Ultrasound-guided central venous vascular access—novel needle navigation technology compared with conventional method: A randomized study

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Abstract
Purpose: Central venous catheter insertion is a common procedure in the intensive care setting. However, complications persist despite real-time ultrasound guidance. Recent innovation in needle navigation technology using guided positioning system enables the clinician to visualize the needle’s real-time position and trajectory as it approaches the target. We hypothesized that the guided positioning system would improve performance time in central venous catheter insertion.

Methods: A prospective randomized study was conducted in a single-center adult intensive care unit. In total, 100 patients were randomized into two groups. These patients underwent internal jugular vein central venous catheter cannulation with ultrasound guidance (short-axis scan, out-of-plane needling approach) in which one group adopted conventional method, while the other group was aided with the guided positioning system. Outcomes were measured by procedural efficacy (success rate, number of attempts, time to successful cannulation), complications, level of operators’ experience, and their satisfaction.

Results: All patients had successful cannulation on the first attempt except for one case in the conventional group. The median performance time for the guided positioning system method was longer (25.5 vs 15.5 s; \( p = 0.01 \)). And 86% of the operators had more than 3-year experience in anesthesia. One post-insertion hematoma occurred in the conventional group. Only 88% of the operators using the guided positioning system method were satisfied compared to 100% in the conventional group.

Conclusion: Ultrasound-guided central venous catheter insertion via internal jugular vein was a safe procedure in both conventional and guided positioning system methods. The guided positioning system did not confer additional benefit but was associated with slower performance time and lower satisfaction level among the experienced operators.

Keywords
Central venous catheter, internal jugular vein, ultrasound guidance, intensive care, guided positioning system

Introduction
Central venous catheter (CVC) insertion is a common procedure in the intensive care setting. Recent guidelines from the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB)¹ and the Association of Anaesthetists of Great Britain and Ireland² recommend real-time ultrasound (US) guidance for CVC insertion, particularly during an internal jugular venous approach.
The needle navigation technology, also known as guided positioning system (GPS), is a recent advancement in US technology. This system allows users to identify real-time needle trajectory and depth as it approaches the vascular target and thus provides better needle visibility leading to shorter execution time, lesser needle repositioning, and lesser tissue manipulation, while improving patient comfort and safety.3

The eZono 4000 (eZono, Jena, Germany) is an US model which is equipped with GPS technology called eZGuide® Adaptive Needle Recognition software. This system enables GPS by creating an electromagnetic field that communicates with a transducer and an electromagnetic sensor sheathed by a vascular access needle. eZGuide is performed free hand with no restriction to either in-plane or out-of-plane methods.4 Through color coding, the US screen displays the alignment of the needle and the position of the tip relative to the imaging plane (Figure 1). This real-time feedback provides accurate needle trajectory, prior to puncturing the patient’s skin, and maintains the chosen route to the target.5,6

We hypothesized that the use of GPS would shorten the performance time in CVC insertion via internal jugular vein (IJV) using the US guidance. The objectives of this study are to compare the procedural efficacy and safety between two groups (conventional two-dimensional (2D) vs GPS method) using eZono 4000.

Materials and methods

This is a prospective randomized study conducted in adult intensive care unit (ICU) in University of Malaya Medical Centre, Kuala Lumpur, Malaysia from February to October 2016. The institutional ethics committee approval was obtained (MEC ID: 2016-2044) and the study was registered with National Medical Research Registry (NMRR-16-334-29476) and ClinicalTrials.gov (NCT03214575). All aspects of the research were undertaken in accordance to the Declaration of Helsinki and adhered to the applicable CONSORT guidelines (Figure 2).

Patients who required central venous vascular access in ICU were recruited. Exclusion criteria were refusal to participate in this study by patient or their legal representative and patient with known history of difficult central venous access of the IJV. After obtaining consent from patient or next of kin, patient would be assigned to either the conventional 2D method or the GPS method using a computer-generated randomization table.

All the operators received a standard 5-min briefing by the investigator and were guided through a hands-on session using the vascular phantom (Blue Phantom Inc., Bothell, WA, USA). An 18-gauge introducer needle attached to a 5-mL Luer-lock syringe was used to cannulate the vascular target using the short-axis venous scan out-of-plane needling approach, with or without the eZono 4000 needle guidance system depending on the group. The operators could practice up to 20 min or until they were ready to perform on actual patient. The short-axis venous scan out-of-plane needling approach was the commonest technique for US-guided CVC insertion via IJV used by our trainees in their daily practice.

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The procedure was performed using the eZono 4000 US machine and its linear array transducer L3-12NGS (3–12 MHz). Operators assigned to the GPS method had the eZGuide software activated, whereas those performing
the conventional procedure had the software technology disabled while using the US machine. The performance time was measured in seconds using a stopwatch. The performance time is defined as the time measured from placing the needle on the skin to successful vessel puncture as indicated by blood withdrawn into the syringe.

The primary outcome was the procedural efficacy measured by successful cannulation based on the performance time and number of attempts. We also assessed the complication rate, that is, secondary tissue injury, hematoma, bleeding, pneumothorax, hemothorax, or arterial puncture. Operators’ level of experience and satisfaction were also recorded.

