New Ultrasound Technology Is a Useful Training Adjunct for Invasive Procedures

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ABSTRACT

Background: The use of ultrasound for procedural guidance is an essential skill in emergency medicine (EM) and a required Accreditation Council for Graduate Medical Education (ACGME) competency for residents. Resident learners develop their skill set through hands-on training and may benefit from an intervention that encourages proper technique, bolsters confidence, and improves procedural success. Clear Guide ONE, a Food and Drug Administration–approved technology, overlays real-time virtual instrument navigation onto ultrasound displays to allow visualization of expected instrument trajectory prior to needle puncture, ensuring alignment with the target.

Objectives: This study investigated computer-assisted instrument guidance as an educational tool for residents in a simulation environment. Primarily, the study evaluated residents' procedural speed and accuracy using ultrasound with and without the guidance device.

Methods: A total of 34 residents were observed performing ultrasound-guided needle placement in ballistic gel models with and without computer assistance in a simulation-based observational crossover study. Scan time before needle insertion, time to target, total procedure time, number of needle redirections, and procedural accuracy were measured. A total of 104 observations were recorded with 52 in each group. Paired-sample t-test analysis was used to compare group performance. Secondary outcomes were derived from survey data assessing resident opinions about the device.

Results: The computer-guidance group significantly outperformed the ultrasound-alone group in mean time to target, number of needle redirections, and procedural accuracy. There was no significant difference in mean scan time before needle insertion or total procedure time. Fifty percent of residents preferred the guidance system. Most residents (67%, $n = 23$) reported that the device increased confidence and the majority (94%, $n = 32$) reported perceived improvement in speed, accuracy, or both.

Conclusions: Use of computer assistance technology for sonographic instrument guidance was successful in improving procedural accuracy, number of needle redirections, and time to target performance metrics and was well received by residents. This educational study suggests that this technology may emerge as a valuable tool in training EM residents to utilize ultrasound for procedures.

Utilizing ultrasound for procedural guidance is an essential skill in emergency medicine (EM) practice and is a required Accreditation Council for Graduate Medical Education (ACGME) competency for EM residents.[1] Sonography is commonly utilized for intravenous catheter placement, nerve blocks, and paracenteses among other core EM procedures and has been shown to improve resident success rates.[2] As novice learners employing an operator-dependent imaging modality, trainees refine their procedural skill set through hands-on ultrasound training using low-cost simulation under expert supervision.[3] Such simulation training has improved resident performance of ultrasound guided procedures in clinical practice.[4]

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Nevertheless, EM residents—especially at junior levels of training—often lack the confidence and procedural mastery to efficiently perform these invasive procedures.[2] A recent survey of EM residents indicates a general consensus that greater ultrasound instruction, beyond current residency expectations, should be required to achieve competency.[5] Accordingly, residents might benefit from an intervention that encourages proper technique, bolsters confidence, and improves procedural success when performing ultrasound-guided procedures.

Clear Guide ONE (CG1) is Food and Drug Administration (FDA) approved to serve as an adjunct to existing ultrasound systems to provide real-time virtual instrument navigation as an overlay on standard ultrasound displays.[6] The device—a binocular optical head that mounts directly onto the ultrasound probe—tracks the operator's needle and displays the expected needle trajectory onto the live ultrasound image (Figure 1). This technology allows operators to visualize the needle's projected subcutaneous path and confirms that a planned approach intersects the desired target (i.e., vein, nerve, peritoneal fluid) by aligning the needle in plane and adjusting the angle of entry. We hypothesized that utilization of this real-time virtual feedback device would increase residents' confidence, speed, and accuracy when performing an ultrasound-guided procedure. All study investigators have no conflicts of interest to report and there was no external support or funding for this study.

Figure 1. Clear Guide Super Probe. Reproduced, with permission, from Clear Guide Medical.[9]

METHODS

Study Design and Setting

This study was a simulation-based observational crossover study that investigated computer-assisted instrument guidance as an educational tool for EM resident learners enrolled in a 4-year residency training program at a large urban referral center. The study was approved by our university institutional review board.

All residents enrolled in our institutional training program were approached for study enrollment and a total of 34 consented to participate. A preintervention survey was distributed to measure enrollees' experience with ultrasound-guided procedures and all enrollees received a brief didactic from industry representatives as an introduction to the computer-assisted CG1 equipment. Enrollees were observed targeting and placing a standard hypodermic needle into a sonographically hyperechoic object, a 4.5-mm BB, embedded at a depth of 4 to 5 cm in a ballistic gel ultrasound model. Enrollees were given 25 minutes to perform the procedure as many times as they were capable both with and without the CG1 device before crossing over to perform the same procedure with the alternative technique.

Measurements

The primary outcome variable was procedural success, measured by overall procedure time, scan time preceding needle insertion, time to target, number of needle redirections (defined as reversing needle trajectory), and needle accuracy (needle tip distance from target measured external to the gel ballistic model once the procedure was complete; scored as 1 for <5 mm, 2 for 5–10 mm, and 3 for >10 mm). These measurements were obtained via live direct observation by four volunteers who were not involved in the study design or implementation. The observers—two EM faculty members and two CG1 staff members—paired with a

participant and followed that resident to each station during the timed observations. Secondary outcomes were measured from blinded data derived from a non-validated survey tool that evaluated residents' ultrasound-guided procedural experience quantitatively, residents' procedural preference and confidence qualitatively, and perceived accuracy via a Likert scale.

Data Analysis

Paired-sample t-test analysis was used to compare group performance, with a confidence level (α) of 0.05. Observer inter-rater reliability was determined with analysis of variance (ANOVA). Qualitative survey data were collated to assess residents' prior experience with ultrasound-guided procedures, their preference for ultrasound alone or the CG1 device, their confidence levels, and their perceived level of accuracy with and without the device. The training levels consisted of 10 PGY1, 10 PGY2, eight PGY3, and six PGY4 EM residents.

