes and attempts required for IAV cannulation; however, evidence to support this hypothesis is lacking. Hence, we have designed this study to analyse the influence of two different arm positions (arm in neutral or abducted to 90° at the shoulder joint) on the first pass success rate of guidewire placement during IAV cannulation in spontaneously breathing patients.

Methods

Patient recruitment

This randomised clinical trial was approved by the Institutional Human Ethics Committee of Mahatma Gandhi Medical College and Research Institute on 02.12.2019 (MGMCRI/Res/01/2019/11) and was prospectively registered with the Clinical Trial Registry of India (CTRI/2020/11/029207). Patients who received central venous catheterisation for various perioperative indications between December 2020 and June 2022 formed the study population. Inclusion criteria were spontaneously breathing patients aged 18 and above, belonging to ASA physical status 1–4. Patients who needed emergency vascular access, critically ill, unable to abduct their shoulder due to any reasons, infection at the site of cannulation and pregnant women, were excluded. Written informed consent was obtained from all participants.

Group allocation

One hundred and twelve patients were enrolled. Block randomisation was performed using an online random number generator (www.randomizer.org) with a block size of 8. The study participants were allocated to one of the two groups by sealed envelope technique: the neutral group and the arm abducted group. Patients in the neutral group had their arm placed close to the torso, and in the abduction group, an arm board was placed parallel to the table surface and the arm was abducted to 90° at the shoulder joint with forearm in supination. An anaesthesia resident generated the random number, prepared the envelopes, and took no further part in the study.

One of the two authors (ST and CR), who were experts in ultrasound-guided vascular access, completed all the catheterisations to reduce the performer bias. On arrival in the operating room, standard monitors were established, and patients were sedated with Inj Midazolam 1 to 3 mg and Inj Fentanyl 50 μ g IV five minutes before the start of the procedure. The right IAV was the primary access site for all patients.

Ergonomics and equipment settings

A SonoSite X-Porte ultrasound system (SonoSite, Bothell, WA, USA) with high-frequency linear array transducer L25x (13–6MHz, 25 mm footprint) was used for all the cannulations. The head was slightly turned to the opposite side, the performer stood on the side of the arm to be cannulated, and the ultrasound machine was positioned across the table from the performer and the arm was placed according to the group allocation.

Scanning and cannulation technique

The ultrasound probe was initially placed beneath the clavicle medial to the coracoid process in the sagittal plane to identify the axillary vessels in the short-axis view. The probe was turned oblique to visualise the IAV in the long axis view, then moved medially to trace the vein disappearing under the clavicular shadow (Figure 1(a)). In an optimised sonogram, the clavicle and its post acoustic shadow occupied one-third, and the IAV in its longitudinal section occupied two-thirds of the USG window (Figure 1(b)). The cannulation procedure was performed adhering to the ASA Practice Guidelines for Central Venous Access 2020 using the Seldinger technique. The vascular access device used was a 7 Fr single or triple lumen CICC made of radiopaque polyurethane (Ablecath Vascular catheter, Guandong Baihe Medical Technology, Guandong, China). After local anaesthetic infiltration with 5 ml of 1% lignocaine, the puncture needle was introduced 0.5 cm lateral to the distal end of the probe (Figure 1(c)). The infraclavicular axillary vein was accessed through the in-plane technique. The guidewire was threaded into the vein on the free aspiration of venous blood (Figure 1(d)). Correct placement of the guidewire was confirmed by scanning the ipsilateral internal jugular vein (IJV) and the confluence of IJV and the subclavian vein. If the guidewire was found in the IJV, then the guidewire was redirected to the subclavian vein by manipulation or removed if not possible for correct placement.

