Original Article

Ultrasound-guided catheterisation of the subclavian vein: freehand vs needle-guided technique*

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Summary
The objective of this prospective, randomised study was to examine the impact of a multi-angle needle guide for ultrasound-guided, in-plane, central venous catheter placement in the subclavian vein. One hundred and sixty patients were randomly allocated to two groups, freehand or needle-guided, and then 159 catheterisations were analysed. Cannulation of the first examined access site was successful in 96.9% of cases with no significant difference between groups. There were three arterial punctures and no other severe injuries. Catheter misplacements did not differ between the groups. Higher success rates within the first and second attempts in the needle-guided group were observed ($p = 0.041$ and $p = 0.019$, respectively). Use of the needle guide reduced the access time from a median (IQR [range]) of 30 (18–76 [6–1409]) s to 16 (10–30 [4–295]) s; $p = 0.0001$, and increased needle visibility from 31.8% (9.7%–52.2% [0–96.67]) to 86.2% (62.5%–100% [0–100]); $p < 0.0001$. A multi-angle needle guide significantly improved aligning the needle and ultrasound plane compared with the freehand technique when cannulating the subclavian vein. Use of the guide resulted in faster access times and increased success at the first and second attempts.

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Introduction
The benefits of real-time ultrasound guidance when compared with landmark-based techniques for the placement of central venous catheters (CVCs) are well established [1]. These include faster procedure times as well as lower complication rates [2–5]. However, severe complications, such as arterial puncture, haematoma, pneumothorax and lung injuries can still occur [6–10]. To date, there have been only a few studies on ultrasound-guided vascular access of the subclavian (axillary) vein [2, 3, 8, 11], and it remains unclear which technique is best. We know from ultrasound-guided regional anaesthesia that inadequate probe manoeuvres, failure to align the needle and the ultrasound beam or needle advances without a good view are common errors in ultrasound guidance [12, 13]. In a comparison of the in-plane and out-of-plane techniques for cannulation of the subclavian vein, the in-plane technique caused less posterior vessel wall penetrations [14]. In a torso phantom, the in-plane technique increased the rate of first-attempt success and reduced the number of needle re-directions [15].

An in-plane needle guide improved needle and ultrasound beam alignment in a vessel phantom [16]. We hypothesised that a needle guide optimises the in-plane technique by reducing alignment errors, decreasing access time and improving success rates and needle visibility.

Methods

This prospective, randomised trial was approved by the Ethics Committee of the Faculty of Medicine of Ruhr University, Bochum, Germany. All patients gave written informed consent. Inclusion criteria were adults requiring a CVC for surgery. Of the 157 patients scheduled for surgery, 160 catheterisations were planned and these were randomly allocated to two groups, freehand and needle-guided (using a multi-angle in-plane needle guide), by using a computer-generated random numbers table and by block permutation. All CVCs were placed using an in-plane technique under ultrasound guidance. All except two CVCs were inserted after induction of general anaesthesia and during mechanical lung ventilation. In two patients, the CVC was placed while awake and was used for induction. Fluoroscopy was not utilised. Monitoring consisted of capnography, electrocardiography (ECG), pulse oximetry and non-invasive or invasive blood pressure measurement.

