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Original Article

A prospective randomised trial comparing insertion success rate and incidence of catheterisation-related complications for subclavian venous catheterisation using a thin-walled introducer needle or a catheter-over-needle technique

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Summary

In clinical practice, both a thin-walled introducer needle and catheter-over-needle technique can be used to allow insertion of a guidewire during central venous catheterisation using the Seldinger technique. We compared the incidence of catheterisation-related complications (arterial puncture, haemothorax, pneumothorax, haematoma and catheter tip malposition) and insertion success rate for these two techniques in patients requiring right-sided subclavian central venous catheterisation. A total of 414 patients requiring infraclavicular subclavian venous catheterisation were randomly allocated to either a thin-walled introducer needle (needle group, n = 208) or catheter-over-needle technique (catheter group, n = 206). The catheterisation-related complication rate was lower in the needle group compared with the catheter group (5.8% vs. 15.5%; p = 0.001). Overall insertion success rates were similar (97.1% and 92.7% in the needle and catheter groups respectively; p = 0.046), although the first-pass success rate was higher in the needle group (62.0% vs. 35.4%; p < 0.001). We recommend the use of a thin-walled introducer needle technique for right-sided infraclavicular subclavian venous catheterisation.

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Introduction

Central venous catheterisation is indicated for fluid resuscitation, total parenteral nutrition, long-term administration of antibiotics, chemotherapy or central venous pressure monitoring. Subclavian venous catheterisation has advantages over the internal jugular and femoral vein routes, with fewer catheter-related infections, a lower incidence of venous thrombotic events, the ability to maintain patency even in patients who are hypovolaemic and increased patient comfort [1–5]. However, subclavian venous catheterisation may be associated with unintentional complications, including: catheter-related bloodstream infection; thrombosis; perforation of great vessels and myocardium; arterial puncture; haematoma; pneumothorax; and misplacement of the catheter tip [1, 3, 6, 7].

In clinical practice, when utilising the Seldinger technique for central venous catherisation, a thin-walled introducer needle or catheter-over-needle technique can be used for initial venous puncture in order to allow subsequent insertion of a guidewire. The ASA Task Force Team suggested that a catheter-over-needle technique may provide more stable venous access if manometry is used for venous confirmation [8]. However, no studies have compared the two techniques in terms of the incidence of catheterisation-related complications such as arterial puncture, pneumothorax and misplacement of the catheter tip during subclavian venous catheterisation.

We hypothesised that during subclavian venous catheterisation, a catheter-over-needle technique would increase the stability of initial venous access and subsequently reduce the possibility of posterior wall puncture, leading to a higher insertion success rate and lower rate of catheterisation-related complications compared with a thin-walled introducer needle technique. In this study, we compared the insertion success rate and incidence of catheterisation-related complications between the two techniques for right-sided subclavian venous catheterisation.

Methods

This prospective single-blind, randomised, two-centre study was approved by the institutional review board at each participating centre (Seoul National University Hospital and Seoul National University Bundang Hospital). Participants undergoing neurosurgical procedures necessitating central venous access were enrolled from April 2014 to February 2015. Patients with infection at the skin puncture site, a pre-existing right-sided central venous catheter, a history of clavicle or shoulder fracture, previous breast or thoracic surgery, anatomical abnormality of the subclavian vein or clavicle, diaphragmatic dysfunction or a history of emphysema or pneumothorax were not studied. All participants gave written, informed consent. Patients were prospectively enrolled to undergo right-sided subclavian venous catheterisation using either a thin-walled needle (needle group) or catheter-over-needle (catheter group) technique. Randomisation was independently conducted at each centre using a computer-generated randomisation program (http://www.randomizer.org). The assignments were kept concealed until the day of surgery and were managed by an anaesthetic nurse blinded to the group assignment.

After anaesthetic induction and tracheal intubation, all patients were placed in the supine position with their shoulders and head in the neutral position [9]. Skin was prepared with a mixture of 2% chlorhexidine gluconate and 72% ethanol. The right infraclavicular approach was performed by one of four pre-assigned board-certified anaesthesiologists (two at each hospital), who had experience of more than 100 central venous catheterisations/peripherally inserted central catheterisations using both of the techniques under investigation. This was done in an attempt to minimise catheterisation-related complications and inter-individual bias [10]. A double-lumen central venous catheter (Arrow International Inc., Reading, PA, USA) was used in this study. Mechanical ventilation was stopped during catheterisation and resumed after the procedure; rescue with additional ventilation was intermittently performed, if necessary, especially in patients with a prolonged procedure time.

