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One-hand guidewire introducer kit for ultrasound-guided central venous catheterization: a proof-of-concept study

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Despite ultrasound guidance for central venous catheterization (CVC), the first-attempt success rate has remained around 52.6–62.1%. A significant reason is that the needle can sometimes be dislodged from the punctured vein during hand shifts. Here, a novel one-hand guidewire introducer (OGI) kit was developed to perform guidewire insertion in the central vein, eliminating hand shifts. To establish a protocol, the OGI kit was validated using a central line training phantom. A total of 48 randomized trials of guidewire insertion in the internal jugular vein in eight pigs were performed using either the conventional kit (group A) or the OGI kit (group B). All trials were technically successful with all eight pigs. First-attempt success rate (50% vs. 75%, $p = 0.035$) and global rating scale (12 (5–15) vs. 14 (8–15), $p = 0.011$) were significantly lower in group A than in group B. The number of needle redirections and guidewire insertions, time to guidewire insertion, and procedure-related complications were significantly higher in group A than in group B. Guidewire insertion using a novel OGI kit could be a promising approach for real-time ultrasound-guided CVC as it offers greater clinical usefulness.

Keywords Central venous catheterization, Internal jugular vein, Ultrasound, One-hand guidewire introducer

Central venous catheterization (CVC) has been routinely performed in operating rooms and intensive care units for venous access and hemodynamic monitoring[1]. Numerous recent studies have confirmed that CVC under real-time ultrasound guidance significantly increases technical success rates and decreases procedure-related complications, and it is considered one of the most important advances in patient safety[2,3]. Presently, the use of dynamic real-time, 2D ultrasound guidance for CVC is highly recommended as a standard technique regardless of the provider's prior experience level[4]. However, even if CVC is performed under ultrasound guidance, the first-attempt success rate has remained around 52.6–62.1%[5,6], and it can be associated with serious complications, including arterial puncture, hematoma formation, pneumothorax, hemothorax, and catheter malposition, especially for beginners who do not have enough experience[5,7,8].

In the CVC procedure under ultrasound guidance, hand shifts should be performed to advance the guidewire. Usually, the left-hand shifts from the ultrasound probe to the puncture needle, and the right-hand shifts from the syringe to the guidewire. During these shifts, control over the needle was sometimes lost, leading to either its dislodgement from the punctured vein or an increased risk of unintentional penetration of the vein or artery[9]. Thus, novel strategies to eliminate hand shifts during the CVC procedure are required to improve the first-attempt success rate and decrease procedure-related complications.

Recently, a novel one-hand guidewire introducer (OGI) kit was developed to perform guidewire insertion without any hand shifts (Fig. 1). We hypothesized that guidewire insertion in the central vein using the OGI kit would improve the first-attempt success rate and may decrease complications during the vein puncture, leading

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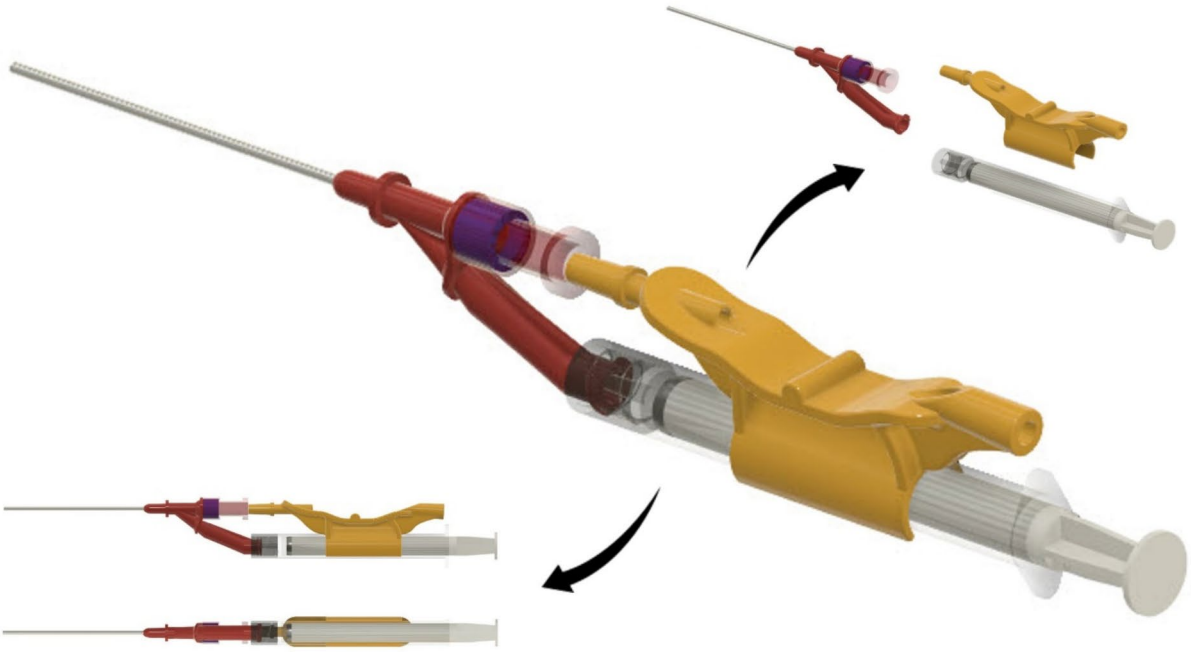