Definitions of study outcomes and rescue measures

First pass success was defined as the correct placement of guidewire in the infraclavicular axillary vein in the first attempt. An attempt was defined as needle entry into and exit from the skin. If venous puncture was unsuccessful at the third attempt, the procedure was termed failure in the allocated group, cross-over to the other group occurred, and cannulation was attempted. After two attempts in the crossed-over arm position, the ipsilateral internal jugular

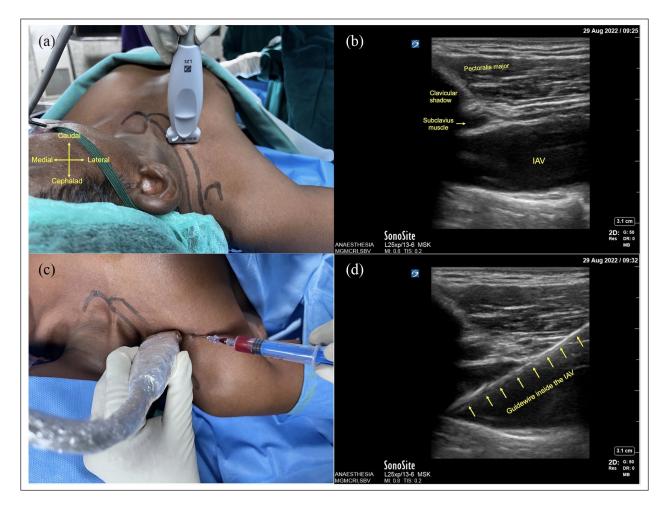


Figure 1. Patient and sonographic images related to in-plane cannulation of the infraclavicular axillary vein. (a) Ultrasound probe position over chest wall. (b) Sonographic image of the right IAV. (c) Needle puncture of IAV with aspirate of venous blood. (d) In-plane visualisation of guidewire inside the IAV. IAV: infraclavicular axillary vein.

vein was cannulated. If the failure to cannulate in the allocated arm position was due to collapsibility of the vein, then crossing over to the other group occurred after two attempts.

The number of attempts for successful cannulation, failure rate, the incidence of guide wire malposition, arterial puncture, and pneumothorax were recorded. On the first postoperative day, the catheter tip position was confirmed with a chest radiograph, and catheter tip malposition, if any, was noted. Catheter tip malposition was defined as migration of catheter tip into ipsilateral IJV or contralateral brachiocephalic vein. Three measurements were taken to derive two study parameters with the patient in a semi-recumbent position. The first two measurements were taken with the arm in a neutral position: (a) distance between catheter skin entry site to a vertical line drawn from the midpoint of sternoclavicular notch over the sternum (mid-sternal line), (b) distance between a vertical line drawn from the ipsilateral coracoid process to the midsternal line (breadth of hemithorax). The ratio between a and b indicated the position of the catheter entry site with respect to the hemithorax of that patient (Figure 2(a)). (c) distance between the catheter skin entry site to the midsternal line in the arm abducted position. The difference between a and c indicated the degree of displacement of the catheter fixation site with arm movement (Figure 2(b)). Catheter care was provided as per the institute vascular access protocol in their appropriate care areas and removed when no longer required.

Sample size calculation

The sample size was calculated with online software (www. sealedenvelope.com, Sealed Envelope Ltd 2012), using the first pass success rate of guidewire placement into the infraclavicular axillary vein as the primary outcome variable.

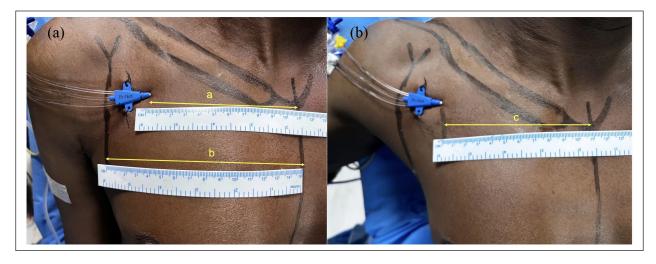


Figure 2a. Measurements taken to calculate catheter entry over hemithorax breadth ratio. (a) Distance between catheter entry site and mid – sternal line with arm in neutral position (b) Distance between the coracoid process and the mid – sternal line (hemithorax Breath).