Before cannulation, an ultrasound examination of the subclavian vein was performed in all patients while in the supine position. The examination included: an adjustment of the ultrasound preset, gain, focus, depth and frequency; arrangement of the respective arm to ensure the optimal degree of arm abduction to reveal the subclavian vein; and scanning to detect vascular pathology (thrombosis). Three different machines were used, depending on availability, and all machines were equipped with linear transducers (MyLab 25 Gold XVG, Esaote Biomedica, Cologne, Germany; Logiq e, GE Healthcare, Solingen, Germany; FlexFocus 800 Analogic Ultrasound Group, Paderborn, Germany). A standard preset for vascular sonography with equal range of frequency (10 MHz), depth of focus zone and compound imaging turned on was used on every machine. The ultrasound examination started with a sagittal transpectoral view depicting the subclavian vein and artery along the short axis. If the artery and vein could not be clearly differentiated, then pulse-wave Doppler was used for verification. The transducer was then slid medially while still in a sagittal view. The most medial position was reached when the vein was visible but not covered by the dorsal extinction of the ultrasound waves from the medial part of the clavicle. The subclavian vein was displayed in the middle of the screen and the ultrasound probe was rotated until the vein was depicted in the long-axis view (Fig. 1). After skin disinfection and sterile draping, the transducer was placed within a sterile sheath (CIVCO Medical Solutions, Kolona, IA, USA). In the needle-guided group, a sterile in-plane needle guide (Infinity Pro; CIVCO Medical Solutions) was clipped on [17] (Fig. 1), and the pre-scanning manoeuvre was then repeated under sterile conditions. After reaching the sonographic endpoint for puncture, a 70-mm (freehand) or 100-mm (needle-guided) 18-G echogenic needle (VascularSono Cannula; Pajunk, Geisingen, Germany) was inserted using the in-plane technique. Due to the design of the needle guide, the effective needle length in the needle-guided group was also approximately 70 mm. Confirmation of the CVC position was taken by a chest X-ray and, if applicable, intra-atrial ECG (Alphacard; B. Braun Melsungen AG, Melsungen, Germany).

All seven participating physicians were members of the junior or senior anaesthesia staff. Before the study, they underwent a standardised 60-min introduction by the study director that included theoretical and practical information on machine set-up, sonoanatomy, needle guide and scanning technique. All participating anaesthesiologists carried out ultrasound-guided regional anaesthesia with different levels of experience that varied from no experience with ultrasound-guided in-plane techniques (n = 3) to at least 25 ultrasound-guided regional anaesthesia in-plane blocks (n = 3) or extensive experience with ultrasound-guided vascular access (n = 1). None had cannulated the subclavian vein under ultrasound guidance with the in-plane technique before this study. Only one anaesthesiologist had used the in-plane needle guide before. All CVC placements were recorded on video and continuous ultrasound loops. Video recording began at the time of sterile examination and stopped after insertion of the guidewire. Various measurements were recorded by a study nurse throughout the procedure or afterwards by video analysis. Placement of the CVC in the first