Fig. 1. Schematic illustration of one-hand guidewire introducer (OGI) kit.

Parameter	Group A ($n=24$)	Group B ($n=24$)	p-value
First-attempt success rate (%)	12 (50%)	18 (75%)	0.035§
Number of needle redirections			0.002§
0	12 (50%)	19 (79.2%)	
1	3 (12.5%)	4 (16.7%)	
2	3 (12.5%)	0 (0%)	
3	4 (16.7%)	0 (0%)	
4	2 (8.3%)	1 (4.2%)	
Number of guidewire insertions			0.009§
1	17 (70.8%)	23 (95.8%)	
2	6 (25%)	1 (4.2%)	
3	1 (4.2%)	0 (0%)	
Time to guidewire insertion (s)	54.5 (26.0–134.0)	24.5 (14.0–70.0)	< 0.001‡
Global rating scales	12 (5–15)	14 (8–15)	0.011‡
Complications (%)			
Posterior wall puncture	7 (29.1%)	2 (8.3%)	0.064§
Hematoma	1 (4.2%)	0 (0%)	0.312§
Total	8 (33.3%)	2 (8.3%)	0.033§

Table 1. Results of guidewire insertion using conventional kit or OGI kit in the porcine internal jugular vein. Data are expressed as number (%), or median (IQR). § χ^2 test; ‡ Mann-Whitney test.

to improved procedural outcomes of the CVC procedure. Therefore, the purpose of this proof-of-concept study was to investigate the procedural outcomes of guidewire insertion with OGI kit compared to a conventional CVC kit under ultrasound guidance in the internal jugular vein of a porcine model.

Results

The study findings of guidewire insertion procedures in the two groups are summarized in Table 1. A total of 48 trials with the conventional kit or OGI kit were technically successful in all pigs (Fig. 2A). First-attempt success rate was significantly lower in group A than in group B (50% vs. 75%, $p=0.035$). For cases without needle redirection, there were 12 cases (50%) in group A and 19 cases (79.2%) in group B ($p=0.002$). For one or more needle redirections, there were 12 cases (50%) in group A and five cases (20.8%) in group B. For a single