Figure 2b. Measurements taken to calculate the catheter entry site movement with change in arm position. (c) Distance between the catheter entry site and mid – sternal line with arm in abduction.

Vezanni et al. have previously reported a 72% incidence of the first pass success rate of guidewire placement during ultrasound-guided infraclavicular axillary vein cannulation with the arm in the neutral position.¹⁰ Based on our previous experience, we hypothesised that arm abduction would increase the first pass success rate by 30 % (72%–93.6%). It was calculated that 48 patients in each group would provide 80 % power with an alpha error of 0.05. We recruited 56 patients in each group to allow a matched block randomisation of 8, adjust for cross-over, and compensate for dropouts.

Data analysis

The data were entered in a Microsoft Excel spreadsheet (Microsoft Corporation, Redmond, Washington, USA). The analysis was performed using the Statistical Package for Social Sciences version 16 (IBM Corp, Armonk, New York, USA). Determination of normality was performed by the Shapiro- Wilk test. Categorical variables include first pass success rate of guidewire placement, failure to cannulate in allocated arm position, guidewire malposition into IJV, the incidence of arterial puncture, pneumothorax, and catheter tip malposition in postoperative X-ray, which was presented as number (%) and analysed with Chi-square test. Relative risk and 95% confidence intervals were reported for categorical variables. Continuous variables such as the ratio between catheter skin entry site and hemithorax breadth and mean distance of movement of the catheter entry site in neutral and abducted arm positions were presented as mean \pm SD and were compared with an unpaired T-test. Ordinal data between two groups (number of attempts in the allocated group) were compared with the Mann-Whitney U test. Two-tailed analysis was done for continuous variables, and a p value less than 0.05 was reported to be significant.

Results

Figure 3 represents the CONSORT diagram. We performed an intention-to-treat analysis (the patients who crossed over to the other group were retained in the allocated group for statistical analysis) for the first pass success rate of guidewire placement, the number of attempts, and failure to cannulate in the allocated group. Per protocol analysis was performed for the rest of the study outcomes.

The physical characteristics of the two study groups were comparable (Table 1). Fifty-two patients in the neutral arm group and fifty-six patients in the arm abduction group were compared according to the intention to treat analysis. The abducted arm position provided high first pass success rate (RR=3.39, 95% CI=1.47–7.85; p=0.004) with fewer attempts (p=0.005) and lower failure rate (RR=1.37, 95% CI=1.16–1.61; p=0.000) when compared to the neutral arm position during IAV cannulation (Table 2). Fourteen patients who could not be cannulated with the arm in the neutral position were crossed over to the abducted arm position.

Sub-group analysis of the fourteen patients who crossed over to the abducted arm group revealed first attempt success in nine patients, and three required a second attempt. Two patients could not be cannulated in both the arm positions and received right internal jugular vein catheterisation, leading to 38 patients in neutral and 68 patients in the abducted arm group for per protocol analysis. The incidence of guidewire malposition did not statistically differ between the groups. The incidence of catheter tip malposition was lower in the arm abducted group compared to the neutral arm position (1.5 vs 15.8%; p=0.012). None of the patients in both groups registered any incidence of arterial puncture or pneumothorax. In the abducted arm position

	Neutral arm position group (n=52)	Abducted arm position group $(n=56)$
Age (years)	49.45 ± 10.64	47.02 ± 15.39
Males	31 (60)	32 (57)
Females	21 (40)	24 (43)
BMI	27.98 ± 4.89	27.92 ± 6.18

Table 1. Baseline characteristics of patients included in the study.

Values are mean \pm SD and number (%).