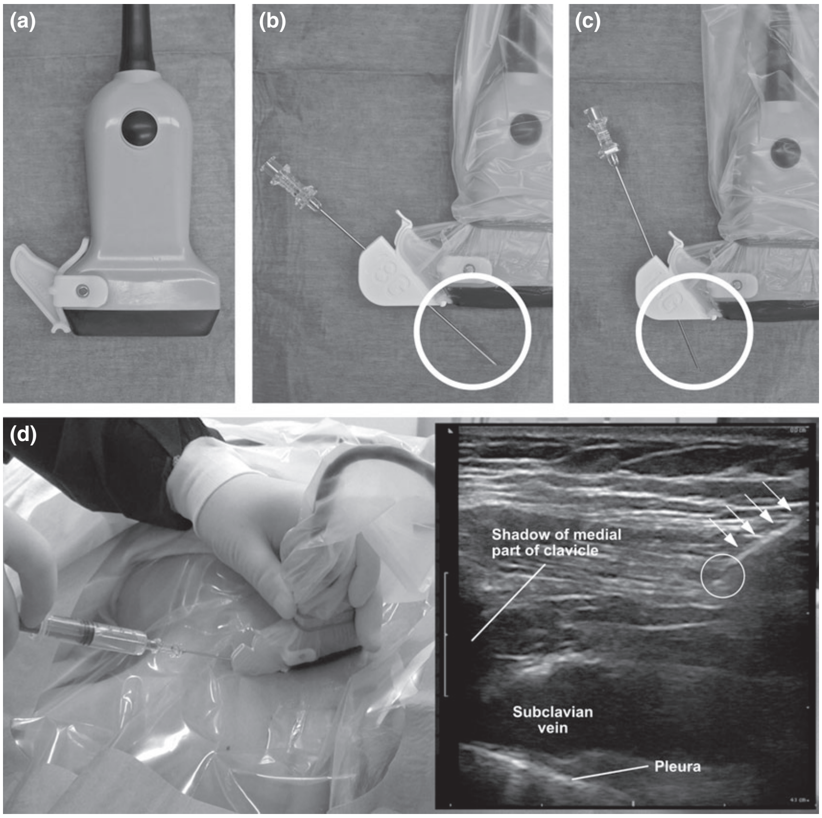

Figure 1 (a) Example of a transducer with the corresponding attached unsterile bracket. (b) Transducer with bracket covered with a sterile sheath and attached sterile multi-angle in-plane needle guide. Example of a feasible insertion angle to display the needle on the ultrasound screen. A longer (100-mm instead of 70-mm) cannula was required in the needle-guided group to compensate for the extended insertion length due to the guide. (c) Demonstration of a too steeply angled inserted needle, which explained one arterial puncture in the needle-guided group. (d) Photograph of a subclavian vein cannulation with the corresponding ultrasound picture. Longitudinal view of the subclavian vein and an in-plane-inserted echogenic needle with the correct angle to reach the most medially located visible part of the vein. Arrow heads point to the needle shaft. The circle marks the opening of the cannula (bevel up).

examined vessel was considered a success. Access time was taken in seconds from the time the skin was punctured to aspiration of blood from the subclavian vein. Needle visibility indicated the percentage of the needle that was visible during the time the needle was in the patient (access time). Every attempt was counted (new skin puncture). Guidewire time was taken in seconds from skin puncture to the time the guidewire was placed. Transducer movements (sliding, tilting, rotating), each change of the needle insertion angle and each new needle pass after 1 cm of withdrawal were evaluated post-procedure by video analysis.

Statistical analysis was performed using Statistica version 10 (StatSoft Inc., Tulsa, OK, USA). Continuous variables were tested for normal distribution using the Kolmogorov–Smirnov test and compared by t-test. In the case of abnormal distribution, the Mann–Whitney U-test was applied. The chi-squared test was used to compare categorical variables. From previous catheterisations, a reduction of at least 25% of the access time with a needle guide was noticed. A sample size calculation was based on this 25% difference and revealed that 80 patients per group would have a power of 95% (G*Power version 3.117 [18]). A p level < 0.05 was considered significant.

Results

We performed 160 CVC placements in 157 patients. The internal jugular vein was cannulated in one patient as the first access site owing to unclear sonoanatomy.

Results were based on 159 subclavian vein catheterisations (Fig. 2). There were no significant differences in patient characteristics (Table 1). Physicians with no experience in ultrasound-guided in-plane techniques performed 68 catheterisations (freehand n = 34, needle-guided n = 34), those with less experience performed 61 catheterisations (freehand n = 29, needle-guided n = 32) and the very experienced one performed 31 catheterisations (freehand n = 17, needle-guided n = 14). The ultrasound machines were used with no difference between the groups. Catheterisation of the first examined site of the subclavian vein was successful in 154 of the 159 cases (96.9%) with no significant difference between groups (freehand 94.9%; needle-guided 98.8%; p = 0.17). A small number of complications were recorded in both groups. One physician in the freehand group aspirated air in a patient scheduled for cardiac valve repair, although there was no pneumothorax seen after thoracotomy. Three arterial punctures occurred (two in the freehand and one in the needle-guided group); one case of haematoma after arterial puncture was seen on a sonograph in the needle-guided group.