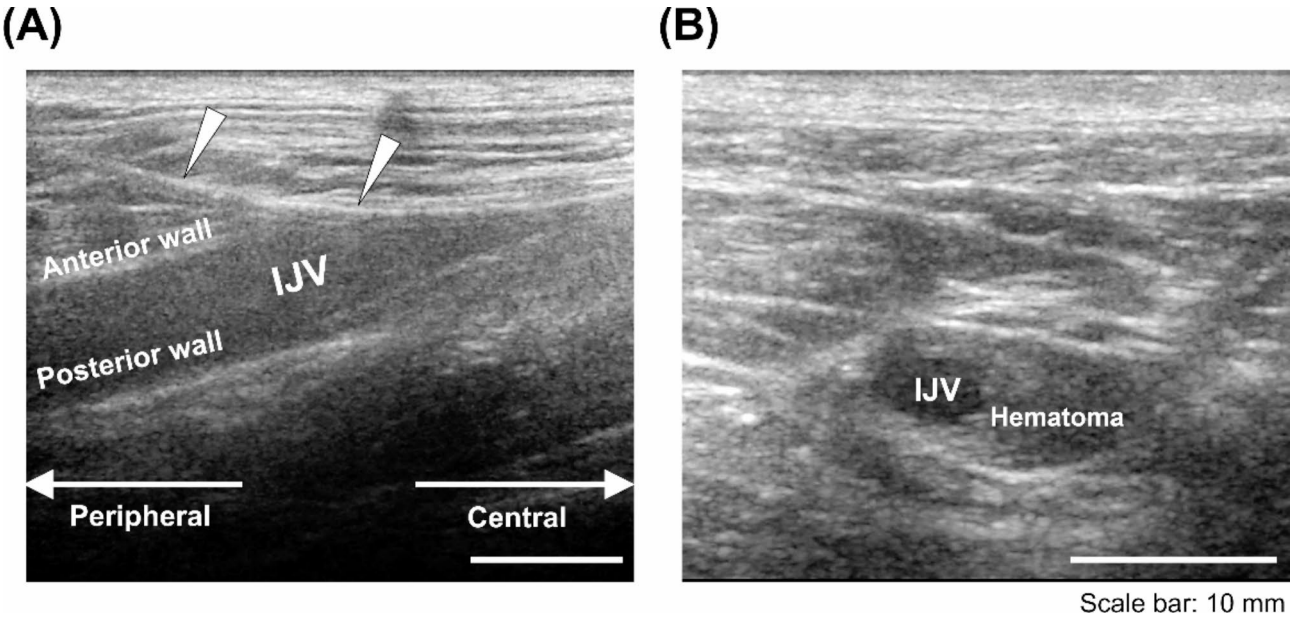

Fig. 2. Outcome ultrasound images. (**A**) Properly placed guidewire (*arrowheads*) in the internal jugular vein (IJV) of the porcine model. (**B**) US image of hematoma case. (scale bars: 10 mm).

guidewire insertion, there were 17 cases (70.8%) in group A and 23 cases (95.8%) in group B ($p=0.009$). For two or more guidewire insertions, there were seven cases (29.2%) in group A and one case (4.2%) in group B. The time to guidewire insertion was significantly longer in group A compared to group B (54.5 (26.0−134.0) vs. 24.5 (14.0−70.0), $p<0.001$). The global rating scale score (GRS) in group A was significantly lower than that in group B (12 (5−15) vs. 14 (8−15), $p=0.011$). The incidence of the posterior wall puncture during the procedure in group A was higher than that in group B (29.1% vs. 8.3%, $p=0.064$). In the post-procedural ultrasound, only one hematoma formation in group A was observed (Fig. 2B). Arterial puncture and guidewire malposition did not occur in both groups. The overall complication rate was significantly higher in group A than in group B (33.3% vs. 8.3%, $p=0.033$).

Discussion

CVC is a common procedure for the management of patients in operating room and critical care units. In the United States, over 5 million CVC procedures are performed each year[10]. Traditionally, CVC is performed using landmark techniques based on knowledge of anatomic structures and palpation of arteries next to the veins. However, it cannot account for anatomic variations at the target site and can lead to serious complications such as arterial puncture, hematoma formation, pneumothorax, and hemothorax[11,12]. In 1984, the use of ultrasound to locate a vessel by placing a mark on the skin was first described[13]. Since then, several meta-analyses have been performed with prospective studies comparing the landmark technique with the ultrasound-guided technique[2,3], concluding that the latter leads to fewer failures and lowers the need for multiple attempts. Despite the proven efficacy and safety of real-time ultrasound-guided CVC, mechanical complications still occur in up to 4.6% of cases[14,15], and the first-attempt success rate has stagnated around 52.6−62.1%[5,6]. Additional puncture attempts after the first-attempt in the central vein may lead to serious complications and failure of CVC. Furthermore, these multiple punctures can be more concerning in patients with blood clotting disorders or pediatric patients.

To promote efficacy and safety, needle-guiding system techniques using ultrasound for CVC have been developed to visualize the needle tip continuously[16–22]. Previous studies have shown significantly increased needle visibility and shorter procedural time when using a needle guidance system. However, most of these methods have not been widely used because they require complex digital hardware that incur extra medical expenses[16–20,23]. Also, fixed and heavy needle-guiding systems are not widely used because they are difficult to manipulate in real-time when clinical adjustments to the target vessel position are necessary[23]. A more recent device for vascular access with the use of a guidewire introducer has been developed to insert a peripherally inserted central catheter line or arterial line. This guidewire introducer consolidates all necessary components for successful peripheral vascular access procedure into one-hand, freeing the other hand to hold the ultrasound probe. However, skipping the blood aspiration step compromises the safety of the procedure for novices, who may struggle to accurately identify the needle tip on ultrasound imaging.

