

A Randomized Crossover Study Comparing a Novel Needle Guidance Technology for Simulated Internal Jugular Vein Cannulation

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ABSTRACT

Background: Despite ultrasound guidance for central line placement, complications persist, as exact needle location is often difficult to confirm with standard two-dimension ultrasound. A novel real-time needle guidance technology has recently become available (eZono, Germany) that tracks the needle during insertion. This randomized, blinded, crossover study examined whether this needle guidance technology improved cannulation of a simulated internal jugular (IJ) vein in an ultrasound phantom.

Methods: One hundred physicians were randomized to place a standard needle in an ultrasound neck phantom with or without the needle guidance system. Video cameras were placed externally and within the lumens of the vessels to record needle location in real time. The primary outcome measured was the rate of posterior wall puncture. Secondary outcomes included number of carotid artery punctures, number of needle passes, final needle position, time to cannulation, and comfort level with this new technology.

Results: The incidence of posterior vessel wall puncture without and with needle guidance was 49 and 13%, respectively ($P < 0.001$, odds ratio [OR] = 7.33 [3.44 to 15.61]). The rate of carotid artery puncture was higher without needle navigation technology than with needle navigation 21 versus 2%, respectively ($P = 0.001$, OR = 12.97 [2.89 to 58.18]). Final needle tip position being located within the lumen of the IJ was 97% accurate with the navigation technology and 76% accurate with standard ultrasound ($P < 0.001$, OR = 10.42 [2.76 to 40.0]). Average time for successful vessel cannulation was 1.37 times longer without guidance technology.

Conclusion: This real-time needle guidance technology (eZono) shows significant improvement in needle accuracy and cannulation time during simulated IJ vein puncture. (ANESTHESIOLOGY 2015; 123:535-41)

IN the United States alone, over 5 million patients require central venous catheter (CVC) access annually.¹ CVC placement, however, is not without risk and can be associated with numerous technical challenges including arterial puncture, hematoma formation, pneumothorax, hemothorax, and catheter placement failure. These complications persist because knowing the location of the needle tip in relation to the target vessel can be challenging. Real-time ultrasound has been shown to improve cannulation success, decrease complications associated with the catheter placement, and decrease the need for multiple attempts.^{2,3} However, continuous needle visualization under ultrasound requires considerable amount of practice and dexterity. The inability to locate the tip of the needle can result in relying on surrogate markers, such as tissue movement, to infer its exact location. Even with the use of ultrasound technology, simulation studies have revealed an inadvertent rate of posterior vessel wall puncture as high as 34 to 64%.^{4,5}

What We Already Know about This Topic

- Despite ultrasound guidance for central line placement, complications persist, as exact needle location is often difficult to confirm with standard two-dimension ultrasound

What This Article Tells Us That Is New

- This study showed that using a simulated neck phantom and a novel needle guidance ultrasound technology decreased posterior vessel wall puncture and carotid puncture while improving needle passes and time

The eZono 4000 (eZono, Germany) is a Food and Drug Administration–approved ultrasound machine that incorporates a proprietary navigation system. The needle–transducer spatial orientation is displayed in the upper corner of the image screen. As the operator moves the needle in three dimensions, the ultrasound displays the needle trajectory and depth, along with color coding of the needle tip as it approaches the plane of the ultrasound beam in real time. This allows the operator

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to identify the correct needle trajectory before skin puncture and maintains the chosen path to the target zone (fig. 1). The tracking system is built into the ultrasound transducer, so no additional hardware is required. However, the needles must be magnetized first and almost any ferromagnetic needles are compatible with this technology.

The objective of this investigator-initiated nonfunded study was to compare the needle tip positioning under ultrasound with and without this novel navigation technology. The primary outcome was the rate of posterior wall puncture in a simulated internal jugular (IJ) and carotid model. Secondary outcomes included number of carotid artery punctures and needle passes, final needle position, time to cannulation, and comfort level with this new technology.

