

Evaluation of vascular puncture needles with specific modifications for enhanced ultrasound visibility: *In vitro* study

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Abstract

AIM: To determine which modification to a vascular puncture needle results in increased visualization during ultrasound (US)-guided vascular puncture.

METHODS: We evaluated US images of a phantom made of degassed gelatin and each of the following four modified versions of a commercially available vascular puncture needle (18 G): re-cut needle, dimple needle, rough-surface needle (rough over the sections of needle located 3-6 mm from the tip), and a needle with four side holes (side holes covered by the sheath). An unmodified commercially available puncture needle was used as a control. Five interventional radiologists evaluated image quality according to the following classification grade: I, invisible; II, poor; III, moderate; IV, good; V, excellent.

RESULTS: The highest score for needle visualization

was obtained for the needle with four side holes. The re-cut needle scored the same as the control. Multiple comparisons were conducted using overall evaluation scores among the commercially available needle, dimple needle, rough-surface needle (3-6 mm), and the needle with four side holes. A significantly higher score was obtained for the needle with four side holes ($P < 0.05/6$).

CONCLUSION: The needle with four side holes was prominently visualized and gained a significantly higher score (compared with the other needles) in a phantom evaluation.

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Key words: Ultrasound visibility; Vascular puncture needle; Side-hole needle; Dimple needle; Rough-surface needle

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INTRODUCTION

A rise in the number of cancer patients worldwide has resulted in an increased frequency of central venous (CV) port placement for chemotherapy or high caloric infusion^[1,2]. Interventional radiologists are commonly request-

ed to perform venous puncture of the jugular, subclavian, and femoral veins^[3-12]. Furthermore, venous puncture of the popliteal vein is necessary for treatment of deep venous thrombosis^[13]. Ultrasound (US) guidance enables the puncture to be performed precisely and quickly, with a low incidence of complications^[1-8,10,14,15]. However, complications such as arterial puncture, pneumothorax, and hemothorax still occur following US-guided puncture, probably because of unclear needle visualization^[1-3,8,11,16]. Previous studies have described devices for gauging the puncture angle and needle depth, and the use of four-dimensional US for improving needle visualization^[17,18]. Biopsy needles and nerve-block needles with a specific coating or type of cut at the needle tip are commercially available for improving US needle visualization^[19-26]. Nevertheless, no vascular needle has been devised specifically for this purpose. We consider that a specific modification to the vascular needle itself would improve needle visualization and thus increase puncture accuracy.

The purpose of this study is to create four types of needle modification for improving US visualization, and to identify the needle modification that is most suitable for increasing needle visualization during US-guided puncture, in testing using an *in vitro* phantom.

MATERIALS AND METHODS

We used a commercially available vascular needle (Medikit, Tokyo, Japan) composed of an inner needle (20 gauge stainless steel, 0.9 mm in outer diameter and 0.6 mm in hollow diameter) and an outer sheath (18 gauge, 1.3 mm, Teflon). We created the following modified versions of the commercially available puncture needle: a re-cut needle, a dimple needle, a file-like rough-surface needle, and a needle with four side holes (Figure 1). The commercially available needle (unmodified) was used as a control (Figure 2). The re-cut needle was made by re-cutting the dorsal aspect of the needle tip (Figure 3). The shaft of the rough-surface needle was filed to a rough surface at a distance of 3-6 mm from the tip (Figure 4). The dimple needle had numerous small dimples (0.08 mm in diameter) added to the shaft at a distance of 5-8 mm from the tip (Figure 5). To produce the needle with side holes, we drilled four side holes of 0.4 mm diameter into the shaft at 4 mm from the tip (Figure 6). The modified regions of the dimple, rough surface, and side hole needles were covered by the sheath.