In the current study, we designed and assessed guidewire insertion with OGI kit for ultrasound-guided CVC that may eliminate the problems associated with conventional ultrasound-guided CVC and the guidewire introducer, and the results thus far have been highly successful. One of the distinct advantages of novel OGI kit was that while the ultrasound probe was held in one hand, the other hand performed blood aspiration and guidewire insertion under real-time ultrasound guidance. It simplifies the procedure by obviating hand shifts, which could cause needle dislodgement from the target vein[9]. Also, It can prevent the guidewire malposition

by visualizing the needle tip while the guidewire is being advanced. Even if the guidewire malposition occurs, it can be immediately corrected under ultrasound guidance. These advantages led to an increase in first-attempt success and GRS, and a decrease in the number of needle redirections, multiple attempts at guidewire insertions, time to guidewire insertion, and procedure-related complications when conducting ultrasound-guided CVC with the OGI kit in this study.

This study has some limitations. First, the current study was conducted in a phantom and animal model. Especially, the distance between the pig's skin and the internal jugular vein (1.5–3 cm) was different from the human's (1.0–1.5 cm)[24–26]. This difference could be a factor contributing to the discrepancies between our experimental results and those obtained in human studies. Further in-vivo research in more human-like environments or follow-up exploratory clinical trials is needed. Second, becoming familiar with newly developed OGI kit takes time because it differs from the conventional CVC method. Based on our experience, professional physicians can be proficient in five attempts, while novices may require ten or more attempts. Third, since our study defined first-attempt success differently from previous studies, CVC insertion success rates and outcomes could differ in clinical practice, potentially affecting the reported advantages of the OGI kit. Therefore, the results of our study should be interpreted with caution and require external validation.

In conclusion, guidewire insertion using a novel OGI kit for CVC appears to be feasible and demonstrates improved procedural outcomes compared to using a conventional kit. Exploratory clinical trials are needed to confirm this conclusion.

Materials and methods

Fabrication of the one-hand guidewire introducer kit

The OGI kit consists of five components: a 16 G introducer needle (Hyupsung Medical, Seoul, Korea), a 3 ml lock syringe (BD 3 ml Syringe, Becton Dickinson Korea), a hemostasis valve (ABLE, Guangdong, China), a Y-connector (Fig. 3A), and a thumb trigger (Fig. 3B). The thumb trigger and the Y-connector of OGI were designed by 3D Systems, Inc. and InnoSis, Inc. using Geomagic Design X (Oqton, USA). Printing was conducted using the additive manufacturing method (height: 50 μm) with a printer (3D Systems, USA). The printing material was MED-AMB 10 (3D Systems, USA). After printing, the printed objects were cured in an LC 3D print Box (3D Systems, USA) for 60 min. Then, the 3D-printed components were assembled with a commercially available 16 G needle, a hemostasis valve, and a 3 ml lock syringe.

Characterization of one-hand guidewire introducer kit

The two ports of the Y-connector are each connected to the lock syringe for blood aspiration and the thumb trigger for guidewire insertion. In this regard, while the ultrasound probe grip is fixed in the left hand, the right hand can consecutively perform blood aspiration and guidewire insertion. The port connected to the thumb trigger has a hemostasis valve to prevent blood backflow during the advance of the guidewire into the jugular vein. A bump is inserted into the thumb trigger to facilitate guidewire control. The total length of OGI kit is 195 mm, height is 30 mm, and width is 12 mm (Fig. 3C,D). Figure 3E shows a gripping method of the OGI kit.