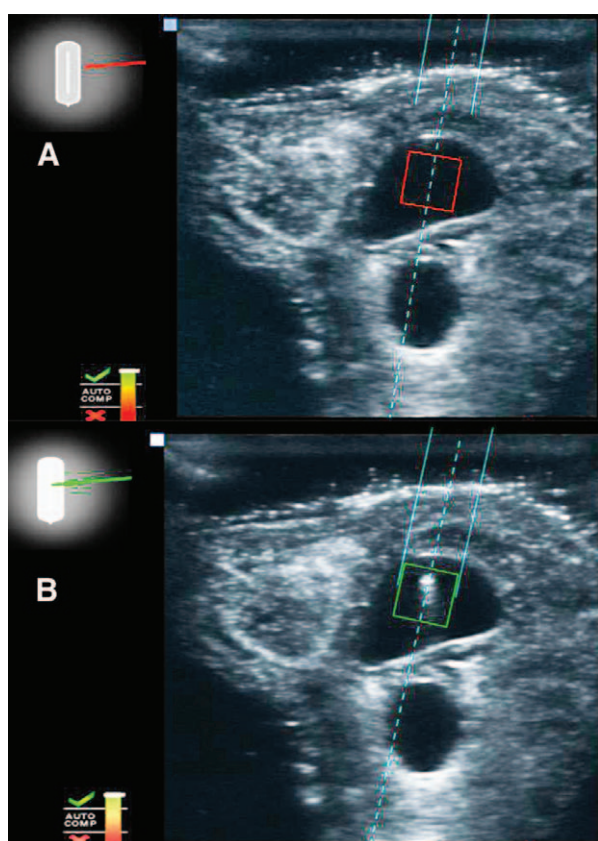


Fig. 1. Ultrasound image of simulated phantom with needle guidance. (A) A superficial internal jugular vein target and deeper circular carotid artery. Superimposed on the image is the real-time electronic needle guidance system. The *dashed line* represents the predicted needle trajectory. The *red box* represents the depth that the needle will cross the plane of the ultrasound. The *solid lines* on either side of the *dashed line* represent the actual depth of the needle. The top left corner shows a diagram of the transducer–needle relation. (B) Shows the same markings as that in A. The needle has been advanced further into the lumen of the simulated internal jugular vein. As the needle tip approaches the plane of the ultrasound beam, the target box changes color from *red* to *green*. At this point, the hyperechoic dot of the needle is also visible within the lumen of the internal jugular vein.

Materials and Methods

After institutional review board approval (Benaroya Research Institute, Virginia Mason Medical Center, Seattle, Washington) and informed verbal consent, a total of 100 physicians were enrolled in this randomized, volunteer, crossover study comparing IJ vessel cannulation in a simulated gel model. Subjects were identified at multidisciplinary continuing medical education courses and at our institution from February 2014 to March 2014.

After informed consent, an investigator guided the subjects through a practice session with and without the eZono 4000 needle guidance technology using a nonanatomical gel block. Participants used an 18-gauge introducer needle (6.35 cm) attached to a 5 ml Luer-lock syringe (Arrow International, USA). Using an out-of-plane technique, the subjects were able to practice for up to 20 min with and without the eZono needle guidance system.

Subjects were then randomized to having the eZono 4000 needle guidance system “on” or “off” during the first simulated vessel cannulation attempt in a custom-built gel phantom (fig. 1). The attempt sequence was determined with an electronic random number generator at the time of study execution. The program assigned each subject with either the number “1” for guidance or the number “2” for no guidance on the first attempt. Subjects were given the same 18-gauge introducer needle and asked to use ultrasound to cannulate the simulated IJ vein in the gel phantom with an out-of-plane approach (fig. 2). The gel phantom had an IJ vein (1.0 cm by 1.1 cm) that was located 1.1 cm deep and a carotid artery (0.7 cm by 0.6 cm) at 2.1 cm deep to the surface. The pressures of the simulated IJ vein were set at 10 to 15 mmHg, whereas the simulated carotid artery pressures were set at greater than 50 mmHg using the same pressure transducer. The two vessel lumens in the gel phantom were easily distinguished by the pressure required to compress them; 10 to 15 mmHg for the IJ and greater than 50 mmHg for the carotid.

For the crossover portion of the study, subjects had a second attempt to cannulate the simulated IJ vein. The second attempt was performed with the opposite ultrasound guidance option (*i.e.*, if the needle guidance system was turned “on” during the first attempt, it would be turned “off” during the second attempt). A “washout” period of at least 15 min was required between attempts to minimize the direct muscle memory, limiting the effect of the first attempt on the second attempt. The endpoint of each attempt was when the subject reported that they presumed successful placement of needle tip inside the IJ vein. After each cannulation, subjects were asked to describe their comfort level with the procedure (measured on an 11-point Likert scale with 0 = extremely uncomfortable and 10 = extremely comfortable).

