Comparison of a novel real-time SonixGPS needle-tracking ultrasound technique with traditional ultrasound for vascular access in a phantom gel model

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Objective: Ultrasound-guided percutaneous vascular access for endovascular procedures is well established in surgical practice. Despite this, rates of complications from venous and arterial access procedures remain a significant cause of morbidity. We hypothesized that the use of a new technique of vascular access using an ultrasound with a novel needleguidance positioning system (GPS) would lead to improved success rates of vascular puncture for both in-plane and out-of-plane techniques compared with traditional ultrasound.

Methods: A prospective, randomized crossover study of medical students from all years of medical school was conducted using a phantom gel model. Each medical student performed three ultrasound-guided punctures with each of the four modalities (in-plane no GPS, in-plane with GPS, out-of-plane no GPS, out-of-plane with GPS) for a total of 12 attempts. The success or failure was judged by the ability to aspirate a simulated blood solution from the model. The time to successful puncture was also recorded. A poststudy validated NASA Task Load Index workload questionnaire was conducted to assess the student's perceptions of the two different techniques.

Results: A total of 30 students completed the study. There was no significant difference seen in the mean times of vascular access for each of the modalities. Higher success rates for vascular access using the GPS for both the in-plane (94% vs 91%) and the out-of-plane (86% vs 70%) views were observed; however, this was not statistically significant. The students perceived the mental demand (median 12.0 vs 14.00; P = .035) and effort to be lower (mean 11.25 vs 14.00; P = .044) as well as the performance to be higher (mean 15.50 vs 14.00; P = .041) for the GPS vs the traditional ultrasound-guided technique. Students also perceived their ability to access vessels increased with the aid of the GPS (7.00 vs 6.50; P = .007). The majority of students expressed a preference for GPS (26/30, 87%) as opposed to the traditional counterpart. Conclusions: Use of the novel SonixGPS needle-tracking ultrasound system (UltraSonix, Richmond, BC, Canada) was not associated with a higher success rate of vascular puncture compared with the traditional ultrasound-guided technique. Assessment of mental task load significantly favored the use of the ultrasound GPS over the traditional ultrasound technique. (J Vasc Surg 2013;58:735-41.)

Percutaneous arterial and venous punctures using ultrasound guidance are common procedures and are considered the standard of care in many centers. Multiple studies have demonstrated that the use of ultrasoundguided puncture improves success rates and decreases procedure-related complications.¹⁻³ However, ultrasound guidance is not free of problems and has a significant learning curve associated with it for the novice.

Recently, three-dimensional and four-dimensional (three-dimensional technique in real time) ultrasound techniques for ultrasound-guided procedures have been

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developed to address some of the shortcomings of the two-dimensional technique.⁴⁻⁶ The SonixGPS system (UltraSonix, Richmond, BC, Canada) is a novel ultrasound system that utilizes an external electromagnetic-emitting device and sensors in the ultrasound transducer and needle to provide a display on the ultrasound screen of the current and projected needle path in real time. This, in theory, may allow precise positioning of the needle tip and may increase the rates of needle tip visualization and, subsequently, may decrease the rates of procedure-related complications.

The objective of this study was to compare the performance characteristics of real-time needle guidance positioning system (GPS) with traditional ultrasonography for "vessel" cannulation using a gel phantom model in a group of medical students. The primary objectives were measured time-elapsed and cannulation success rates. The secondary objective was perception of the assigned task using a previously validated task load questionnaire.

METHODS

This prospective randomized crossover study was conducted at Vancouver General Hospital in Vancouver, British Columbia, Canada. The study was approved by

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the University of British Columbia research ethics board, as well as the undergraduate medical education office Research Access Committee. The study involved the participation of volunteer medical students from all 4 years of undergraduate medical education, and written informed consent was obtained. Medical students were chosen as test subjects because they are most prone to cause complications as novice operators; it is in their hands that this technology is most likely to be beneficial. Because some medical students were formerly working as technicians in allied medical industries such as radiology and ultrasound, all medical students were asked to quantify their previous experience with ultrasound as either falling into one of four categories: no experience, novice (less than 20 ultrasound-guided vascular access procedures), intermediate (between 20 and 50 ultrasound-guided vascular access procedures), or advanced (>50 ultrasound-guided vascular access procedures). The medical students were then randomized using a sealed envelope technique to perform ultrasound-guided vascular access on a gel phantom model beginning with either traditional ultrasound or the GPS ultrasound system.