Central line training phantom study

To establish an optimal protocol of guidewire insertion with OGI kit, a phantom study was conducted using the central line training phantom (Redmond, WA, USA). It was developed for simulating ultrasound-guided CVC procedure. The phantom has excellent durability after 1000 needle punctures in a 1 cm^2 area[27]. Technical details about this phantom have been described previously[28,29]. The lumens of both vessels were filled with different clear water to detect arterial puncture (vein: blue, artery: red). The protocol of guidewire insertion with the OGI kit was established as follows: (1) Prepare the kit: insert the 0.032-inch guidewire into the distal port of the thumb trigger and advance to just before the hemostasis valve. (2) Puncture the internal jugular vein under real-time ultrasound guidance. (3) Confirm the distal end of the introducer needle in the internal jugular vein, and perform blood aspiration using the little finger of the right hand (Fig. 4A). (4) Advance guidewire with the thumb of the right hand under real-time ultrasound guidance without hand shifts. (5) Move the ultrasound probe toward the brachiocephalic vein to check whether the guidewire was placed correctly in the brachiocephalic vein (Fig. 4B,C).

Animal study design

This study was approved by the Institutional Animal Care and Use Committee (IACUC approval number: 2024-20-085) and confirmed to US National Institutes of Health guidelines for the humane handling of laboratory animals. A total of eight juvenile pigs weighing 55–70 kg (mean weight, 62 kg; International Animal Experiment Center, Pocheon, Korea) were used. Right and left internal jugular veins were divided into the proximal, middle, and distal portions, respectively, and a total of six guidewire insertion procedures at the six different portions of the internal jugular veins of each pig were performed. The guidewire insertion procedures with a conventional CVC (Cat. HS-C-100-2, Hyupsung Medical, Seoul, Korea) kit or OGI kit were randomly performed and divided into two groups. Group A received the guidewire insertion procedure with the conventional kit, and group B received the procedure with OGI kit. A total of 48 trials (24 trials in each group) were performed and compared between the two groups to investigate the efficacy and safety of guidewire insertion with OGI kit. All pigs were housed under the same environmental circumstances (temperature of 24 °C ± 2 with a 12-h day-night cycle) and were supplied with water and food ad libitum. All animals were euthanized with 75 mg/kg potassium chloride via intravenous injection after the procedures.