For data collection, lumens of both vessels were filled with clear water. Video cameras were placed inside both the simulated artery and vein to monitor for vessel puncture and assess final needle position (fig. 2). A third video camera was



Fig. 2. External image of the simulated phantom. Picture of ultrasound transducer, needle, and neck simulation phantom. Superimposed in the bottom left corner is an image from the camera placed within the lumen of the simulated vessel imbedded within the neck simulation phantom. The superimposed image shows the needle completely traversing the simulated internal jugular vein to puncture the posterior wall of the vein.

placed externally to record the subject's hands to track needle passes. Recordings of each subject were reviewed by a blinded investigator to determine the incidence of posterior vessel wall punctures (primary outcome), carotid artery punctures, time from "skin" puncture to final needle, accuracy of needle placement within the target vessel at the conclusion of the procedure, and the number of passes (defined as any needle withdrawal of >0.5 cm and reinsertion).

Statistics

A total sample size of 100 subjects was determined by first assuming a conservative incidence for the primary outcome, posterior vessel wall puncture, is 36% under standard ultrasound use. We felt that an intervention that resulted in a 67% decrease in the incidence of posterior wall puncture would be considered clinically significant ($P \leq 0.05$, statistical power = 80%).

Data analysis included descriptive statistics and regression analysis to evaluate the effect of baseline characteristics on primary and secondary endpoints. Continuous variables were summarized using means and SDs, whereas categorical variables were presented using counts and percentages. Generalized linear models were used to determine which baseline covariates of interest were related to each dependent outcome. Binary outcomes (vessel wall puncture, needle tip within lumen, and carotid artery puncture) were based on the logistic distribution and results displayed as odds ratios (ORs), whereas continuous outcomes (time to cannulation, needle passes, and comfort score) followed either a log-normal or Poisson distribution and results summarized using the expected rate ratio. Each regression model included navigation technique ("treatment group"), randomized treatment sequence, and navigation attempt (first or second), as well as the covariate of interest. A P value of 0.05 or less was

Table 1. Baseline Characteristics of Subject Variables

Variables (n = 100)	%
Sex	
Male	59
Female	41
Type of practice	
Private	50
Academic	50
Specialty	
Anesthesiology	78
General surgery	11
Other	11
Years of practice	
<5	50
5–9	12
10–19	21
>20	17
Regular ultrasound use for vascular procedures	
Yes	64
No	36
Ultrasound readily available for use	
Yes	90
No	10
Number of ultrasound procedures performed per month	
<1	39
1–5	48
6–10	10
>10	3
Number of ultrasound procedures supervised per month	
<1	84
1–5	13
>5	3

considered statistically significant, and Statistical Analysis System (SAS Institute Inc., USA) version 9.2 was used for all analyses.

Results

Demographic data of the 100 subjects who participated in this study are found in table 1. Due to the crossover nature of this study, the baseline characteristics of both groups were identical. The proportion of navigation technology turned on and off as the first attempt was 53 and 47%, respectively. None of the outcome analyses found significant differences based on either the navigation attempt (first or second) or the randomized navigation sequence. The incidence of posterior vessel wall puncture without and with needle guidance was 49 and 13%, respectively ($P < 0.001$, OR = 7.33). Cannulation of the IJ with posterior wall puncture was also associated with private practice compared with academic ($P = 0.023$, OR = 2.57), not using ultrasound regularly for vascular access ($P = 0.024$, OR = 2.51), and not having the ultrasound readily available ($P = 0.017$, OR = 4.65). Factors that were not associated with posterior vessel wall puncture included sex, experience in practice, specialty, and the number of ultrasound-guided vascular access procedures

Table 2. Posterior Vessel Wall Puncture (Primary Outcome) Model Results with Odds Ratios, 95% CIs, and *P* Values for Each Covariate

Variables	Odds Ratio (95% CI)	<i>P</i> Value
Navigation used	0.14 (0.06–0.29)	<0.001
First navigation attempt	1.48 (0.70–3.16)	0.305
Randomized sequence (navigation ON followed by navigation OFF)	1.49 (0.65–3.45)	0.341
Sex (female)	0.52 (0.24–1.15)	0.106
Practice type (academic)	0.39 (0.17–0.88)	0.023
Years of practice		0.432
<5 vs. ≥20	0.47 (0.16–1.39)	
5–9 vs. ≥20	0.40 (0.09–1.69)	
10–20 vs. ≥20	0.75 (0.22–2.52)	
Specialty (anesthesia)	0.98 (0.29–3.35)	0.768
Number of ultrasound procedures performed		0.617
<5 vs. >100	2.40 (0.79–7.26)	
6–25 vs. >100	1.82 (0.62–5.37)	
26–50 vs. >100	1.75 (0.47–6.59)	
51–100 vs. >100	1.58 (0.43–5.83)	
Ultrasound procedures performed monthly		0.876
<1 vs. >5	1.38 (0.40, 4.83)	
1–5 vs. >5	1.29 (0.38, 4.39)	
Less than one ultrasound procedure supervised monthly	1.49 (0.51–4.31)	0.460
Regular ultrasound use for vascular access	0.40 (0.18–0.88)	0.024
Readily available for use	0.22 (0.06–0.76)	0.017