Study protocol. A standardized short video presentation was shown to the students introducing them to the concept of ultrasound-guided vascular access and the objectives of the study. This video demonstrated both the traditional ultrasound-guided method as well as the use of the GPS needle positioning system for both the in-plane and out-of-plane techniques that would be used in the study. The in-plane technique required the students to obtain a view of the simulated vessel in the longitudinal axis and insert the needle in the same plane as the ultrasound to cannulate the vessel. The out-of-plane technique required the students to obtain a cross-sectional view of the vessel and insert the needle perpendicular to the transducer into the vessel. Both in-plane and out-of-plane techniques have been described for vascular access, and we wanted to assess if this technology would be useful for either or both. The technology is meant to aid in both techniques. For in-plane techniques, there is a footprint of the transducer and a line representing the needle position relative to the transducer. For out-of-plane techniques, based on the needle trajectory, the point where the needle will intersect the ultrasound plane is indicated by an "X." These visual aids allow participants to use different cues to aid in vascular access, and we wanted to test both.

Students were told what modality (SonixGPS or non-GPS) they would be starting with and that they would also cross over to the other modality after completion of the required trials with their initial starting method. We controlled for any training effect by randomizing subjects to start with either traditional ultrasound or SonixGPS ultrasound. After the video, a live demonstration of both techniques was performed for both in-plane and out-of-plane techniques following a standard script. Students were given the opportunity to ask questions at this point.

A 5-14 MHz 38-mm SonixGPS-enabled transducer and a 8-cm 19-gauge GPS needle was used with the SonixTablet ultrasound machine (Ultrasonix, Richmond, BC, Canada) for all attempts. The needle guidance system was turned on and off based on the randomized technique. A gel phantom (Blue Phantom, Redmond, Wash) containing an embedded simulated blood vessel filled with red dye was used as the target. The embedded simulated nerve adjacent to the blood vessel was used for demonstration and practice purposes. A 5-minute time period was then allotted to allow the students to familiarize themselves with the ultrasound equipment and allow a practice run in their initial assigned modality for both in-plane and out-of-plane views using the gel model. The gel model is a blue phantom soft tissue training block model that is blue and opaque, such that the underlying structures are not directly visible. The dimensions of the training block are 17 cm x 13 cm x 6 cm. There is a simulated vascular structure imbedded in the model, which allows for the aspiration of red dye. The diameter of the simulated vessel is 1 cm and the center is 3 cm from the surface, so it is similar to a femoral vessel in a patient with a normal body habitus. The gel is more homogenous but does contain multiple other structures to simulate nerve and lymph nodes. It is acoustically easier to see through with ultrasound compared with real tissue. Thus the gel model provides a good simulation to femoral artery and internal jugular vein cannulation.

Once the practice period was completed, each student began the trial with his or her assigned modality. The outof-plane technique (short-axis) was used first regardless of the initial modality followed by the in-plane (long-axis) technique (Figs 1 and 2). To perform the out-of-plane technique, students were instructed to obtain a crosssectional view of their target vessel with the ultrasound probe in their nondominant hand and to advance the needle with their dominant hand until the needle tip was visualized at their target prior to entering the lumen of the vessel. The students were instructed to indicate when they felt that they were successful in their attempt. The timing of the trial began from when the student placed the ultrasound probe onto the surface of the gel model to when he or she verbalized his or her perceived successful attempt. Success or failure was confirmed by the instructor's ability to, or failure to, aspirate a small volume of red fluid from the vessel. The students were then instructed to withdraw the needle from the model and to remove the probe from the surface of the model in preparation for a subsequent attempt. Three out-ofplane trials were performed with the time and success/ failure recorded for each. A maximum of 15 minutes was allowed for access attempts.

