A Randomized Trial of Ultrasound Image–based Skin Surface Marking versus Real-time Ultrasound-guided Internal Jugular Vein Catheterization in Infants

Koji Hosokawa, M.D.,* Nobuaki Shime, M.D., Ph.D.,† Yuko Kato, M.D.,‡ Satoru Hashimoto, M.D., Ph.D.§

Background: Ultrasound-guided central venous catheterization has been recommended to increase the procedural success rate and enhance patient safety. However, few studies have examined the potential advantages of one ultrasound technique with another, specifically in small infants.

Methods: The authors randomly assigned 60 neonates and infants weighing less than 7.5 kg to an ultrasound-guided skin-marking method (n = 27) versus real-time ultrasound-assisted internal jugular venous catheterization (n = 33). The times to successful puncture of the internal jugular vein and to catheterization were measured. Attempts at needle punctures for successful catheterization were counted. Procedural complications were recorded.

Results: In the real-time group, compared with the skin-marking group, venous puncture was completed faster (P < 0.03), the time required to catheterize was shorter (P < 0.01), and fewer needle passes were needed. Specifically, fewer than three attempts at puncture were made in 100% of patients in the real-time group, versus 74% of patients in the skin-marking group (P < 0.01). A hematoma and an arterial puncture occurred in one patient each in the skin-marking group.

Conclusions: The real-time ultrasound guidance method could enhance procedural efficacy and safety of internal jugular catheterization in neonates and infants.

SUCCESSFUL central venous catheterization in neonates or small infants is a challenging procedure for anesthesiologists. The internal jugular vein offers a convenient and reliable access in these patients,1 justifying the pursuit of procedural refinements for its safe catheterization. Ultrasound guidance is useful to increase the procedural success rate and lower the risk of complications.2–8 The skin surface–marking method, guided by ultrasound, allows a more precise targeting of the vein and increases the rate of successful catheterizations, compared with the traditional anatomical landmark method.2,5 The real-time use of ultrasound during needle insertion might provide additional help with venous puncture in real time. Questions remain, however, with respect to the method of choice.9,10 Although the National Institute for Clinical Excellence guidelines in the United Kingdom recommend specifically the use of the real-time method in adults and children,8 a recent pediatric study has yielded conflicting results, reporting a 78% success rate associated with the real-time ultrasound method,9 significantly lower than that associated with the anatomical landmark method. To the best of our knowledge, no study has directly compared the performance of these two ultrasound-guided methods.

We have previously examined the effect of ultrasound as the surface-marking method and found a significantly higher 97% success rate, compared with a 62% with the anatomical landmark method, performed by anesthesiologists with limited experience in patients with an approximately 7.6-kg average body weight.11 That study also highlighted the lower success rate of jugular vein punctures in small patients despite the use of the ultrasound-guided skin-marking technique.

Therefore, we sought to expand the application of ultrasound by conducting a randomized study. The aim of this trial was to compare the outcomes associated with the real-time method with those associated with the skin surface–marking method in infants and neonates.

Materials and Methods

The protocol was approved by the Institutional Ethics Committee of the University Hospital of the Kyoto Prefecture School of Medicine (Kyoto, Japan). The Committee did not request that written parental consent be obtained because the procedure using ultrasound guidance was already widely practiced.

Between September 2005 and August 2006, we enrolled 60 consecutive neonates and infants weighing less than 7.5 kg, scheduled to undergo surgery for congenital heart disease. Skin erosions or hematomas at or near the insertion site, or visible recent catheterization scars were exclusion criteria. Patients with a persistent left superior vena cava or who had undergone previous bidirectional cavopulmonary shunt surgery were included.

Study Protocol

Using the envelope method, the patients were randomly assigned to skin surface marking, using two-dimensional ultrasonography before the insertion attempt (skin-marking group) versus real-time two-dimensional ultrasonography (real-time group).

This article is featured in “This Month in Anesthesiology.”

 Please see this issue of ANESTHESIOLOGY, page 5A.

* Research Associate, Department of Anesthesiology. † Clinical Fellow. ‡ Associate Professor, § Clinical Professor, Division of Intensive Care Medicine.

Received from the Department of Anesthesiology and Division of Intensive Care Medicine, University Hospital, Kyoto Prefectural School of Medicine, Kajii-cho, Kamigyo-ku, Kyoto 602-8566, Japan. This article is featured in “This Month in Anesthesiology.”