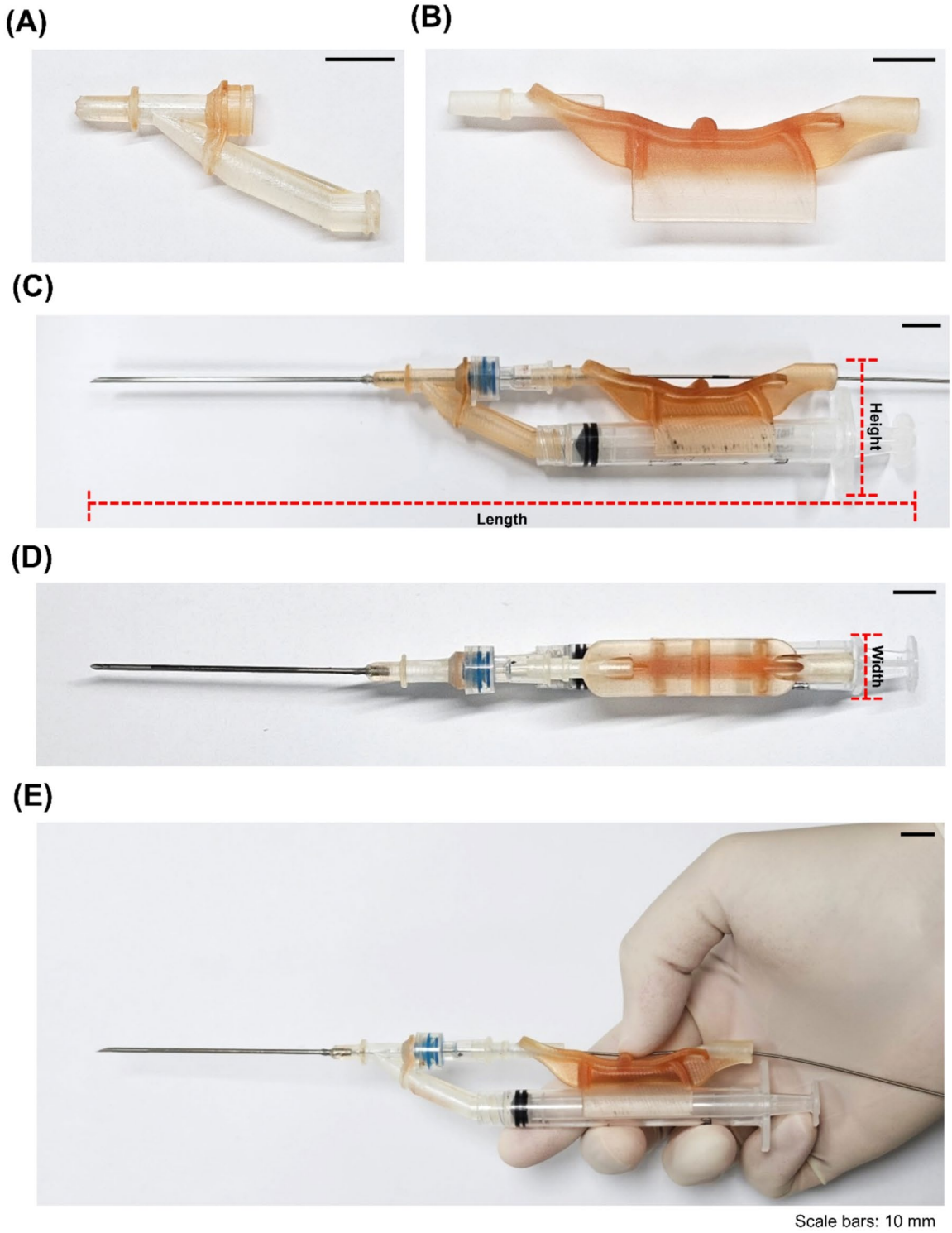

Fig. 3. Preparation for one-hand guidewire introducer (OGI). (**A**) 3D-printed a Y-connector and (**B**) a thumb trigger. (**C**) Lateral view and (**D**) top view of the OGI. (**E**) Gripping method of the OGI. (scale bars: 10 mm).

Guidewire insertion procedures in the porcine internal jugular vein

All pigs were anesthetized intramuscularly with a mixture of 50 mg/kg zolazepam and 50 mg/kg tiletamine (Zoletil 50; Virbac, Carros, France) and 10 mg/ kg xylazine (Rompun; Bayer HealthCare, Leverkusen, Germany) before the experiment. Anesthesia was maintained by inhalation of 0.5–2% isoflurane (Ifran®; Hana Pharm. Co., Seoul, Korea) with 1:1 oxygen (510 mL/kg/min). The pig was positioned in Trendelenburg. Aseptic disinfection and draping were conducted. Preprocedural ultrasound scanning (iU22; PHILIPS, Amsterdam, Netherlands) was performed to