Central venous catheters were inserted using both an anatomical landmark and ultrasound-guided technique. In participants allocated to the needle group and in whom the landmark method was used, the skin was punctured with a sharp, hollow, thin-walled standard 18G access needle (Fig. 1a) at a point 1 cm lateral and inferior to the mid-clavicular line below the clavicle. The needle, with the bevel facing up, was

Figure 1 The two types of introducer needle used in this study. (a) Catheter-over-needle. The distance between the needle tip and catheter tip is approximately 2.0 mm. The 18G radiopaque catheter (outer diameter 0.9 mm, total length 8.8 cm, flexible sheath 6.3 cm) is threaded over the 20G access needle and then used as a guiding sheath for the guidewire. (b) Thin-walled introducer needle. The standard 18G access needle (outer diameter 0.9 mm, total length 8.8 cm, needle shaft 6.3 cm) is directly used for guidewire insertion.

directed and advanced towards the suprasternal notch. If regurgitation of venous blood into the syringe was not achieved, the needle was withdrawn slowly to the subcutaneous tissue and then advanced by redirecting it above or below the sternal notch with negative pressure to the syringe. After venous puncture was achieved, a transducer was connected to the needle to check the pressure waveform. A guidewire was then passed into the vein through the needle, after which the needle was removed. In the catheter group, the skin was punctured with an 18G catheter-over-needle supplied in the same catheterisation kit (Fig. 1b). The venous access technique was the same as that in the needle group. When venous puncture was confirmed, the guiding sheath was advanced over the needle into the vessel. The needle was removed and the guidewire advanced through the guiding sheath. In both groups after successful placement of the guidewire, a dilator was inserted over the guidewire to facilitate insertion of an indwelling catheter. The indwelling catheter was advanced and fixed 13–15 cm from the catheter tip. Successful intravascular placement of the catheter was confirmed by aspiration of blood through the catheter lumen. If pulsatile blood flow and/or an arterial pressure waveform was observed, the needle was removed and the puncture site was compressed for 5 min. When an ultrasound-guided approach was used, the technique was performed in real-time using a SonoSite S-nerve (S-nerve™; Sonosite, Bothell, WA, USA) equipped with a high-resolution 7.5-mHz transducer, which was covered with sterile ultrasonic gel and wrapped in a sterile sheath as in previous studies [11, 12]. The short-axis view with the colour Doppler technique was first used to identify the subclavian vein, after which the ultrasound transducer was rotated at a 90° angle. The skin puncture site was more laterally located than that in the landmark method because of shadowing of the clavicle. The subclavian vein was then cannulated according to group allocation in the same manner as previously described.

The first pass success rate for subclavian venous catheterisation was defined as successful catheterisation at the first attempt without any complication and/or technical disturbance such as failed venous puncture and difficulties in insertion of the guidewire, dilator or catheter. The total insertion time was defined as time between skin puncture with the introducer needle and intravascular placement of the indwelling catheter. Subclavian venous catheterisation was defined as having failed according to the following criteria: failure of venous puncture after six needling attempts; failure of insertion of the guiding sheath, dilator or indwelling catheter; arterial puncture; or air aspiration during the procedure [9]. After subclavian venous catheterisation had failed, femoral or internal jugular venous catheterisation was performed. Haematoma was defined as a localised collection of blood around the puncture site and blood vessels, and was confirmed by a blinded observer after catheterisation using sonography, inspection and manipulation. A chest radiograph was obtained immediately after surgery to confirm position of the catheter tip and to detect potential complications such as pneumothorax or haemothorax. Misplacement of the catheter tip was defined as localisation of the catheter tip in the ipsilateral internal jugular vein or contralateral subclavian vein.