Each covariate is entered into a model with the covariates listed in the statistical methods section.

performed or supervised (table 2). Further analysis in the subgroup categories outlined in table 1 failed to identify any other subcategory associated with posterior vessel wall puncture or other outcomes measured.

The rate of carotid artery puncture was significantly higher without needle navigation technology than with needle navigation: 21 *versus* 2%, respectively ($P = 0.001$, OR = 12.97) (table 3). Final needle tip position being located within the lumen of the IJ was 97% accurate with the navigation technology and 76% accurate with standard ultrasound ($P < 0.001$, OR = 10.42). Irregular use of ultrasound ($P = 0.006$, OR = 4.18) and not having ultrasound available in practice ($P = 0.03$, OR = 4.53) also were associated with less accuracy of placement of the needle tip within the lumen of the IJ.

Continuous variables assessed included time to cannulation, number of needle passes, and comfort score with the procedure (table 3). Average time for successful vessel cannulation was 28.0 ± 35.1 s without navigation and 18.7 ± 17.9 s with navigation ($P < 0.001$). Least-squares means analysis revealed that not using navigation resulted in a procedure time 1.37 times longer than if navigation was used. The mean number of needle passes per attempt was 1.3 ± 0.8

passes with navigation and 1.93 ± 2.4 passes without navigation ($P < 0.001$). The average comfort level of the group using the navigation technology was not statistically higher than those that did not use the navigation software: 8.0 *versus* 7.4, respectively ($P = 0.092$).

Discussion

This study reveals that a novel free-hand electronic needle guidance technology that displays needle location in real time decreases the rate of posterior wall puncture in a simulated IJ vein. It is recognized that out-of-plane needle visualization with ultrasound is not a simple technique as exact needle location is often difficult to confirm.^{4–6} Reflective of this fact, complications from vascular access procedures persist despite ultrasound use.^{7–11} Advancements in ultrasound technology that can improve needle localization have the potential to further decrease the morbidity of central line placement over standard two-dimension real-time ultrasound. The eZono 4000 needle guidance system may significantly decrease the potential complications associated with IJ cannulation as well as reduce the time it takes to successfully place a CVC. In this study, participants were seven times more likely to pierce the back wall of the target vessel when the needle guidance system was not activated. Although posterior vessel wall puncture has not been specifically associated with acute complications *in vivo*, it remains a surrogate of needle accuracy for ultrasound needle guidance studies.^{4,5}

Despite consensus statements and meta-analyses stating that real-time ultrasound should be used, if available, for central line placement,^{2,3,12–15} adoption of ultrasound use is not necessarily widespread.^{16,17} In the United Kingdom, ultrasound was promoted as the preferred method for placement of IJ venous cannulation in 2002.¹⁸ A follow-up survey over 5 yr later found that only 27% of respondents used ultrasound as their preferred method of cannulation, despite 78% of respondents having ultrasound readily available.¹⁶ Since then, numerous studies have attempted to explore the reasons why ultrasound guidance for CVC placement is not used more frequently despite its availability. These surveys cite increased procedure time, lack of training with ultrasound, and a generalized feeling that ultrasound guidance is unnecessary.^{17,19} Efficient ultrasound-guided CVC placement requires repetitive practice and training.²⁰ The lack of comfort and technical skills to perform needle guidance with ultrasound may be one of the primary reasons adoption of standard two-dimension technology for vascular access has been delayed. A needle guidance system that intuitively displays the location of the needle may increase comfort and improve accuracy while mitigating the technical training required with ultrasound-guided vascular access.