**Statistical analysis**

Based on a pilot sample of 10 patients using the conventional 2D method, mean successful performance time was 14 s (standard deviation (SD): 9). We deemed that a 40% reduction in performance time required for successful cannulation is clinically significant. Considering 90% power, this required a minimum sample size of 47 per group to detect the above differences with a two-sided significant level of 0.05. To compensate for shifting from normality, we recruited 50 patients per group in our study.

All data were analyzed using SPSS software version 22.0 (IBM Corp., Armonk, NY, USA). Variables with normal distribution were expressed as mean ± SD and compared with the parametric unpaired two-tailed t test. Data with skewed distribution were compared with the Mann–Whitney U test and expressed as median (interquartile range). Categorical data were presented as frequencies (percentages) and compared with the χ² test. All tests were two-sided, with statistical significance defined as p < 0.05.

**Results**

A total of 108 patients were screened for eligibility for the study (Figure 2). Eight patients were excluded due to reasons such as unable to obtain consent (n=3) and IJV cannulation was not suitable (n=5). No differences in the demographic profile were observed (Table 1). All patients were critically ill based on Sequential Organ Failure Assessment (SOFA) and Simplified Acute Physiology Score (SAPS II score). Most cases were ventilated and 24 patients were coagulopathic requiring blood product transfusion prior to and during the procedure.

All patients had successful cannulation on the first attempt except for one case in the conventional group which required the second attempt (Table 2). The median performance time for the GPS method was significantly longer (25.5 s vs 15.5 s; p<0.01). One case from the conventional group developed hematoma following cannulation (Table 2). Patient was a known case of coagulopathy requiring blood product transfusion prior to the procedure. No other adverse events were observed in this study.
All the operators were trainees in the anesthesia residency program with prior experience in using US guidance for CVC cannulation (Table 3). Majority of them had more than 3 years of anesthesia experience (86%). The operators’ satisfaction level was assessed using a numerical scale of 1–10 in which a score $\leq 6$ is considered not satisfied and $\geq 7$ as satisfied (Table 4). All operators from the conventional group were satisfied compared to only 88% operators in the GPS group ($p=0.012$).

**Discussion**

Our study showed 100% successful cannulation with US guidance, which all patients in the GPS group had successful cannulation on the first attempt and only one patient required second attempt in the conventional group. This study demonstrates the high success rate for CVC insertion using US guidance either with the conventional or with the GPS method.

US guidance for CVC insertion has been advocated as an important measure to improve the efficacy and quality of procedures and reduce procedure-related morbidities.$^7,^8$ The use of US enhances safety in several steps including the evaluation of puncture site, recognition of local pathology, verification of guidewire/catheters in a vessel, information on catheter tip position, and recognition of complications. A recent meta-analysis involving 35 trials shows that US-guided CVC placement for IJV reduces the total rate of complications when compared to traditional
Table 3. Operator’s years of experience in anesthesia training.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Conventional (n = 50)</th>
<th>GPS (n = 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator’s years of experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 to &lt;2 years</td>
<td>3 (6)</td>
</tr>
<tr>
<td>in anesthesia training, n (%)</td>
<td>2 to &lt;3 years</td>
<td>14 (28)</td>
</tr>
<tr>
<td></td>
<td>3 years and above</td>
<td>43 (86)</td>
</tr>
</tbody>
</table>

GPS: guided positioning system.

Table 4. Operator’s satisfaction level.

<table>
<thead>
<tr>
<th>Satisfaction score (numerical scale)</th>
<th>Conventional</th>
<th>GPS</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0.012a</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>1</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>2</td>
<td>18</td>
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<tr>
<td>7</td>
<td>3</td>
<td>9</td>
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<td>8</td>
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GPS: guided positioning system.

Landmark cannulation techniques (3.96% vs 13.48%, risk ratio 0.29 (95% confidence interval (CI): 0.17–0.52)). The overall success rate was notably higher in the US group compared to the landmark technique group (97.6% vs 87.64%, risk ratio 1.12 (95% CI: 1.08–1.17)). US reduces the number of attempts and the time taken for successful cannulation. Furthermore, US guidance during IJV CVC cannulation reduced the rate of inadvertent arterial puncture, hematoma formation, and other complications such as thromboembolism, pneumothorax, and nerve injury.

In our department, we routinely perform short-axis US scan and out-of-plane needling approach in US guidance CVC placement for IJV. This approach allows better visualization of the vein in relation to adjacent anatomical structures, with shorter time for needle placement and higher success rate compared to the long-axis and in-plane approach.

Needle navigation technology versus the conventional method

Needle navigation technology is a recent advancement in US technology which may improve the outcome in CVC cannulation. Kim and colleagues demonstrated that the electromagnetic guidance by eZono significantly decreased the time required for needle placement by novices in both in-plane and out-of-plane approaches. A randomized crossover study by Auyong et al. demonstrated that real-time needle guidance technology by eZono showed a significant improvement in needle accuracy and performance time during cannulation of a simulated IJV in an US phantom. There were also other studies using magnetic field needle guidance technology by other US machines such as SonixGPS™ and Venue 50 GE Healthcare. Those studies also showed an improvement in success rate and performance time. However, all the studies mentioned above were performed on the simulated phantom model and the recruited operators were novices in the US-guided vascular access.