The student was then instructed to obtain the in-plane (longitudinal axis) view and to repeat the cannulation attempts. For the in-plane view, the students were instructed to obtain a full longitudinal view of the vessel and visualize the needle shaft and tip while puncturing the vessel. The timing of the trial began when the student placed the ultrasound probe onto the surface of the gel model and ended when he or she verbalized his or her

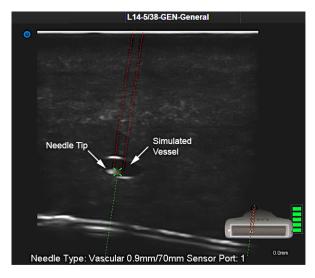


Fig 1. Out-of-plane with guidance positioning system (GPS): The simulated vessel is seen in the short axis and the needle tip is seen within the target. Based on the needle trajectory, an "X" is displayed onscreen where the needle will intersect the ultrasound plane. The "X" changes from white to green when the needle tip intersects the ultrasound plane. The needle position is indicated by the *red silhouette* and the projected path in *green*. On the bottom right, the footprint of the transducer is displayed with the relative needle position.

perceived successful cannulation. Success or failure was confirmed by the ability or failure to aspirate the red fluid from the lumen of the vessel. After each attempt, the students were required to remove the needle and ultrasound from contact with the gel model. The students made three attempts at vascular access in the in-plane view, and a maximum of 15 minutes was allowed for this portion of the study.

After the six attempts in their initial modality were completed, the students were then required to repeat the above procedure using the other modality starting with the out-of-plane view followed by the in-plane view. Time and success/failure were again recorded as previously described.

Once the access attempts were completed, the students were then asked to fill out a postprocedure validated NASA Task Load Index (NASA-TLX) questionnaire (Fig 3). This questionnaire uses a visual analogue scale (0 = low to 20 = high) and rates the mental, physical, and temporal demand of a task as well as the perceived performance, effort, and frustration level of the subject as it relates to a particular task. The mental demands determine the level of intellectual or perceptual work that goes into completing the task.

The physical demands determine the amount of physical effort that one exerts for completion of the task. The temporal demand attempts to measure the perception of time pressure that the participant experiences. The effort component of the questionnaire assesses both the mental and the physical work that goes into completion of the

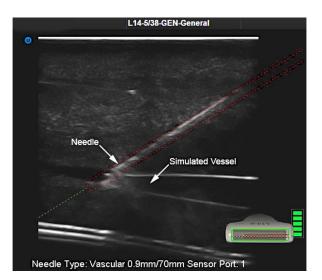


Fig 2. In-plane ultrasound view with guidance positioning system (GPS): The simulated vessel is seen in the long axis and the needle is seen entering the target with the needle tip just beyond the posterior wall. The SonixGPS provides information on needle position indicated by the *red silhouette* and the projected path in *green*. On the bottom right, the footprint of the transducer is displayed onscreen with the relative needle position.

task. The frustration component is aimed at quantifying the amount of stress that the participant experiences during the task. Participants are also asked to rate their performance on a scale of 1-10 with 1 representing a poor performance.

Statistical analysis. Tests for normal distribution were performed using the Shapiro-Wilk test of normality for small sample sizes. The Wilcoxon signed test for non-parametric repeat measures was then used to compare the relevant data with the application of the Bonferroni adjustment for repeat testing. Categorical measures (success/failure) were compared using a χ^2 analysis. Comparisons based on initial randomization modality were performed using the Mann-Whitney *U* test.

RESULTS

Thirty medical students participated in this study. The majority of the students did not have any exposure in using ultrasound-guided vascular access (25/30; 83%), a small number (4/30; 13%) had performed less than 20 supervised procedures, and one student (1/30; 3%) completed between 20 and 50 ultrasound-guided procedures as part of a graduate-level thesis. The majority of the students were from the preclinical years (18/30; 60%; Table I).

The mean times for each attempt of ultrasound-guided puncture with and without GPS guidance is shown in Table II. There was no statistical difference in mean times between ultrasound-guided puncture with GPS or no GPS in either the in-plane or out-of-plane view, and no differences based on level of experience were seen. Similarly, there was no difference in the mean times based on initial Please answer the following questions; on the visual analog scales please mark your response with an "X"

	Ultrasound (no GPS)	-	U <u>ltrasound (with G</u> P	S)
a. Overall value of the simulator as a training and/or testing tool	poor es	I xcellent	poor	 excellent
b. Mental Demand (how much mental & perceptual activiti was required? Was the task easy or demanding, simple or complex	y	 high	l low	_ _ _ _ high
C. Physical Demand (how much physical activity was required? Was the task easy or demanding, restful or laborious?)	llow	 high	l	_ _ _ high
d. Temporal Demand (how much time pressure did you feel? Was the task pace slow & leisurely or rapid & frantic?)	llow	 high	l low	_ _ _ high
e. Performance (how successful do you think you were in accomplishing the task? how satisfied are you with your performance	:) poor	l good	poor	 good
f. Effort (how hard did you have to work (mentally & physically) to accomplish your level of performance?)	llow	 high	l low	_ _ _ high
g. Frustration Level (how insecure, discouraged, irritated versus secure, content, relaxed did you feel during the task?)	 low	 high	 low	 high
h. If you had a choice, which modality would you	use for Ultrasound guided needle pun	cture?	U/S (no GPS)	U/S (with GPS)
i. Rate your U/S guided (no GPS) vascular access	ability (0-10): 0	1 2 3 4	5 6 7 8 9 10	
j. Rate your U/S guided (with GPS) vascular acce	ss ability (0-10):	0 1 2 3	4 5 6 7 8 9 1	10
Other comments (use reverse side if needed)				