The primary outcome measure was the incidence of catheterisation-related complications including mechanical complications (arterial puncture, pneumothorax, haemothorax or haematoma) and malpositioning of the catheter tip. Secondary outcome measures were first-pass and overall success rates of subclavian venous catheterisation, number of needling attempts for successful venous puncture, total insertion time and incidence of other technical difficulties such as the number of manipulation attempts for the

guidewire, guiding sheath, dilator and indwelling catheter. An anaesthetic nurse blinded to the group allocation recorded all these measures.

Sample size was calculated using PASS software (ver. 11.0; NCSS, UT, USA). Previous studies showed that the incidence of catheterisation-related complications was 19% when the thin-walled needle technique was used for right-sided subclavian venous catheterisation [13]. Assuming that the complication rate using the catheter-over-needle technique would be reduced by 10%, we calculated that minimum sample size in each group was 188 with a type 1 error of 0.05 and power of 0.8. To compensate for possible dropouts of 10%, the final sample size was 209 patients per group. SPSS software version 21.0 (SPSS Inc., Chicago, IL, USA) was used for the statistical analysis. Fisher's exact test was performed to compare categorical data such as incidence of catheterisation-related complications and success rate of subclavian venous catheterisation. An independent t-test was used to compare continuous data such as total insertion time and number of dilator insertion attempts. A p value < 0.05 was considered to indicate statistical significance.

Results

In total, 416 patients were enrolled in this study and two patients were excluded from analysis because they declined to participate after entering the operating room. Thus, 414 patients were included in data analyses: 208 patients in the needle group and 206 patients in the catheter group (Fig. 2). Baseline participant characteristics were comparable between the two groups (Table 1).

The incidence of catheterisation-related complications was significantly lower in the needle group

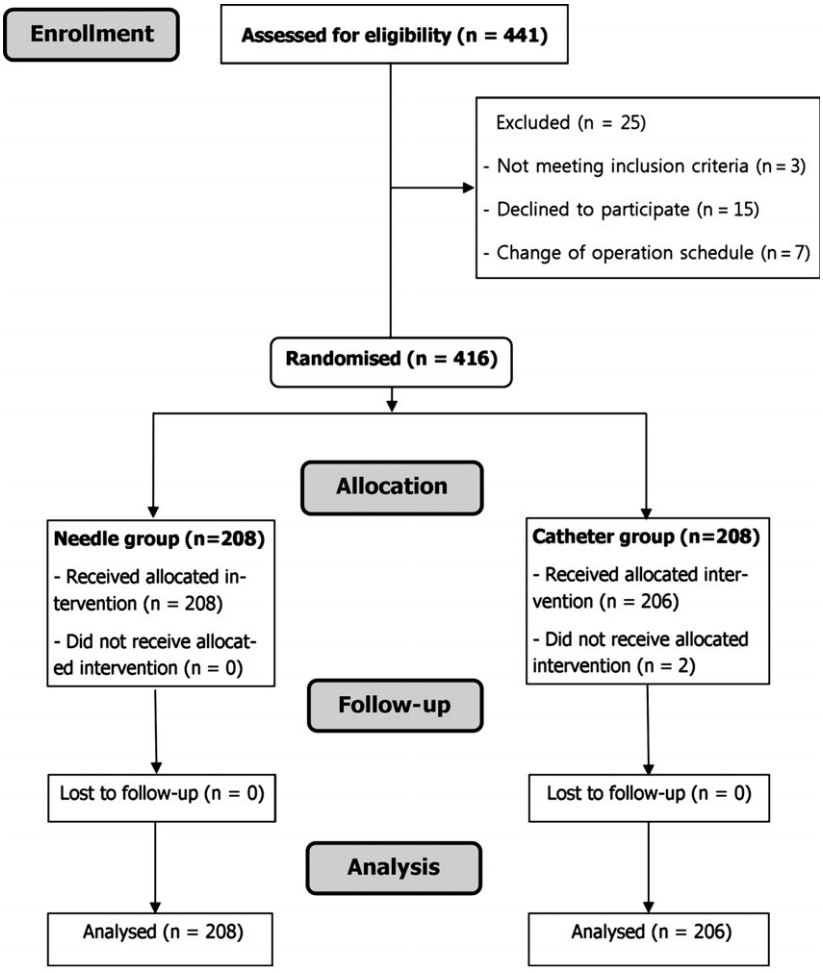

Figure 2 CONSORT flow diagram.