Success rates at the first and second attempts were higher in the needle-guided group (first attempt 65 (81.1%); second attempt 76 (95.0%)) than in the freehand group (53 (67.1%) and 66 (83.5%), p = 0.041 and 0.019, respectively). The decrease in access time in needle-guide group is displayed in Fig. 3. Access time was compared between patients with a body mass index (BMI) of 20–30 $kg.m^{-2}$ or > 30 $kg.m^{-2}$ (Fig. 3). Guidewire time was higher in the freehand group (median (IQR [range]) 72 (46–193 [25–1672]) s) than the needle-guide group (54 (44–75 [22–634]) s; p = 0.0009). Fewer needle passes (mean (IQR [range]) 2 (0–4 [0–28] vs 1 (0–2[0–16]; p = 0.01) and angle corrections (5 (3–12 [0–58]) vs 2 (1–3[0–16]); p < 0001) were required in the needle-guide group compared with the freehand group, respectively. Probe manoeuvres were reduced in the needle-guide group compared with

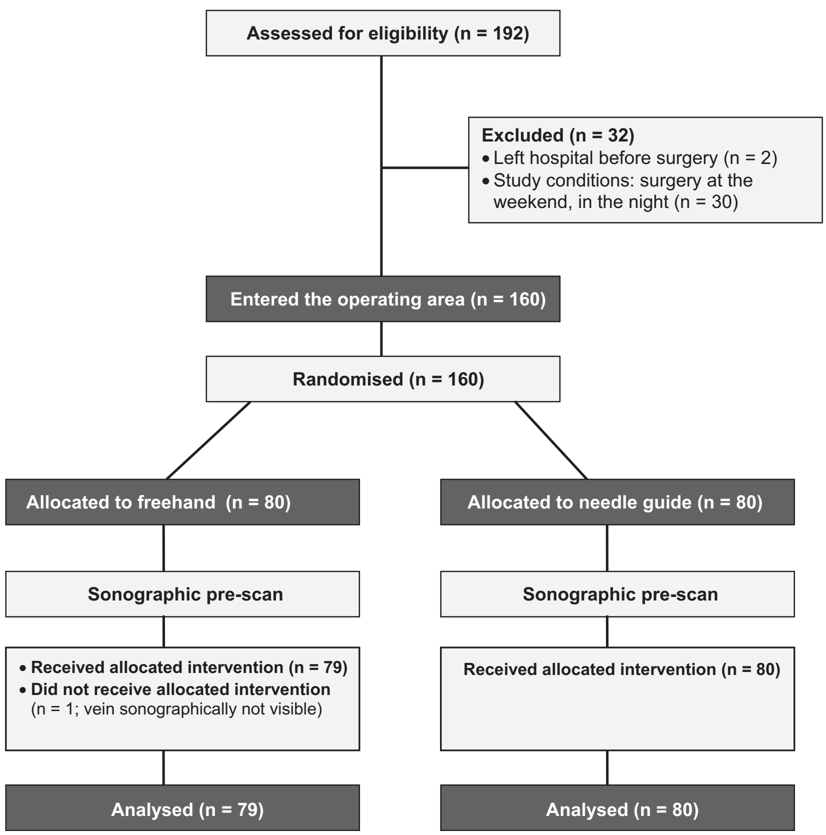

Figure 2 Flow diagram of study subjects receiving an ultrasound-guided in-plane cannulation of the subclavian vein by freehand or needle guidance.

the freehand group (sliding: 2 (0–5 [0–61]) vs 0 (0–1 [0–7]); p = 0.0001; rotating: 0 (0–1 [0–29]) vs 0 (0–0 [0–3]); p = 0.005; tilting: 0 (0–1 [0–23]) vs 0 (0–0 [0–17)]; p = 0.0296). Needle visibility was increased in needle-guide group (Fig. 4). Catheter-related study recordings and findings are listed in Table 2.

Table 1 Characteristics and pre-operative data of patients receiving an ultrasound-guided central venous catheter placement of the axillary vein by freehand or needle guidance. Values are mean (SD), number (proportion) or number.