Fig 3. Modified NASA Task Load Index (NASA-TLX) questionnaire. GPS, Guidance positioning system; U/S, ultrasound.

modality with the exception that randomization to in-plane GPS first improved mean times for in-plane with no GPS (P = .013). There was progressive shortening of mean times from the first attempt compared with subsequent attempts in all four modalities.

There was a numerical difference in the number of successful punctures. The number of successful punctures for in-plane ultrasound guidance without GPS was 82/90 (91%) compared with 85/90 (94%) for in-plane ultrasound guidance with GPS. Similarly, for the out-of-plane method, a total of 63/90 (70%) vs 77/90 (86%) successful attempts for ultrasound-guided puncture without GPS and with GPS was noted, but this failed to reach statistical significance.

All medical students completed the poststudy questionnaire. The results of the poststudy NASA-TLX questionnaire are shown in Table III. Comparison of the two modalities by this questionnaire revealed a statistically significant difference in favor of the GPS in most fields. The GPS had a higher overall simulator perceived value (19.00 vs 17.75; P = .007); it had a lower mental demand of the task (12.00 vs 14.00; P = .035); the self-assessment of performance was higher (15.50 vs 14.00; P = .041); the overall effort of the task was lower (11.25 vs 14.00; P = .044); and the overall self-assessment of learner ability was higher (P = .007). The majority of students expressed a preference for GPS (26/30; 87%) as opposed to the traditional counterpart.

DISCUSSION

Simulation training in central venous catheter insertion has been shown to improve performance in clinical practice.^{7,8} Rates of first cannulation and insertion have also been shown to correlate with simulation training, and importantly, these higher rates of success translate to reduced complications. In this study, we compared the GPS-equipped ultrasound with that of conventional duplex ultrasound for ultrasound-guided vascular puncture by medical students. Although we did not find significant differences in the learners' speed or puncture success rates, there were significant differences in favor of the GPS system in multiple parameters in the NASA-TLX.

The NASA-TLX questionnaire is one of the most widely used validated tools for measuring subjective mental workload and has been used in various fields from flight simulation to vigilance tasks.^{9,10} It has also been used to

Table I. Medical student demographics

Variable ^a	N = 30 (100%)
Gender	
Male	19 (63)
Female	11 (37)
Medical student year	
MS 1 (Year 1)	6 (20)
MS 2 (Year 2)	12(40)
MS 3 (Year 3)	6 (20)
MS 4 (Year 4)	6 (20)
Experience with ultrasound-guided	
vascular access	
No experience	25 (83)
Novice (<20 ultrasound-guided procedures)	4 (13)
Intermediate (20-50 ultrasound-guided procedures)	1 (3)
Advanced (>50 ultrasound-guided procedures)	0

MS, Medical school.

^aData are presented as No. (%).

quantify mental workload in surgery such as comparing laparoscopic vs robotic suturing as well as laparoscopic performance.^{11,12} This study shows that the medical students found the needle guidance with GPS ultrasound to be less mentally demanding than traditional ultrasound (median, 12.0 vs 14.00; P = .035). There was also the perception that the performance with the GPS ultrasound was better than with traditional ultrasound (median 15.50 vs 14.00; P = .041).