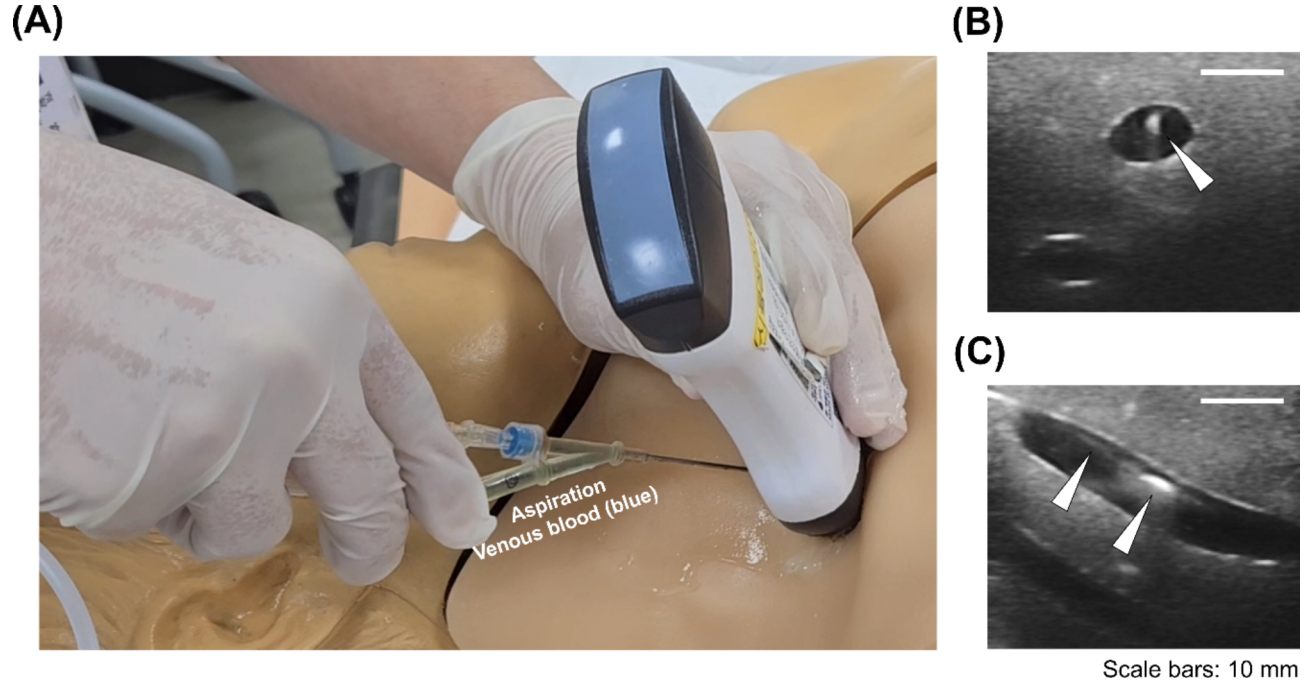

Fig. 4. Photographs and ultrasound images of the guidewire insertion using one-hand guidewire introducer (OGI) in a phantom. (**A**) Venous aspiration. (**B**) Out-of-plane and (**C**) in-plane US images after guidewire (*white arrowheads*) insertion. (scale bars: 10 mm).

determine the proximal, middle, and distal portions of the internal jugular vein. A guidewire insertion procedure using the conventional kit was conducted in group A (Fig. 5A). After obtaining the proper ultrasound view and determining the needle entry site, the needle was gently inserted and advanced out of plane view until the needle tip reached the internal jugular vein under real-time ultrasound guidance. When the distal end of the needle was located in the target jugular vein under ultrasound view, a negative aspiration pressure was applied to the syringe to check whether the needle is correctly located in the vein[30]. After venous blood aspiration, hand shifts were performed; the left hand shifted from the ultrasound probe to the puncture needle, and the right hand shifted from the syringe to the guidewire. After advancing guidewire, the ultrasound probe was moved toward the brachiocephalic vein to check whether the guidewire was placed correctly in the target vein. A guidewire insertion procedure using the OGI kit was performed in group B (Fig. 5B and Video S1). The process from obtaining the proper ultrasound view to inserting needle tip was identical to that of group A. When the distal end of the needle was confirmed in the target jugular vein under ultrasound view, the blood aspiration was performed using the little finger of the right hand without hand shifts. Then, guidewire was advanced into the punctured jugular vein using the thumb of the right hand under real-time ultrasound guidance. Post-procedural ultrasound scanning was performed to confirm the location of the inserted guidewire and the presence of possible complications immediately after the procedure. If resistance was encountered during guidewire advancement, the guidewire was completely removed, and needle reinsertion was performed under ultrasound guidance. This procedure was performed in the same way at the different portions of the internal jugular vein. All procedures were conducted by an anesthesiologist with 10 years' experience.

Outcome assessments

Each trial was recorded using a video camera, and procedural outcomes were analyzed based on the videos. The effectiveness of the guidewire insertion procedure with OGI was assessed and compared between the study groups considering the following variables: first-attempt success, number of needle redirections and guidewire insertions, time to guidewire insertion, global rating scales, and procedure-related complications including posterior wall puncture, arterial puncture, hematoma, and guidewire malposition. First-attempt success was defined as the successful placement of the guidewire in the internal jugular vein on the first-puncture attempt without needle redirections and guidewire reinsertion[31]. Time to guidewire insertion was calculated from skin puncture to guidewire placement into the target internal jugular vein. Guidewire insertion must be confirmed via ultrasound view. The technical performance and overall quality were assessed with a GRS score (total score: 15): the GRS consisted of seven items, each rated on a 5-point rating scale[32]. The GRS predominantly assessed more general behaviors and the overall performance of the participant. The seven items included preparation for the procedure, respect for tissue, time and motion, instrument handling, flow of procedure, knowledge of procedure, and overall performance. Among them, three items (time and motion, instrument handling, and flow of operation) were used to quantitatively measure the overall performance of guidewire insertion[33].