	Freehand (n = 79)	Needle guide (n = 80)
Age; years	66.8 (10.0)	67.5 (12.4)
Weight; kg	81.7 (21.0)	85.6 (20.9)
Height; m	1.70 (0.1)	1.71 (0.1)
BMI; kg.m^{-2}	28.1 (6.1)	29.4 (7.3)
ASA physical status		
1	0	1 (1.3%)
2	13 (16.3%)	12 (15%)
3	36 (45%)	39 (48.8%)
4	30 (37.5%)	28 (35.0%)
Sex: male/female	44/36	47/33
Surgery		
Orthopaedics	25	23
Cardiac/lung surgery	51	53
Plastic surgery	2	4
Visceral surgery	2	0
Side of catheterisation; left/right	70/10	74/6

Discussion

This is the first clinical, prospective, randomised trial of ultrasound-guided subclavian vein cannulation with a multi-angle in-plane needle guide. The guide decreased access time and increased needle visibility by improving needle and ultrasound plane alignment. Comparing success rates of different studies can be difficult owing to the varying definitions of success, e.g. first attempts, changes of operator or time limitations. Varying success rates among ultrasound-guided subclavian vein catheterisations have been reported (92% on the first and 100% on the third attempt [11]; 92% [3]; 96% [19]; 99.5% [20]; 100% [2]). In the present study, success was defined as catheter placement in the first examined site. Based on this definition, the success rate was 96.9% although, after changing the insertion site, all catheters were placed successfully. All unsuccessful catheterisations on the first site were conducted by physicians with little or no experience of in-plane techniques, demonstrating the dependency of the operator's experience [3, 7].

We expected a high success rate without any severe complications with the use of a real-time visual technique. However, despite ultrasound and the additional use of a needle guide, three arterial punctures occurred. In the first case in the freehand group, a physician with no experience in the use of ultrasound-guided in-plane

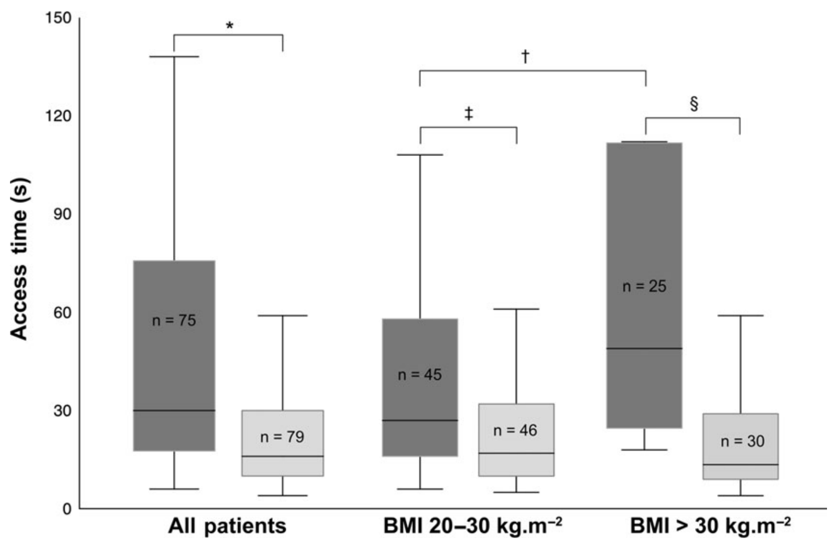

Figure 3 Access times (skin puncture to aspiration of blood) for all patients and patients with a body mass index of 20–30 kg.m^{-2} or > 30 kg.m^{-2}. Dark grey: freehand group; light grey: needle guide group. Horizontal line = median; box: IQR; whisker: 1.5 interquartile range. *p < 0.0001; †p = 0.02; ‡p = 0.01; §p < 0.0001.

techniques lost sight of the target and needle. While he was trying to align the vein, needle and ultrasound plane, he advanced the needle without a sonographic depiction, which is contrary to the concept of ultrasound-guided vascular access. The second arterial puncture in the freehand group occurred because the physician mistook the subclavian artery for the subclavian vein, despite satisfactory needle depiction and alignment. The third occurred in the needle-guided group for the same reason as in the first case – the needle was too steeply inserted in the needle guide and appeared first on the screen after being advanced to a depth of 4–5 cm (Fig. 1C). Did the needle guide provide the physician with a false sense of security? In an anatomical landmark-based technique, it is likely that such a steep angle would not have been used. In summary, arterial punctures could not be avoided in either group. These complications were due to misinterpretation of the sonoanatomy, false use of the needle guide or blind advancement of the needle.