Needle guidance systems for central venous access procedures are not new. Prior needle guidance technologies used during the placement of CVCs have shown promise in further

Table 3. Secondary Outcomes

Categorical Outcome Variables	%	Odds Ratio (CI)	P Value
Carotid artery puncture			
Navigation OFF	21	12.97 (2.89–58.18)	0.001
Navigation ON	2		
Needle tip within lumen of internal jugular vein at final needle position			
Navigation OFF	76	0.10 (0.02–0.36)	<0.001
Navigation ON	97		
Continuous Outcomes Variables	Mean ± SD	Rate Ratio (CI)	P Value
Time to cannulation (s)			
Navigation OFF	28.0 ± 35.1	1.37 (1.15–1.61)	<0.001
Navigation ON	18.7 ± 17.9		
Needle passes (n)			
Navigation OFF	1.9 ± 2.4	1.49 (1.19–1.87)	<0.001
Navigation ON	1.3 ± 0.8		
Comfort with the procedure (0–10)			
Navigation OFF	7.4 ± 2.3	0.92 (0.83–1.01)	0.092
Navigation ON	8.0 ± 1.9		

assisting users already using ultrasound.²¹ However, most of these needle guidance systems require additional hardware or disposable pieces that must be attached to the ultrasound probe in a sterile manner.^{22–26} The eZono 4000 needle guidance system does not require the use of specific introducer needles or extra attachments. The tracking of the needle is accomplished through sensors embedded within the ultrasound transducer. Ultrasound scanning and needle positioning for vascular access are dynamic processes as vessels can collapse, pulsate, and be displaced within the body. One reason standard fixed needle guidance systems have not become commonplace may be that they usually require specific or fixed angles of insertion. This does not allow the user to make dynamic changes as the target vessel becomes displaced. The eZono 4000 needle guidance system does not have such limitation, as it can be advanced in any angle or direction.

The primary limitation of this study is that all outcomes were collected from a simulated IJ vein embedded in a gel phantom; therefore, further studies in human subjects will be necessary to confirm these results. But a clinical trial using this technology on human subjects would not be able to replicate the crossover study fashion, as two identical cannulations would be impossible to perform. Furthermore, there is no *in vivo* system that is considered the accepted standard for tracking needle location, so incidence of posterior vessel wall puncture or carotid puncture would be almost impossible to accurately track. To best simulate a physiologic IJ placement, our custom gel phantom was designed with specific pressures in each of the vessels. The needle cannulation of this model attempted to replicate a true clinical experience with a low pressure venous system and a high pressure arterial system, something that has not been previously described in studies of this nature. However, care must be taken in interpreting the incidence of outcomes in our gel phantom study, as they could relate to actual *in vivo* complications. The simulated nature of our CVC cannulations

may have led to higher than previously described carotid artery puncture rates, perhaps due to the IJ vein and carotid vessel orientation. In addition, the study subjects understood that this was a simulation, as opposed to an actual patient, which may lead to a more cavalier attitude during needle insertion. Also, as we could visually track all needle punctures of the carotid, the actual incidence may be higher than previously reported, as other methods of counting carotid punctures may not be as accurate.^{27,28} As there was no way to blind subjects from the activation of the needle guidance system (all subjects practiced with the technology before the study cannulations), this may have introduced some inherent bias in certain users that the technology was already superior. This may have also artificially increased the rate of complications noted in our data.

A second limitation of this study is the crossover design itself. There is inherent bias in any methodology where there may be carryover effects from the first attempt to the second. To control for this, we adjusted our results for each subject's attempt sequence, randomized subjects' order in which they used the needle guidance technology, and required a 15-min washout period between attempts. Our results revealed that there was no statistical effect of attempt sequence.

A third limitation of this study is that a large portion of subjects (50%) in this study came from a single academic institution where ultrasound is readily available and regularly used for CVC cannulation. Therefore, the results may not be representative of national academic practices as a whole. Finally, the technology itself also has several limitations. First, needles must be magnetized with a sterile disposable magnet. This does add an additional step to the ultrasound guidance process; however, this action only takes a few seconds to accomplish. Second, the eZono 4000 guidance system currently does not have the accuracy necessary to aid in needle visualization beyond a depth of 3.5 cm, so deeper cannulations may not benefit from this technology.

In conclusion, this study shows that the eZono 4000 needle guidance system improves needle accuracy and reduces complications during simulated IJ vein cannulation. The significant improvements shown in all measured outcomes suggest that this technology has the ability to attenuate morbidity associated with CVC placement. Further studies in human subjects are necessary to corroborate these results.

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Competing Interests

The authors declare no competing interests. eZono AG (Jena, Germany) loaned the study equipment to the researchers for research use only during study recruitment phase.

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