Table 2. Results of procedural data of the study analysed by intention

Result	Neutral arm position group (n=52)	Abducted arm position group (n=56)	þ Value	RR	95% CI
First pass success rate of guidewire placement	27 (51.9%)	44 (78.6%)	0.004*	3.39	1.47–7.85
Number of attempts in the allocated group			0.005*		
First attempt	27 (51.9%)	44 (78.6%)			
Second attempt	15 (28.8%)	12 (21.4 %)			
Third attempt	10 (19.2%)	0			
Failure in the allocated group	14 (26.9%)	0	0.000*	1.37	1.16-1.61

RR: relative risk; CI: confidence interval.

Values are number (%).

*Statistically significant difference between the groups

Table 3.	Secondary	outcomes	(per	protocol	anal	ysis).
----------	-----------	----------	------	----------	------	--------

Results	Neutral arm position group (n=38)	Abducted arm position group (<i>n</i> = 68)	p Value
Guidewire malposition (IJV)	7 (18.4%)	7 (10.2%)	0.235
Catheter tip malposition	6 (15.8%)	1 (1.5 %)	0.012*
Catheter entry site: Hemithorax breadth ratio (%)	82 ± 12	76 ± 9	0.006*
Catheter skin entry site movement between neutral and abducted arm position (mm)	2.3 ± 0.4	0.6 ± 5	0.129

Values are number (%) and mean \pm SD.

*Statistically significant difference between the groups.

group, the catheter entered the skin more medially with respect to the hemithorax breath (76 vs 82%; p=0.006). However, the displacement of the catheter skin entry site was not significantly different between the groups (0.6 vs 2 mm; p=0.129) (Table 3).

Discussion

Infraclavicular axillary veins are conventionally cannulated with the arm in a neutral position.^{11–14} This randomised trial shows that the abducted arm position offers a significantly higher first pass success rate with fewer overall attempts, lower failure rate and catheter tip malposition compared to the arm in the neutral position during USG-guided IAV cannulation.

The relevant anatomical changes that occur during arm abduction and contribute to the enhanced ultrasound visibility of IAV have been thoroughly established. Arm abduction moves the lateral end of the clavicle cephalad over the rib cage,¹⁵ and this exposes the 2–3 cm proximal length of IAV, otherwise obscured by the post acoustic shadow of the clavicle when the arm is in a neutral position.^{8,15} This proximal portion of the IAV is also less collapsible because it is tethered to the clavipectoral fascia enclosing the subclavius muscle.¹⁶ As the IAV ascends over the rib cage it receives the cephalic venous drainage and at its proximal end, becomes more prominent and superficial before disappearing under the clavicle.⁸ Arm abduction also straightens the vein, reduces the arteriovenous overlap and aligns anterior and posterior walls during US visualisation.¹⁷ All these factors would have contributed to the higher first pass success rate of IAV cannulation with abducted arm position. In contrast, when the arm is in a neutral position, the caudad movement of the clavicle obscures the proximal superficial part of the IAV, leaving the deeper distal part for visualisation. In addition,

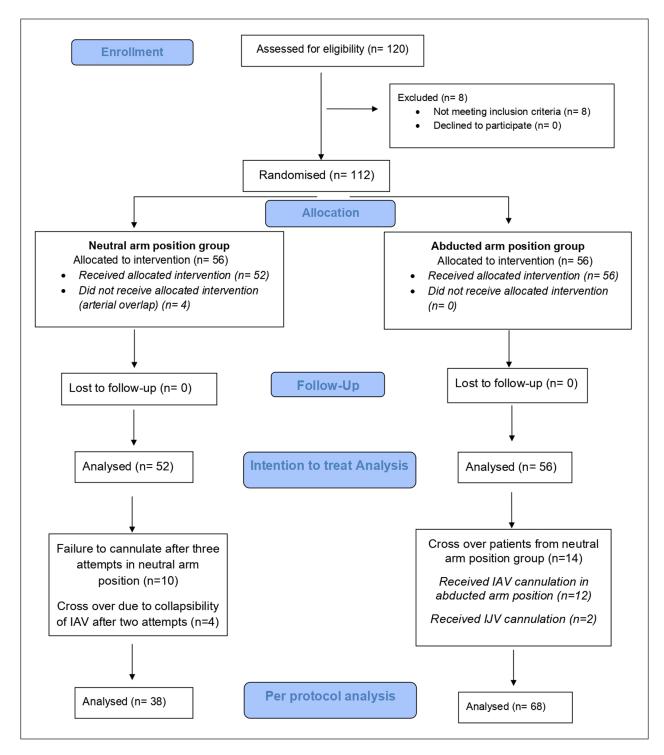


Figure 3. CONSORT diagram.