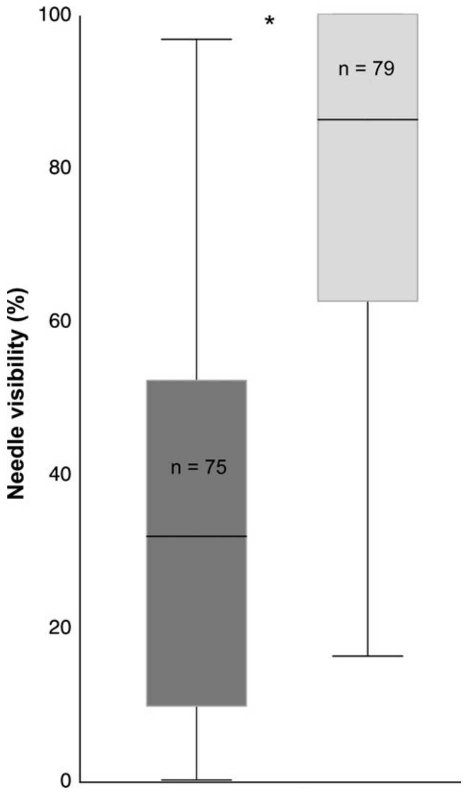

Figure 4 Needle visibility (percentage of access time) of freehand (dark grey) and needle guide group (light grey). Horizontal line = median; box: IQR; whisker: 1.5 interquartile range. *p < 0.0001.

No pneumothorax was detected postoperatively by chest X-ray in the patients receiving non-cardiac surgery. In patients with cardiac surgery where the pleura was opened and the catheter was placed on the same site (as in mammary artery bypass grafting), pneumothorax could not be diagnosed by chest X-ray. An attempt to overcome this limitation involved asking the cardiac surgeon to detect pneumothorax after the thoracotomy. Other than the one case of air aspiration in the freehand group, the surgeon did not find any pneumothoraces.

In landmark-based subclavian vein cannulation, Sharma and colleagues observed catheter misplacement in 12.8% [19]. Kang and colleagues reported catheter

Table 2 Central venous catheter-related outcomes of freehand and needle-guide groups. Values are number (proportion).

	Freehand (n = 79)	Needle guide (n = 80)	p
Change to other insertion side	3 (3.8%) (n = 79)	1 (1.25%) (n = 80)	0.31
Positive intra-atrial-ECG*	66 (95.7%) (n = 69)	66 (94.3%) (n = 70)	0.71
Correct catheter position on chest x-ray†	76 (97.4%) (n = 78)	72 (91.1%) (n = 79)	0.10
Catheter tip misplacements			
Internal jugular vein	2 (2.6%)	1 (1.3%)	0.17
Contralateral vein	0	1 (1.3%)	
Right atrium	0	1 (1.3%)	
Too deep in superior vena cava	0	4 (3.1%)	
Problem advancing the guidewire	9 (12.0%)	7 (8.8%)	0.52

*Intra-atrial ECG not applicable in all patients (e.g. atrial flutter).
†Missed chest X-ray in follow-up but positive intra-atrial ECG.

misplacements in a range from 1.2% to 8.1% depending on the position of the arm [20]. A slightly higher but non-significant incidence of catheter tip misplacements was observed in the needle-guided group. The overall rate was 5.7% (9 of 159). Four catheters were identified by chest X-ray in the internal jugular or contralateral brachiocephalic vein in patients with a left-sided subclavian vein approach and sinus rhythm. Misplacement could possibly have been prevented by using CVCs more than 16 cm in length. The reported rate of misplaced catheters by Fragou and colleagues, using the same freehand in-plane puncture technique, was slightly higher (9%) than our rate [2].