Table 1 Characteristics of patients who underwent right-sided subclavian venous catheterisation using a thin-walled introducer needle (Needle group) or catheter-over-needle technique (Catheter group). Data are mean (SD) or number (proportion).

	Needle group n = 208	Catheter group n = 206
Age; y	51.0 (13.1)	50.4 (12.9)
Male sex	93 (45%)	76 (37%)
BMI $kg.m^{-2}$	24.3 (3.6)	24.0 (3.6)

Table 2 Catheterisation-related complications between a thin-walled introducer needle (Needle group) and catheter-over-needle (Catheter group) technique for right-sided subclavian venous catheterisation. Data are number (proportion).

	Needle group n = 208	Catheter group n = 206	p value
Total complications*	12 (5.8%)	32 (15.5%)	0.001
Arterial puncture	2 (1.0%)	6 (2.9%)	0.174
Pneumothorax	0	2 (1.0%)	0.247
Haemothorax	0	0	–
Malposition of catheter tip	4 (1.9%)	8 (3.9%)	0.258
Contralateral subclavian vein	1	4	
Ipsilateral internal jugular vein	3	4	
Haematoma	8 (3.8%)	21 (10.2%)	0.012
Haematoma only	6	16	
Haematoma plus arterial puncture	2	2	
Haematoma plus malposition of catheter tip	0	3	

*Patients with ≥ 2 complications are counted as a single patient.

compared with the catheter group (5.8% vs. 15.5%, respectively, p = 0.001; Table 2). Among the catheterisation-related complications, the incidence of haematoma was lower in the needle group (3.8% vs. 10.2%, p = 0.012). First-pass success rate and overall success rates were significantly higher in the needle group compared with the catheter group (62.0% vs. 35.4% (p < 0.001) and 97.1% vs. 92.7% (p = 0.046), respectively; Table 3). In the needle group, failure was observed in six patients: arterial puncture (n = 2); failed venous puncture (n = 2); and failed insertion of dilator (n = 2). In the catheter group, failure was observed in 15 patients: arterial puncture (n = 6); failed venous puncture (n = 1); failed insertion of guiding sheath (n = 5); and failed insertion of dilator (n = 4). Mean (SD) total insertion time (101.9 (58.3) s vs. 122.9 (75.6) s, p = 0.002) was shorter in the needle group. Mean number of manipulation attempts for dilator insertion was also lower in the needle group (1.2 (0.5) vs. 1.5 (0.8); p < 0.001).

The use of the anatomical landmark technique to locate the vein was similar in both the groups and was the predominant technique used (n = 156 in both groups). Although the total number of complications was higher when the landmark method was used, this did not reach statistical significance (12.2% vs. 5.9%, p = 0.073). First pass success rate for cannulation was similar but overall success rate was lower for the landmark compared with ultrasound technique (48.1% vs. 51.0%, p = 0.649; and 93.3% vs. 100%, p = 0.007, respectively).

Discussion

This prospective randomised study showed that a thin-walled needle technique decreased the incidence of catheterisation-related complications and increased initial and overall success rates of right-sided infraclavicular subclavian venous catheterisation compared with a catheter-over-needle technique.

When a thin-walled needle technique is used for subclavian venous catheterisation, the failure rate is 2.5–12.1%, with a variable incidence of associated complications: pneumothorax (1.0–3.1%); arterial puncture (0.5–7.8%); haematoma (0.6–5.4%); and malposition of catheter tip (2.0–15.0%) [1, 3, 6, 11]. In accordance with previous studies, the failure rate of catheterisation and incidence of catheterisation-related complications using a thin-walled needle technique were 2.9% and 5.8%, respectively, with a higher complication and lower success rate when a catheter-over-needle technique was used. The total insertion time, which might be an objective parameter for evaluating the ease of subclavian venous catheterisation, was greater with a catheter-over-needle technique. However, this study showed that there were no differences between the two techniques in terms of the success rate of venous puncture on first needling attempt or overall number of needling attempts for subclavian

Table 3 Procedural characteristics of right-sided subclavian venous catheterisation for thin-walled introducer needle (Needle group) and catheter-over-needle (Catheter group) techniques. Data are mean (SD) or number (proportion).