Address correspondence to Dr. Shime: Division of Anesthesiology and Intensive Care Medicine, University Hospital, Kyoto Prefectural University of Medicine, 465 Kajii-cho, Kamigyo-ku, Kyoto 602-8566, Japan. shime@koto.kpu-m.ac.jp. This article may be accessed for personal use at no charge through the Journal Web site, www.anesthesiology.org.
Operators and Assistants

The operators performing the jugular venous catheterizations were 10 fellows of our anesthesia department, who had had between 3 and 6 yr of training in clinical anesthesia and formal training in adult central venous catheterization, without special training in pediatric central venous catheterization. They were assisted by one of two experienced anesthesiologists specialized in the perioperative management of pediatric cardiac patients, who manipulated the ultrasonography probe. The operator was replaced by another similarly experienced trainee after three consecutive unsuccessful puncture attempts.

Central Venous Catheterization

Central venous catheterization was performed after the patient was under general anesthesia, chemically paralyzed, endotracheally intubated, and connected to a ventilator, with application of 5 cm H₂O positive end-expiratory pressure. With the patient in the 30° Trendelenburg position, a shoulder roll was placed to extend the neck, which was rotated to expose the puncture site. The bed was also rotated, as needed, to allow a horizontal access to the right jugular vein, selected as the initial target. However, in presence of a left superior vena cava, or when the right jugular vein diameter was less than 3 mm, the left vein jugular was selected. A double-lumen, 17-gauge central venous catheter (Nippon-Sherwood, Tokyo, Japan) was inserted by the Seldinger technique, using a 24-gauge indwelling cannula and 0.18-inch guide wire combined with a dilator.

Skin-surface Marking

The location of the internal jugular vein (fig. 1A) was marked as a line on the skin surface with the assistance of a 7.5 MHz iLook15 or SonoSite180 two-dimensional ultrasonograph (both from SonoSite, Bothell, WA), and the operator performed the venous puncture along the cutaneous marking (fig. 1B).

Real-time Method

With the use of the same instrumentation, the operator performed the venous puncture assisted by two-dimensional ultrasonographic imaging in real time (figs. 1C and D), with the probe protected by a sterile cover, handled by an assistant.

Assessment of Study Endpoints

Successful venous cannulation was confirmed by measuring the intravascular pressure with a 24-gauge indwelling catheter inserted in the vessel. The time needed to place the indwelling cannula in the vein (successful puncture) or the time needed to insert the catheter (successful catheterization) was measured. The indwelling cannula in the vein was confirmed by blood back-flow, and suitable insertion of catheter was confirmed by smooth pass-through of the guide wire and easy aspiration of blood. The time was counted from the start of the first puncture. Procedures successfully completed within 60 s were recorded as less than 1 min. When the procedure was unsuccessful, the time was recorded as greater than 20 min. The number of attempts to achieve a successful puncture was also measured. Complications, including hematoma, pneumothorax, or arterial puncture were recorded.

Sample Size and Statistical Analysis

We estimated that the random assignment of 60 subjects was needed to provide an 80% power to detect a 50% shortening of the time to successful puncture, at a
Table 1. Baseline Characteristics of the Study Groups

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<th>Skin-marking Group (n = 27)</th>
<th>Real-time Group (n = 33)</th>
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<tr>
<td>Age, months</td>
<td>4.6 ± 3.8</td>
<td>4.9 ± 5.6</td>
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<tr>
<td>Male/female, n</td>
<td>12/15</td>
<td>17/16</td>
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<tr>
<td>Body weight, kg</td>
<td>4.7 ± 1.4</td>
<td>4.7 ± 1.7</td>
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<tr>
<td>Vein diameter, mm</td>
<td>5.2 ± 1.0</td>
<td>4.7 ± 1.2</td>
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<tr>
<td>Vein depth, mm</td>
<td>5.5 ± 1.2</td>
<td>5.4 ± 1.0</td>
</tr>
<tr>
<td>Right/left jugular</td>
<td>24/3</td>
<td>30/3</td>
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<tr>
<td>puncture, n</td>
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Unless specified otherwise, values are mean ± SD. All between-groups differences are statistically nonsignificant (Fisher exact test).

Results

Of 60 patients enrolled to this randomized study, no patient was excluded. The baseline characteristics of the study groups are shown in table 1. There were no significant differences between the two groups in age, sex, body weight, diameter of the vein, depth of the vein beneath the skin, and side of successful puncture (Fisher exact test).