Ball and colleagues examined the impact of a needle guide in a vessel phantom and found no significant difference in access time between the freehand and needle-guided groups [16]. In contrast, the current study demonstrated a significantly shorter access time with a reduction of 52.9%. The different results between experimental and clinical studies could contribute to suboptimal cannulation settings in hospitals and the individual anatomical condition of the patient. The differences might be a result of the fast-paced environment of the operating theatre and suboptimal puncture conditions, such as standing, bright ambient light, a non-optimised operator–patient machine array, non-planar patient surfaces, obese patients and the need both to monitor and to control anaesthesia at the same time. Fragou and colleagues compared landmark-based vs ultrasound-guided in-plane subclavian vein access [2]. We used an in-plane ultrasound technique in the freehand group similar to that used by Fragou et al. in the ultrasound group. Their slightly faster access times compared with our results (mean (SD) 26.8 (12.5) s; 95% CI 16.4 –39 s) vs median (IQR [range]) 30 (18–76 [6–1409]) s) may be due to their extensive operator experience (> 6 years of CVC placement experience) and the lower BMI of their patients. However, with the use of a needle guide, similar access times were reached by anaesthetists with significantly less experience (median [range] 16 [10–30]). Shorter learning curves with a needle guide for inexperienced operators have been described in ultrasound-guided vascular access simulation [21]. This supports our assumption that a needle guide is especially helpful for less trained physicians. Furthermore, use of a needle guide narrows the range of the access time, making the cannulation process in distinct clinical settings more reliable.

Although all but two cannulations in our trial were performed in anaesthetised patients, short access time is more important for conscious patients, especially the obese. Obesity has been associated with an increased risk of failed catheter placement [22] and a decreased first attempt success rate [23]. In this study, access time was not impaired in obese patients when a needle guide was used (Fig. 3). The positive time-saving effect of a needle guide was also demonstrated with a 27% reduction in ‘block time’ in a regional anaesthesia phantom [24] and a shortened ‘task time’ [25], which refers to the guidance of the needle to a longitudinally displayed rod inside a phantom. However, in this study, longer access times and more probe and needle manoeuvres were not associated with an increased rate of mechanical complications.

Two other studies did not have 100% needle visibility throughout the puncture using the in-plane technique [16, 25]. After analysing the videos, we found two main reasons for improper needle and ultrasound plane alignment: unintentional sliding or tilting of the transducer while the cannula was attached to the needle guide and inserted into the patient; and inserting the needle at an angle too steep leading to late needle depiction on the ultrasound screen (e.g. first depiction after 2–3 cm advancement, Fig. 1C). However, even without 100% needle visibility, a needle guide doubled the percentage of time that the needle was visible during the cannulation process compared with the freehand group. This is due to better alignment by keeping the cannula strictly in-plane and by decreasing probe manoeuvres, such as rotating, sliding and tilting. However, the decreased number of probe manoeuvres and better alignment did not decrease mechanical complications. Reasons for this could be that ultrasound guidance per se is a highly effective technique for subclavian vein access [2, 26] or that the study was not powered to answer this specific question.

This study has a number of limitations. The exact rate of pneumothorax cannot be provided for all included patients because of the high number (65%) who received cardiac surgery. In some obese patients, an intra-atrial signal could not be elicited when the left-sided subclavian vein was cannulated. Central venous catheters longer than 16 cm should have been used to elicit a p-wave change in all patients. A separate echogenic needle was used in cannulations to enable accurate measurement of needle visibility. However, the use of a standard needle, not optimised for ultrasound, would possibly reveal different results. There is also an increased cost of adding a needle guide and a special echogenic needle. Both medical devices increase the cost of our CVC kit by about £11–12 (€16–17; $18–19). Because ultrasound-guided vascular access is an effective but operator-dependent technique, these increased costs may be reasonable for untrained physicians accessing the subclavian vein in obese and conscious patients.

Competing interest

No external funding or competing interests declared.

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