The students also perceived that less effort (both mental and physical) was involved with the GPS ultrasound than with traditional ultrasound (median 11.25 vs 14.00; P = .044). Students also judged that their ability at vascular puncture improved with the aid of the GPS ultrasound technique compared with its traditional counterpart (7.00 vs 6.50; P = .007). Additionally, a majority of students (26/ 30, 87%) expressed a preference for the GPS ultrasound technique if given a choice. These findings may be rationalized by assuming that the novice uses less visual cues to achieve their goal than the expert user and that hand positioning and the surface angle of penetration is difficult for the inexperienced to master. In other words, seasoned practitioners understand how the topographic position of the hand and needle correlate to the final objective of needle tip visualization and successful puncture, something presumably learned through observation, performance, and experience. The visualization on the output monitor of exactly where the target will end up and the ability to change the orientation and location of this target by making the necessary hand position and needle angle adjustments is likely important for those learning the technique. The mental effort of anticipating where the needle tip will cross the plane of the ultrasound in the out-of-plane view is essentially minimized by having a visual display of needlebeam alignment with GPS ultrasound. Further assessment in seasoned users of ultrasound would be interesting.

Our results suggest that the greatest benefit of GPS was the reduction of physical and mental stress associated with the procedure. We believe GPS technology has a useful role as a teaching tool for novices who can practice ultrasound guided vascular access in a safe environment with minimal risk. This method may offer an attractive alternative for teaching vascular access techniques and help minimize complications from both arterial and venous access procedures. Furthermore, it has the potential to be applied to real clinical situations that would allow the teacher/observer direct visualization of trainee performance and immediate correction of undesired technique.

Ultrasound-guided vascular puncture has been shown to improve safety in both arterial and venous access procedures. Despite its safety record, there is room for improvement, as incidence of posterior vessel wall puncture during ultrasound-guided vessel cannulation can be surprisingly high. An incidence of 34% was recently described using a simulation model,¹³ and 64% of trainees accidently penetrated the posterior vessel wall during attempted internal jugular central venous line placement despite the use of ultrasound guidance.¹⁴ This undesired result can also lead to complications during and after any endovascular procedure and can result in increased hospitalization costs and number of interventions. Our study examined a novel needle GPS that allows visualization of the needle tip at all times during the procedure. Theoretically, constant visualization should minimize the incidence of posterior vessel wall perforation. Unfortunately, our rudimentary gel model was unable to examine this posterior wall perforation specifically.

In a simulated vascular access model, Stone et al showed that a long-axis (in-plane) approach to ultrasound-guided vascular access was associated with a higher rate of needle tip visualization compared with the short-axis (out-of-plane) view.¹⁵ The long-axis approach may not be practical in every situation, as it requires more room longitudinally, and visualization of adjacent structures in the short axis is sometimes more crucial. In this study, we examined both short- and long-axis (out-of-plane and in-plane) techniques. Numerically, the long-axis technique trended toward a higher success rate at 93% compared with 78% using the short-axis method but failed to reach statistical significance.

For the in-plane method, the number of successful cannulations was higher with the in-plane approach for both the traditional ultrasound and the GPS compared with the out-of-plane approach (91% and 94% vs 70% and 86%, respectively). This finding may be explained by the observation from a study by Stone et al, in which traditional ultrasound-guided in-plane and out-of-plane methods were compared using a gel simulation model.¹⁵ They found that there was no significant difference in mean puncture time (14.8 seconds out-of-plane and 12.4 seconds in-plane) but that the visibility of the needle tip at the time of puncture was higher in the in-plane view (62% compared with 23%). Higher visibility of the needle tip just prior to puncture presumably translates into higher success rates as may be seen from our data. Intuitively, the

	Attempt number	Mean time, seconds	Successful puncture, %	95% Confidence interval	Standard deviation
In-plane, no GPS	1	41.14	83	24.14-58.07	45.34
	2	31.35	93	21.69-40.99	25.84
	3	24.68	97	17.73-31.62	18.59
	Mean	32.39	91		
In-plane GPS	1	43.45	93	35.13-51.77	22.28
	2	31.27	97	23.62-38.92	20.49
	3	29.45	93	21.89-37.00	20.23
	Mean	34.72	94.33		
Out-of-plane, no GPS	1	60.50	70	40.78-80.21	52.81
	2	34.02	70	20.19-47.84	37.01
	3	29.76	70	23.01-36.50	18.06
	Mean	41.33	70		
Out-of-plane GPS	1	49.45	70	33.93-64.98	41.57
	2	34.97	90	23.83-46.11	29.83
	3	33.69	97	26.18-41.20	20.12
	Mean	39.37	85.67		

Table II. Mean time of puncture by attempt with 95% confidence intervals

GPS, Guidance positioning system.