the neurovascular bundle takes a downward curve at this juncture, dives deep to reach the axilla, making it more challenging to align the ultrasound beam, needle, and vein during cannulation.

During arm abduction, the decreased angle between the subclavian and the internal jugular veins may have contributed to the reduced incidence of guide wire malposition.¹⁷ However, the increased incidence of catheter tip malposition in the neutral arm position cannot be attributed to misplaced guide wires because they were redirected to the SVC prior to catheter threading. Even though the catheter enters the skin more laterally on the mobile part of the pectoral region when the arm is in neutral position, there was no clinically significant

6

difference in the movement of the catheter skin entry site between the groups. Therefore, we hypothesise that the movement of the in vivo extravascular portion of the catheter could be the cause for catheter tip malposition.¹⁸ A higher incidence of the guide wire and catheter tip malposition in the neutral arm position has been previously described by numerous authors.^{12,13,17}

The fundamental limitation of our study was that all the cannulations were performed by experienced operators to reduce performer bias. Hence the results cannot be extrapolated to novice trainers. We have not defined ideal catheter tip position in the SCV/SVC-RA junction, as fixed length polyurethane catheters were used in our low resource setting which did not offer the scope of adjusting catheter tip after placement. Since we did not have any strategy in place to detect final catheter tip position during the procedure, we have diagnosed catheter tip malposition post procedure with chest Xray which is not in line with current recommendations. Identification of catheter tip during the procedure with transthoracic echocardiography could have reduced malposition during the insertion time. The higher incidence of failure to cannulate in the neutral arm group could be partly contributed by the robust research protocol that crossing over to the other group occurred after two attempts in case of significant vein collapsibility which is known to occur more commonly in neutral arm position. Keeping in mind the unknown influence of the longer intrathoracic course of the left brachiocephalic vein, we have cannulated right IAV in all patients.

Conclusion

Placing the arm in the abducted position increased the first pass success rate, decreased the number of attempts, and lowered the incidence of catheter tip malposition compared to the arm in the neutral position during USG-guided IAV catheterisation. Hence, 90° abduction at the shoulder joint can be proposed as the ideal arm position for infraclavicular axillary vein cannulation in spontaneously breathing patients.

Acknowledgements

We thank the faculty and postgraduates of the department of Anaesthesiology, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth University, Puducherry, India, for their help in the data collection.

Author contributions

Dr Saranya Nagalingam acquired data, revised the article, and approved the final version. Dr Sivashanmugam T has contributed to the concept of the work, acquisition, data analysis drafted and revised the article and approved the final version. Dr Charulatha Ravindran has contributed to data acquisition and analysis, drafted, and revised the article, and approved the final version. Dr Rani Ponnusamy has contributed to data analysis, revised the article, and approved the final version.