Procedural Success Rates

The times to successful puncture and catheterization were significantly shorter ($P = 0.03$, log rank, and $P < 0.01$, respectively) in the real-time group than in the skin-marking group (figs. 2A and B). Catheterization was completed within less than 20 min in 100% of patients in the real-time group, compared with 89% in the skin-marking group ($P = 0.08$, Fisher exact test). Significantly fewer needle passes were needed in the real-time group than in the skin-marking group. The vein was successfully punctured with fewer than three attempts in 100% of patients in real-time group, compared with 74% of patients in the skin-marking group ($P < 0.01$; table 2). An externally visible hematoma developed and an artery was punctured without development of hematoma, each in separate patients, in the skin-marking group.

Discussion

This prospective randomized study identified significant advantages associated with the use of real-time ultrasonography performed at the time of central venous catheterization in the smallest patients ever reported. The real-time ultrasound-assisted method saved a significant amount of time needed for the catheterization and made fewer needle passes compared with the ultrasound-guided skin-marking method. This superior performance of the real-time ultrasound method seems beneficial even for neonates or infants.

Ultrasound-guided central venous catheterization uses real-time ultrasound during catheter insertion or before the procedure to mark the skin surface. Both methods have been associated with higher success rates than the traditional anatomical landmark method, even when performed by operators with limited experience (table 3). The National Institute for Clinical Excellence guidelines have recommended the real-time use of ultrasound during central vein catheterization in all patients, children and adults. However, a controversy has recently emerged with respect to the use of the real-time method in the pediatric population. In the study by Grebenik et al., the outcomes associated with the real-time method were surprisingly poor compared with the anatomical landmark method. We hypothesize that, when the procedure is attempted by experienced oper-
ators, the use of ultrasound might be a disturbance, and that the presence of the ultrasound probe in a limited work space represents an impediment. The compression of small veins by the bulky probe is another potential problem in small infants. It is noteworthy that the studies that found advantages associated with the real-time method tended to be performed by fellows, whereas studies reporting negative outcomes were performed by experienced anesthesiologists (the “old dog and new trick” phenomenon).

We have cautiously introduced the use of ultrasound in our clinical practice. We wished to become familiar with ultrasound before studying its use in real time, therefore, began with a comparison between the anatomic landmark and the ultrasound-guided skin-marking method, where we found a significantly higher success rate with the latter (62% vs. 97%). The success rate in the skin-marking group in the current study was also high (89%), despite the inclusion of smaller and more challenging patients. After having become familiar with ultrasound, our success rate associated with the real-time method was 100%, similar to that of our previous study showing a benefit of the ultrasound-guided, skin-marking method. These observations indicate that, before applying it clinically in real time, appropriate training should be acquired in the use of ultrasound. Because, in our practice, the use of ultrasound has increased the success rate of central venous catheterization and patient safety, we now use preferentially the real-time method.

The high cost of devices has become a critical factor when considering the introduction of ultrasound instrumentation in clinical practice. Several studies have addressed the issue of cost-effectiveness and found a significant economic benefit conferred by ultrasound. The new-generation, handheld ultrasound devices we used in this study are user-friendly, expeditious, and economical, particularly suited for applications in the operating room.

Our study was limited by its small sample size and by the unblinded assessment of outcomes. Because the success rate of the skin-marking method was nearly 90%,

<table>
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<th>Table 3. Comparison with Previous Studies</th>
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<tr>
<td><strong>Reference (Year)</strong></td>
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<tr>
<td><strong>Success Rate</strong></td>
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<tr>
<td>Alderson et al. (1993)</td>
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<td>Shime et al. (2004)</td>
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<td>Grebenik et al. (2004)</td>
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<td>Levy et al. (2005)</td>
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<td>Current study</td>
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NA = not applicable.
more than 800 subjects would have to be enrolled to detect a 5% higher rate of successful catheterization (80% power at 5% significance), which is a most important outcome measure. Therefore, we examined clinically important surrogate endpoints, such as procedural time or number of attempts needed to achieve a successful procedure.

In conclusion, compared with skin marking, the real-time ultrasound method was associated with more expeditions and less invasive internal jugular vein catheterization procedures in neonates and infants and might represent a valuable option in this special population.

The authors thank the anesthesia fellows who participated in this trial.

References