 Table III. Results of modified NASA-TLX poststudy questionnaire

Task question ^a	No GPS median (IQR)	GPS median (IQR)	P value
Overall value (a)	17.75 (4.3)	19.00 (2.6)	.007
Mental demand (b)	14.00 (3.4)	12.00 (7.5)	.035
Physical demand (c)	9.25 (11.3)	6.50 (8.3)	.116
Temporal demand (d)	11.00 (6.9)	9.75 (9.6)	.103
Performance (e)	14.00 (6.3)	15.50 (4.8)	.041
Effort (f)	14.00 (5.3)	11.25 (7.8)	.044
Frustration level (g)	10.50 (8.1)	7.50 (8.9)	.145
Learner assessment of own ability (i & j)	6.50 (3.0)	7.00 (3.0)	.007
Preferred modality (h) ^b	4/30 (13)	26/30 (87)	

GPS, Guidance positioning system; IQR, interquartile range; NASA-TLX, NASA Task Load Index.

^aSee Fig 3.

^bActual numbers with (%).

traditional ultrasound-guided out-of-plane method would seem to be more technically challenging, as it relies heavily on visual cues as well as the anticipated location of the needle tip as it crosses the plane of the ultrasound beam. Undoubtedly, this is more difficult for the novice user. The GPS ultrasound allows the novice user to perform target-needle-beam alignment and needle advancement with greater confidence to the target. Although our results are not statistically significant, this finding may help explain the observations of the out-of-plane success rates of 70% for traditional ultrasound compared with the 86% success rate for the targeted view. It would be interesting to compare the experienced participant with the novice participant to see if there is a difference in success rates and to expand our sample size.

In our study, we endeavored to minimize learning or training effects by randomizing the students to begin with either the GPS feature turned on or off. It would not have been surprising to see improvement in cannulation times in subsequent attempts just based solely on immediately preceded attempts. However, this study was not designed to specifically address the issues of learning and learning curve generation. In order to generate these curves, it would be necessary for each participant to perform many more punctures with each modality, something that was not feasible in this present work, as there are just not enough data points. The reader is further directed to the work by Kestin¹⁶ and the work by Schuepfer et al¹⁷ for a discussion of approaches to measure competence and generation of learning curves for technical procedures.

In our study, no statistical differences were seen in the time required to obtain vessel access using either the traditional ultrasound guided or the GPS. As mentioned, the small sample size employed in this study was underpowered to detect such small time differences. In each modality, the average time to successful cannulation improved from the first to the third attempt. However, a cumulative sums analysis to generate learning curves is not possible in this study nor was it the intent. This study has some limitations. First, it is underpowered to detect a difference between groups with respect to time to successful puncture and the number of successful punctures. However, it lays the groundwork for a larger study by providing valuable data on effect size. Second, we only included novice medical students. Inclusion of experienced practitioners would have allowed wider inferences to be made. Third, we used a gel model for vascular puncture. This gel model is incapable of detecting posterior wall punctures or tangential punctures, and a more sophisticated model with topographic mapping would be helpful. Our end point was aspiration of colored fluid as an indicator of vascular puncture in keeping with real-life clinical practice, and we believe our results have clinical validity with respect to femoral artery and internal jugular vein

puncture. The gel model is not meant to simulate a vessel with variable depth and a tortuous course over a short skin length. Inclusion of actual patients requiring central venous and arterial cannulation as well as those with variable vessel depth and tortuous vessels and obese and nonobese patients would have provided valuable in vivo data as well as a comparison of this technology with traditional techniques. In the future, it would be interesting to increase the sample size of this study as well as increase the number of attempts per person. In this manner, a cumulative sums analysis could be performed to gauge the learning that occurs with this GPS technique. Furthermore, a study to properly assess GPS ultrasound as a potential teaching tool would be useful, as well as its effect on mental task load reduction comparing novices with experienced practitioners.

CONCLUSIONS

The use of a novel ultrasound GPS was not associated with a higher success rate of vascular puncture compared with the traditional ultrasound-guided technique. Assessment of mental task load significantly favored the use of the ultrasound GPS over the traditional ultrasound technique.

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AUTHOR CONTRIBUTIONS

Conception and design: HV, RT, DK, JC Analysis and interpretation: DK, JC Data collection: DK Writing the article: DK, HV, RT, AS, JC Critical revision of the article: HV Final approval of article: HV Statistical analysis: Not applicable Obtained funding: Not applicable Overall responsibility: HV

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