We performed an *in vitro* experimental study using a Xario US machine (Toshiba Medical, Tokyo, Japan) with an 11 MHz linear-array probe and a phantom made of degassed gelatin. The probe-to-surface angle was approximately 30°. Under US guidance, the phantom was punctured by each of the five needles, to a depth of approximately 1.5 cm from the surface of the gelatin. We obtained five images of needle puncture for each needle. The total of 25 images (5 images × 5 needles) was piled and arranged at random. Five interventional radiologists with more than 2 years experience in CV port placement

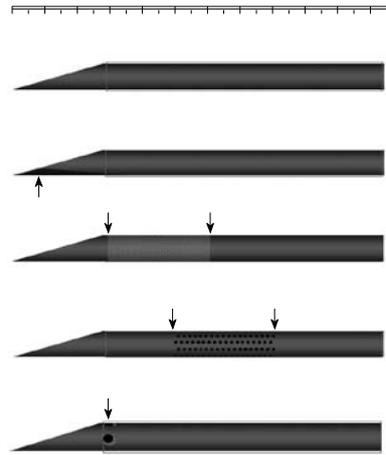


Figure 1 Schematic drawings of a commercially available puncture needle and four newly devised vascular puncture needles (18 gauge). Top to bottom: re-cut needle, dimple needle, rough-surface needle (rough over the section of needle located 3-6 mm from the tip), and needle with four side holes.

checked the image quality of the needle and evaluated its practical utility for vascular puncture according to a classification grade. The grades were as follows: I, invisible; II, poor; III, moderate; IV, good; V, excellent.

Statistical analysis

We performed multiple comparisons among the commercially available needle, dimple needle, rough-surface needle, and the needle with four side holes (the re-cut needle was excluded because similar scores were obtained between this needle and the commercially available needle). The Mann-Whitney test was used to compare categorical variables of grade scores given by the radiologists among the commercially available needle, dimple needle, rough-surface needle, and the needle with four side holes. Bonferroni's method was used to adjust for multiple (6 times) comparisons post-test. For the Mann-Whitney test and Bonferroni's correction, $P < 0.05$ and $P < 0.05/6$ were considered to indicate significant difference, respectively.

RESULTS

The scores for needle visualization are listed in Table 1. The highest scores for needle visualization were obtained for the needle with four side holes, followed by the dimple needle, the rough-surface needle, and the re-cut needle. The needle with the re-cut modification yielded the same score as the control. Multiple comparisons were conducted using the control needle and the three needles with the modifications whose scores were significant higher than the control, and the significantly highest score was obtained for the needle with four side holes ($P < 0.05/6$).

DISCUSSION

The ease of performing needle puncture of the subclavian vein depends on the width of the vein and the thickness of subcutaneous fat^[4,6,11]. A subclavian vein that

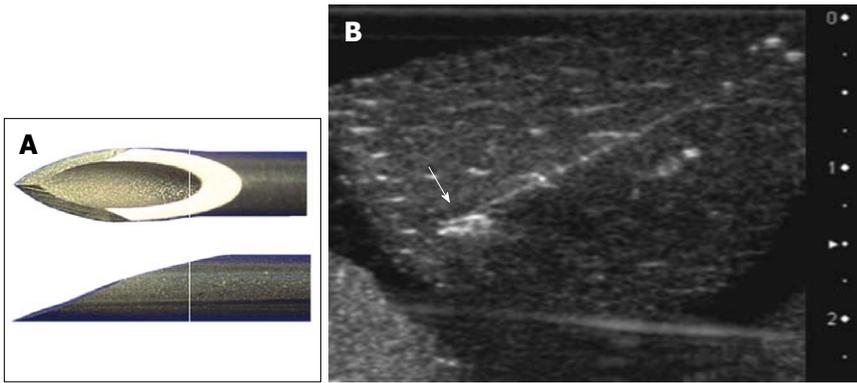


Figure 2 Commercially available vascular needle (control). A: Needle tip; B: Corresponding ultrasound image. The arrow indicates the needle tip.

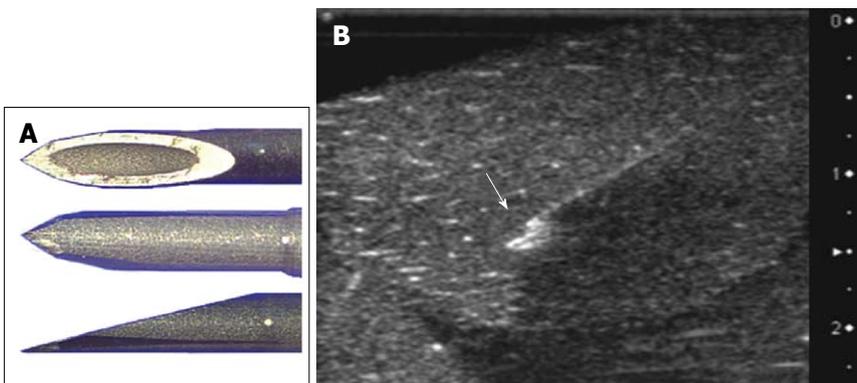


Figure 3 Vascular needle with re-cutting of the dorsal aspect of the tip. A: Needle tip; B: Corresponding ultrasound image. The arrow indicates the needle tip.