RESULTS

A total of 104 observations among 34 residents were recorded: 52 observations each in the computer-guidance group and ultrasound-alone group (Table S1, available as supporting information in the online version of this paper, which is available at https://doi.org/onlinelibrary.wiley.com/doi/10.1002/aet2.10048/full). ANOVA of the inter-rater reliability of the volunteer observers for each category showed a difference amongst the groups, with the exception of their measurements of accuracy. The computer-guidance group significantly outperformed the ultrasound-alone group in mean time to target, number of needle redirections, and accuracy to target. There was no significant difference in mean scan time before needle insertion or total time of procedure. These results are summarized in Table 1.

Survey data revealed that 50% of residents (n = 17) preferred the computer-assisted instrument guidance system to ultrasound alone. Most residents (67%, n = 23) reported that the device increased confidence. The vast majority (94%, n = 32) reported perceived improvement in speed, accuracy, or both. When stratified by ultrasound experience and training level reported by respondents on the preintervention survey, less-experienced learners preferred the device and believed that it improved procedural confidence and proficiency, although this finding was not statistically significant.

DISCUSSION

Despite generalized acceptance of ultrasound for procedural guidance as an essential skill for all graduates of ACGME-accredited EM residencies, EM residents have expressed concern regarding the current standard of training and may lack the confidence and procedural mastery to efficiently perform ultrasound-guided invasive procedures.[2,5]

This study demonstrates that resident learners benefit from a simple technologic intervention that promotes proper technique and confidence to improve procedural success. Utilization of a real-time virtual instrument navigation device as an adjunct to existing ultrasound systems improves most observed performance metrics and was acceptable to EM residents at various levels of training. Additionally, the most statistically significant findings were also the most clinically relevant as improved procedural accuracy and decreased number of needle redirections may result in less patient discomfort and fewer procedural complications.

Table 1
Comparison of Group Performance With Ultrasound Alone Versus Ultrasound With CG1 Device

	Ultrasound Alone (95% CI)	CG1 Device (95% CI)	p-value (α = 0.05)
Number of observations	52 (–)	52 (–)	—
Mean time scanning before needle insertion (s)	47.8 (31.9–63.7)	66.1 (28.9–103.4)	0.31
Mean time to target (s)	71.3 (50.5–92.2)	48.5 (33.5–63.4)	0.04
Mean total time (s)	119.1 (86.7–151.5)	114.6 (71.9–157.3)	0.84
Mean number of needle redirections	2.5 (1.8–3.1)	0.8 (0.5–1.2)	0.0002
Accuracy*	2.0 (1.8–2.3)	1.3 (1.1–1.4)	0.00002

*Needle tip distance from target: scored as 1 for <5 mm, 2 for 5–10 mm, and 3 for >10 mm.
ACGME = Accreditation Council for Graduate Medical Education; CG1 = Clear Guide ONE.

Although efficiency is a hallmark of the competent emergency physician, our data suggest that the CG1 device does not improve overall time to procedural completion. We found that, compared to the ultrasound alone group, the CG1 group spent more time scanning before needle insertion but significantly less time to reach the target after needle puncture. We believe that user unfamiliarity with the CG1 device explains our finding of increased preprocedural scanning time, while total procedural time trended toward improvement and mean time to target statistically improved in the CG1 group due to the operator's ability to visualize the needle trajectory. A trend toward overall benefit from the device was seen more in the PGY4 group, the group with the most previous experience with procedural ultrasound. We surmise that with frequent use of this novel device, operators would require less preprocedural scanning time and the overall time to procedural completion would also decrease.

Over the past decade, this technology has rapidly evolved from experimental feasibility studies to FDA approval to proven clinical efficacy for ultrasound-guided procedures in regional anesthesia and interventional radiology care settings.[7,8] We consider its use to be practical in EM as our experience during this study has confirmed that the device is both affordable and attainable for medical educators. While we do not advocate that training with this device supplant any of the other multimodal educational techniques currently in use for training residents in ultrasound-guided procedures, our results show that this training tool can effectively decrease the time to reach an intended procedural target while increasing accuracy and the confidence of residents and should be considered as an adjunct for medical education.

LIMITATIONS

Although our study population was small, our results are bolstered by each enrolled participant performing multiple procedures, thereby increasing our sample size to over 100 observations. Furthermore, while our crossover study design strengthens our findings by limiting selection bias, there is the potential for carryover effect which our study was not powered to detect. Additionally, though study participants were drawn from a single academic medical center residency program with a robust and active ultrasound division, our ultrasound curriculum for resident learners is similar to other training programs and meets the core competencies shared by all ACGME-accredited EM residency training programs. Finally, although the observers measuring outcomes were not involved in the study design, blinding and video review were infeasible because of the material limitations of the CG1 device, which must be physically mounted to the ultrasound probe to function.

CONCLUSION

Utilization of a real-time virtual instrument navigation device as an adjunct to existing ultrasound systems can effectively increase resident learners' confidence, speed, and accuracy in performing core skills expected of competent emergency physicians and should be considered as an educational adjunct for learners in emergency medicine and any other specialty that utilizes ultrasound to perform invasive procedures. Future investigations might evaluate the applicability of similar technologies for training nonphysician healthcare providers, including nurses, who currently perform or are expected to perform ultrasound-guided invasive procedures.

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Supporting Information

The following supporting information is available in the online version of this paper available at http://onlinelibrary.wiley.com/doi/10.1002/aet2.10048/full

Data Supplement S1. Comparison between subjects scanning with traditional ultrasound and the Clear Guide ONE™ device.