This study would be the first to evaluate the efficacy and safety of conventional US versus GPS for CVC placement in human subjects and involved experienced operators. This study should reflect the actual practice in an ICU setting. Our results showed that the GPS method has a longer median performance time. US scanning and needle positioning for vascular access are dynamic processes as vessels can collapse, pulsate, and be displaced within the body. Scanning and needling accessibility can also be affected by the patient’s anatomical variation. The simulated phantom models cannot mimic the above scenario. GPS has low flexibility that compels the operator to adapt patient’s anatomy to the procedure and not the opposite. After all, the use of US is operator dependent, that is, relies on operator’s skill and dexterity, and not depending on “ultrasound needle guidance/GPS” alone. In needle tip navigation, the operator needs to constantly manipulate the angulation of the probe to follow the needle tip tracking during needling advancement. Likewise, for the in-plane technique, the operator needs to maintain the alignment of the probe and needle in order to visualize the entire needle at all time. The above-mentioned scenario requires a good control of needle probe manipulation.

Safety and complications

Our study was conducted on critically ill patients in ICU, who are vulnerable and at risk of complications related to CVCs. This complication can cause serious morbidity and mortality. To minimize the risk of complication, we only recruited operators with at least 1 year of anesthesia experience and had previous exposure to US-guided vascular access. CVC placement is a routine procedure in the anesthesia training program. As a result, we had 100% success rate and 99% completed on the first attempt. The potential immediate complications that resulted from the needle cannulation are secondary tissue injury, hematoma, bleeding, pneumothorax, hemothorax, or arterial puncture. We only had one case of hematoma and it was attributed to patient’s coagulopathic state despite receiving blood product transfusion prior to the procedure.

Another study evaluated the safety and effectiveness of training program for US-guided IJV catheterization in 118 patients in a single-center ICU. The study reported a 90% success rate with 77% on the first attempt and major complications occurred in 4% of the cases. Operators with more than 15 previous US-guided cannulations (regarded as experienced) would have an increased success rate...
(95% vs 79%, \( p=0.01 \)).\(^{16}\) The skills in US-guided IJV CVC placement can easily be acquired with training.\(^{17}\)

Limitations

This study has several limitations. Our primary limitation is that the number of subjects recruited was not adequately powered to assess the outcomes like success rate and complication rate. Both techniques showed no differences in success and complication rates.

The second limitation is that the operators have lack of training using the GPS method. Any newly introduced technology would require learning curve to master. A 5-min orientation followed by practical session on phantom model may be inadequate. Performing on a simulated phantom model can be totally different from handling a human subject. The operators in this study had considerable experience in US-guided vascular access and therefore introducing the new modality of navigation system did not offer additional advantage. The results could be different if the operators were novices. The electromagnetic needle guidance system may be beneficial for US-guided peripheral nerve blocks or vascular cannulation in the early learning period.\(^{12}\)

The operators in the GPS group reported that the image including the target box (square) and trajectory pathway became unstable when the magnetized needle was placed too near to the US transducer. They required more time to make adjustments such as angulating the needle against the transducer until the target box falls into the cross-sectional image of the IJV before advancing the needle toward the target. As the system is too sensitive, a rapid movement of the needle may cause the target box to move out of the cross-sectional image of IJV and this factor again contributes to a longer performance time.

In this study, we did not measure the time after successful cannulation until completion of the whole procedure as it will be subjected to many potential technical problems which did not reflect the US guidance itself such as the time taken to insert and advance the guidewire, and dilatation before catheter insertion using the Seldinger technique. However, the time taken to complete the whole procedure would be important, as the tracking system might compel the operator to adjust the hitting angle of the needle, thus influencing the subsequent introduction of the guidewire and catheter direction and time to complete the whole procedure.

We did not evaluate the incidence of posterior vessel wall puncture. Although posterior vessel wall puncture has not been specifically associated with acute complications in vivo, it remains a surrogate of needling accuracy for US needle guidance.\(^{5}\)

We recommend future studies to be performed using the GPS method in human subjects, comparing the performance time between novice and expert operator and comparing the lateral in-plane technique\(^{18,19}\) versus the usual short-axis venous scan and out-of-plane needling approach. The lateral short-axis view in-plane needling technique was described by Pittiruti et al.\(^{19}\) for percutaneous IJV cannulation. This technique allows a panoramic anatomical view and the entire length of the needle. The subcutaneous tract of the catheter has a straighter course with a less acute angle and lower possibilities of catheter kinking.

Conclusion

US-guided CVC insertion via IJV is a safe procedure in both the conventional and GPS methods. GPS did not confer additional benefit but was associated with slower performance time and lower satisfaction level among the experienced operators.

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Declaration of conflicting interests

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