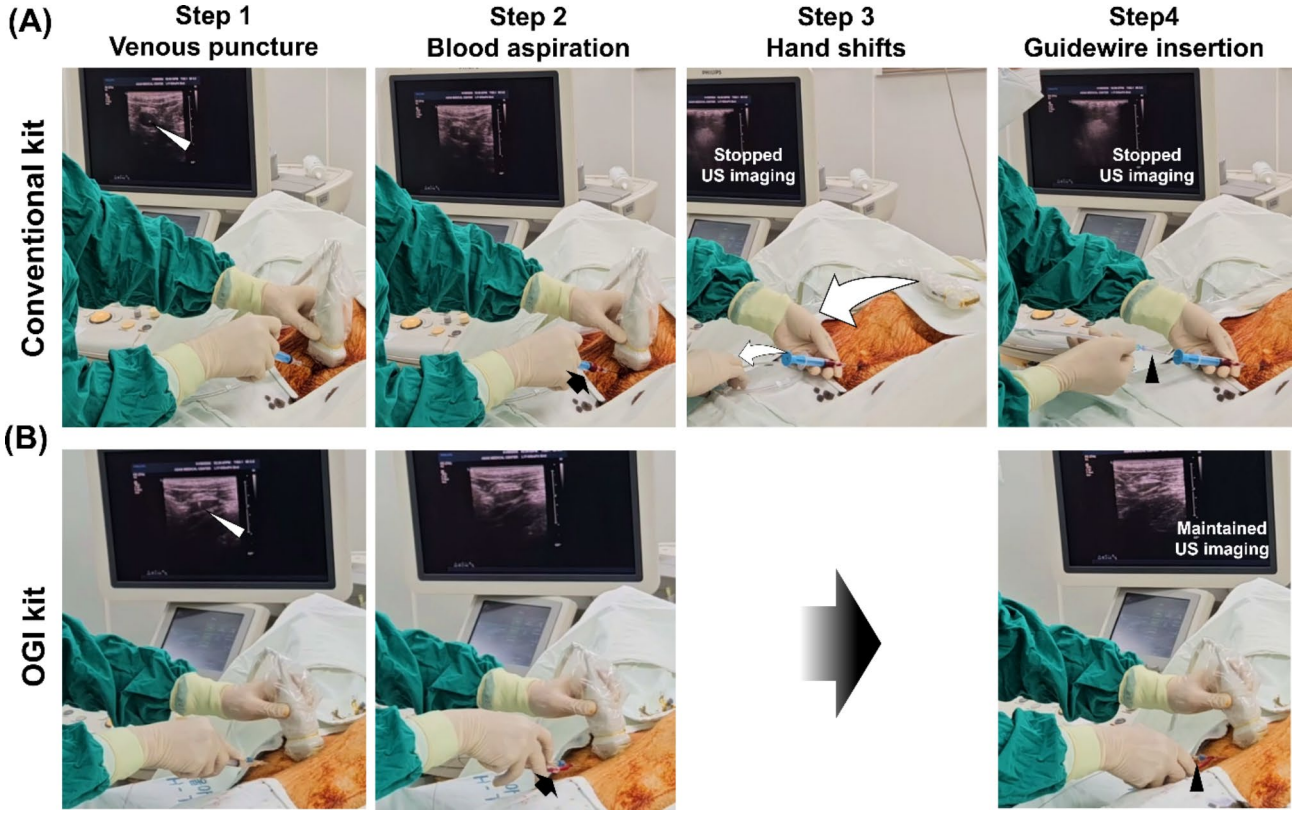

Fig. 5. Representative photographs showing the technical steps for guidewire introduction under ultrasound guidance in porcine internal jugular vein using (**A**) the conventional central venous catheterization (CVC) kit or (**B**) one-hand guidewire introducer (OGI). Step 1: venous puncture and confirm needle tip (*white arrowheads*) in internal jugular vein; Step 2: perform blood aspiration (*black arrows*); Step 3: hand shifts (from ultrasound probe to syringe, from syringe to guidewire) (*white arrows*); Step 4: advance the guidewire (*black arrowheads*).

Statistical analysis

Data are expressed as number (proportion) or median (IQR), as appropriate. Differences between the groups were analyzed using the χ^2 and Mann-Whitney tests depending on the nature of the variables. p-values < 0.05 were considered statistically significant. Statistical analyses were performed using SPSS v27.0 (IBM, Chicago, IL, USA).

Data availability

The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Declarations

Competing interests

The authors declare no competing interests.

Additional information

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