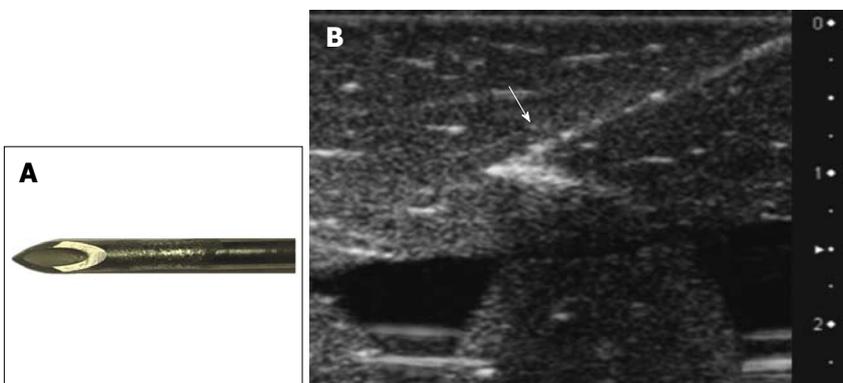


Figure 4 Vascular needle with a rough-filed surface at 3-6 mm from the tip of the needle. A: Needle tip, shaft; B: Corresponding ultrasound image, with the rough surface indicated by the arrow.

is thin due to dehydration is sometimes difficult to puncture, even if US is used^[4]. Thick subcutaneous fat tissue pushes the subcutaneous vein deep, causing a long needle puncture route and generating increased echo from the thick fat, causing poor visualization of the puncture needle^[4,11]. In deep vein thrombus, poor visualization of the puncture needle during needle puncture of the popliteal vein is caused by the elevated echogenicity of the thrombus in the vessels and thick limb edema, with subcutaneous fat pushing the popliteal vein deep^[13]. Therefore, modifications to improve visualization of the vascular

puncture needle would improve safety during these procedures^[17,20-26].

Of the four modified needles assessed in the present study, the re-cut modification showed no significant increase in needle visibility compared with the control. Of the three modifications that increased visibility, the needle with four side holes was visualized most prominently on US, followed by the dimpled needle and the rough-surface needle. The difference in visualization appears to depend on the size of the modification: the minute grooves of the rough surface had the least effect on echogenicity,

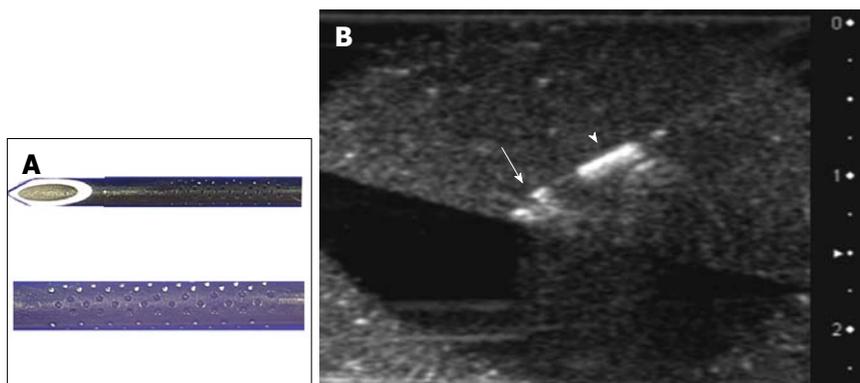


Figure 5 Vascular needle with dimples placed at 5-8 mm from the tip (dimple needle). A: Needle tip, shaft; B: Corresponding ultrasound image, with the dimples indicated by the arrowhead and the needle tip indicated by the arrow.