Data accessibility

Research data can be obtained by sending an email to the corresponding author at ravindrancharulatha@gmail.com

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Trial Registry number

Clinical Trial Registry – India URL – http://ctri.nic.in Registration number – CTRI/2020/11/029207 Date of registration – 18.11.2020

ORCID iD

Charulatha Ravindran (D) https://orcid.org/0000-0002-4905-0645

References

- Practice guidelines for central venous access 2020: an updated report by the American Society of Anesthesiologists Task Force on central venous access. *Anesthesiology* 2020; 132: 8–43.
- Chen YB, Bao HS, Hu TT, et al. Comparison of comfort and complications of implantable venous access port (IVAP) with ultrasound guided internal jugular Vein (IJV) and axillary Vein/subclavian Vein (AxV/SCV) puncture in breast cancer patients: a randomized controlled study. *BMC Cancer* 2022; 22: 248.
- Spencer TR and Pittiruti M. Rapid Central Vein Assessment (RaCeVA): A systematic, standardized approach for ultrasound assessment before central venous catheterization. J Vasc Access 2019; 20: 239–249.
- Bodenham A and Lamperti M. Ultrasound guided infraclavicular axillary vein cannulation, coming of age. Br J Anaesth 2016; 116: 325–327.
- Ford DR, Witting MD, Vora MV, et al. No effect of Valsalva maneuver or Trendelenburg angle on axillary vein size. J Emerg Med 2013; 45: 452–457.
- Kim HJ, Jung SH, Min J, et al. Comparison of the neutral and retracted shoulder positions for infraclavicular subclavian venous catheterization: a randomized, non-inferiority trial. *Br J Anaesth* 2013; 111: 191–196.
- Sadek M, Roger C, Bastide S, et al. The influence of arm positioning on ultrasonic visualization of the subclavian vein: an anatomical ultrasound study in Healthy Volunteers. *Anesth Analg* 2016; 123: 129–132.

- Ravindran C, Thiyagarajan S, Velraj J, et al. Arm position and collapsibility of infraclavicular axillary vein during voluntary breathing: an ultrasound-guided observational study. *J Vasc Access* 2020; 21: 39–44.
- Pittiruti M, Biasucci DG, La Greca A, et al. How to make the axillary vein larger? Effect of 90° abduction of the arm to facilitate ultrasound-guided axillary vein puncture. *J Crit Care* 2016; 33: 38–41.
- Vezzani A, Manca T, Brusasco C, et al. A randomized clinical trial of ultrasound-guided infra-clavicular cannulation of the subclavian vein in cardiac surgical patients: short-axis versus long-axis approach. *Intensive Care Med* 2017; 43: 1594–1601.
- Buzançais G, Roger C, Bastide S, et al. Comparison of two ultrasound guided approaches for axillary vein catheterization: a randomized controlled non-inferiority trial. *Br J Anaesth* 2016; 116: 215–222.
- Sharma A, Bodenham AR and Mallick A. Ultrasoundguided infraclavicular axillary vein cannulation for central venous access. *Br J Anaesth* 2004; 93: 188–192.
- 13. O'Leary R, Ahmed SM, McLure H, et al. Ultrasoundguided infraclavicular axillary vein cannulation: a useful

alternative to the internal jugular vein. *Br J Anaesth* 2012; 109: 762–768.

- Su Y, Hou JY, Ma GG, et al. Comparison of the proximal and distal approaches for axillary vein catheterization under ultrasound guidance (PANDA) in cardiac surgery patients susceptible to bleeding: a randomized controlled trial. *Ann Intensive Care* 2020; 10: 90.
- 15. Sivashanmugam T, Kulandyan I, Velraj J, et al. Sonographic visualization and cannulation of the axillary vein in two arm positions during mechanical ventilation: a randomized trial. *J Vasc Access* 2020; 21: 210–216.
- Kawagishi K, Tokumine J and Lefor AK. The relationship of the subclavius muscle with relevance to venous cannulation below the clavicle. *Anesthesiol Res Pract* 2016; 2016: 6249483.
- Ahn JH, Kim IS, Shin KM, et al. Influence of arm position on catheter placement during real-time ultrasound-guided right infraclavicular proximal axillary venous catheterization. *Br J Anaesth* 2016; 116: 363–369.
- Jahagirdar SM, Laxmimani, Athiraman U, et al. Migration of subclavian venous catheter tip: patient positioning in ICU makes a difference. *Indian J Crit Care Med* 2013; 17: 193–194.