	Needle group n = 208	Catheter group n = 206	p value
Success rate of catheterisation			
First attempt*	129 (62.0%)	73 (35.4%)	< 0.001
Overall	202 (97.1%)	191 (92.7%)	0.046
Total insertion time; s	101.9 (58.3)	122.9 (75.6)	0.002
Successful venous puncture at the first attempt	155 (74.5%)	146 (70.9%)	0.405
Number of needling attempts for venous puncture	1.4 (1.0)	1.5 (1.0)	0.649
Number of manipulation attempts for:			
Catheter-over-needle sheath insertion	–	1.3 (0.7)	–
Guidewire insertion	1.2 (0.6)	1.2 (0.6)	0.725
Dilator insertion	1.2 (0.5)	1.5 (0.8)	< 0.001
Central venous catheter insertion	1.1 (0.3)	1.1 (0.4)	0.237
Venous puncture†			
During the needle advancement	178 (87.3%)	189 (95.0%)	0.008
During the needle withdrawal	26 (12.7%)	10 (5.0%)	
Incidence of rescue mechanical ventilation	19 (9.1%)	25 (12.1%)	0.343

*Catheterisation at the first attempt without any complication or technical problem such as failed venous puncture or difficulty in insertion of the guidewire, dilator or catheter.
†Eleven cases (eight arterial puncture, three failed venous puncture even after six attempts) with failed venous puncture are not considered.

venous puncture. Taken together, such findings suggest that the technical difficulty frequently encountered during subclavian venous catheterisation is related to other aspects of the procedure, such as dilator or guiding sheath insertion after venous puncture, rather than identification of the subclavian vein.

There are some technical problems associated with the catheter-over-needle technique. First, there is 2–3 mm between the tip of the introducer needle and guiding sheath. Therefore, although the introducer needle tip may be placed in the target vessel lumen and blood aspirated via the introducer needle, the guiding sheath can still be placed outside of the vessel. To thread the guiding sheath into the blood vessel, both the guiding sheath and introducer needle need to be advanced further into the vessel. This can lead to puncture of the posterior wall of the vessel, adjacent subclavian artery or pleura. In addition, if the guiding sheath is not sited in the subclavian vein lumen, this can result in failure of guidewire advancement and injury to the subclavian vein. Second, the guiding sheath is flexible and its lumen can be distorted by external force; specifically, it can be compressed by the surrounding connective tissue or clavicle after removal of the introducer needle. This may cause failure of guidewire insertion or bending of the guidewire itself. Finally, threading the dilator over the guidewire is more difficult with a catheter-over-needle technique because of resistance of the skin at the puncture site. During insertion of the dilator, if multiple attempts or additional use of a scalpel blade are required, this may result in distortion of the guidewire or subcutaneous tissue and vessel injury, leading to failed catheterisation, haematoma formation, haemothorax or pneumothorax.

Two recent studies compared these two needle techniques for internal jugular venous catheterisation [14, 15]. In agreement with our findings, Lee et al. showed that a catheter-over-needle technique in adult patients was associated with a lower success rate for guidewire placement on the first attempt, and more difficult dilator insertion during internal jugular venous catheterisation [15]. In contrast, a study examining internal jugular venous catheterisation in paediatric patients reported no significant benefit of a thin-walled needle technique over a catheter-over-needle technique with respect to initial success rate of guidewire insertion, time to successful guidewire insertion and catheterisation time [14].

There are some limitations to this study. First, it was not possible for the investigators to be blinded to the catheterisation technique, which could be a source of bias. Second, the proportion of obese patients was small in the study cohort. This may limit

extrapolation of our results because central venous catheterisation is generally more difficult in obese patients [16–18] and further research is warranted in this population. Third, as both ultrasound and landmark methods were used to locate the subclavian vein, it is possible that this could have influenced the results of the study.

In summary, a catheter-over-needle technique increased the incidence of catheterisation-related complications and decreased success rate compared with a thin-walled needle technique for right-sided subclavian venous catheterisation. We therefore recommend the use of a thin-walled needle technique for right-sided infraclavicular subclavian venous catheterisation in adult patients.

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