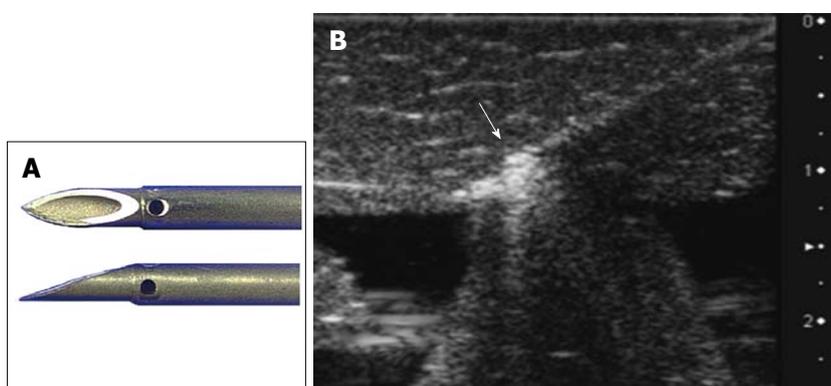


Figure 6 Vascular needle with four side holes, each 0.4 mm in diameter, drilled at 4 mm from the tip of the needle. A: Needle tip, shaft. The side holes are covered by the outer sheath. B: Corresponding ultrasound image. The arrow indicates the needle tip with side holes.

Table 1 Ultrasound visibility of variously modified vascular needles

	Visibility score					
	I	II	III	IV	V	
Needle						
Control	5	19	1	0	0	A
Re-cut	4	18	3	0	0	B
Rough surface	0	2	13	7	0	C ^a
Dimple	0	0	2	14	9	D ^{a,b}
Four side holes	0	0	0	7	18	E ^{a,b,c,d}

^a*P* = 0.000 vs A; ^b*P* = 0.000 vs C; ^c*P* = 0.000 vs D; ^d*P* < 0.05/6, adjusted with Bonferroni correction; The Mann-Whitney test with Bonferroni correction was used to compare grade scores adjusting for multiple (6 times) comparisons post-test. Each *P* value between two groups was < 0.05/6.

while the large-sized modification of the 0.35-mm side holes had the greatest effect on echogenicity, followed by the 0.08-mm dimple modification. We consider that the larger the size of the modification, the greater the echo reflection generated, and that the adherence of air to the four side holes enhanced echogenicity.

A weakness of the present study is that it is limited to an *in vitro* study, rather than the clinical situation. A number of clinical cases should be warranted for the possible use of the needle with four side holes. The degree of visibility of the puncture needle in human fat tissue could

be greater or less than that in the phantom. However, no fundamental data exist regarding the visibility of puncture needles. The present data will provide a basis for considering modifications to puncture needles. It would be possible to combine the features of side holes and rough surface in a puncture needle, and this appears to be a valid subject for future development.

In conclusion, we created and tested four modified needles for vessel puncture with the aim of enhancing their visibility under US. Among the devices, needle tip visualization was most prominent in the needle with side holes, and its visualization score was significantly higher in evaluation using a phantom.

COMMENTS

Background

Ultrasound (US) guidance enables vascular puncture to be performed precisely and quickly, with a low incidence of complications. However, complications such as arterial puncture, pneumothorax, and hemothorax still occur following US-guided puncture, probably because of unclear needle visualization.

Research frontiers

No vascular needle has been devised specifically for clear needle visualization. The authors consider that a specific modification to the vascular needle itself would improve needle visualization and thus increase puncture accuracy.

Innovations and breakthroughs

The authors created four types of needle modification for improving US visual-

ization, and to identify the needle modification that is most suitable for increasing needle visualization during US-guided puncture. Four modified versions of a commercially available vascular puncture needle (18 G) were evaluated: recut needle, dimple needle, rough-surface needle (rough over the sections of needle located 3-6 mm from the tip), and a needle with four side holes (side holes covered by the sheath). The highest score for needle visualization was obtained for the needle with four side holes. The needle with four side holes was prominently visualized and gained a significantly higher score (compared with the other needles) in a phantom evaluation.

Applications

The needle with four side holes could be applied in cases with a thin subclavian vein due to hydration, thick fat causing a long needle puncture route and poor visualization of the puncture needle, and would improve safety during these procedures.

Peer review

The paper under consideration is very new and should be accepted for publication in the wider interest as a preliminary study.

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