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BRIEF COMMUNICATION

Portable ultrasound: the next generation arrives

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Abstract
Purpose A new category of handheld devices has recently emerged that are even smaller than current portable models, with their main advantages being increased portability and affordability relative to their counterparts. However, these new devices have not yet been thoroughly evaluated in the clinical setting.
Methods A prospective, non-blinded, three-phase study was designed to evaluate a handheld ultrasound device as compared to a common compact ultrasound machine for the performance of paracenteses and thoracenteses on human patients.
Results For the vast majority of straight-forward evaluations, the handheld device was sufficient to safely complete the procedure without further imaging. For difficult cases with smaller fluid collections or anatomic aberrations, further localization with the common compact machine continued to be useful to improve the operator's confidence in the findings.
Conclusion This novice handheld device represents only one of what appears to be a growing number of new ultra-portable ultrasound devices on the market. These devices represent a new and exciting form of ultrasound technology that may benefit patients and physicians in multiple venues. While they are unlikely to replace standard ultrasound devices for many of the more complex applications, their extreme portability allows for ultrasound imaging in more diverse situations that has previously been practical. Based on our limited experience, the image quality is adequate and the learning curve is reasonable. Future integration of PDA technology could further the utility of these devices and additional study will be important to further define their appropriate niche and clinical utility.

Keywords Portable ultrasound · Procedures · Patient safety · Proceduralist

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Introduction

Ultrasound technology is rapidly evolving to become smaller, more affordable, and more user-friendly. A new category of smaller handheld devices has recently emerged whose main advantages include increased portability and affordability. The incorporation of such a device into the initial physical examination could potentially lend to faster diagnosis and treatment. Early applications of portable ultrasound have been in the field of echocardiography, and some concern exists about whether image quality is being unsafely compromised to achieve greater portability [1, 2].

At least three such battery-powered devices are either on the market or soon to be released: the handheld unit we tested has recently been granted FDA approval for use on human subjects, and as such very little field testing has thus far taken place. The unit has a probe that can be held in one hand and is attached by a stethoscope-like cord to the main unit which is approximately $4'' \times 6''$; together they weigh <2 lbs. The main unit houses the imaging screen, the battery, and the hardware and software. To achieve the smaller size, engineers removed the transducer motor and some of the probe's crystal components, resulting in more work for the operator to acquire static images (B-mode) or real-time imaging guidance (in M-mode).

We designed a prospective study to test a novice handheld device for the performance of ultrasound-guided paracenteses and thoracenteses.

Setting

Cedars-Sinai Medical Center is a 957 bed, tertiary care teaching facility located in Los Angeles, California. The Signos was evaluated by the Procedure Center, a unique operation responsible for the provision of myriad invasive medical procedures for inpatients and outpatients [3].

Methods

A prospective, non-blinded study was designed to evaluate a Signos handheld ultrasound device for paracenteses and thoracenteses on human patients. There were no exclusion criteria. The study was performed by a single operator (advanced proceduralist) and divided into three phases: In phase one, the Signos was applied to all consecutive cases in a 2-week period. Each evaluation began with the patient being scanned and marked for needle entry using the Signos, and was then reevaluated (and remarked, as needed) using the Sonosite *M-Turbo*, which is our current "gold standard" ultrasound device used in the Procedure Center. The M-Turbo can be carried, but usually resides on a wheel-based portable stand. Each Signos scan was graded as *excellent* (high level of correlation with Sonosite), *adequate* (slightly less informative but enough to proceed), *marginal* (confirmation with Sonosite was useful and provided necessary information), or *poor* (inadequate to proceed without additional imaging). Lastly, each study was flagged if it needed to be "remarked" with the Sonosite prior to beginning.

In phase two, the Signos was again used by the same experienced proceduralist for the same procedures. Each case was evaluated and marked for needle entry with the Signos. In this phase, the Sonosite was only used *if needed* to confirm localization and/or remark. Each study was again graded: excellent (excellent image quality, no confirmation with Sonosite needed), adequate (slightly less informative but adequate to proceed), marginal (confirmation and additional information was obtained with the Sonosite), or poor (inadequate to proceed without additional confirmation/remarking). Cases were also marked as "solo" (without Sonosite) or "added" (Sonosite used).

Phase three was an educational phase using Signos and Sonosite, designed to evaluate the experience of novice trainees during a one-day training session; their experiences were captured by a brief questionnaire (Fig. 1).

The Signos was on loan from Signostics for evaluation of its use, and the Sonosite M-Turbo is owned by the Procedure Center.

Fig. 1 Signos evaluation survey

PHASE THREE: PRODUCT EVALUATION

Signos is a portable ultrasound device that has been available to veterinarians and has recently received FDA approval for use on human subjects. I have been asked to evaluate the utility of this device for use for performing paracentesis and thoracentesis. Please note, I have no vestment or interest in this product or the parent company, Signostics, what-so-ever. In other words, it will not break my heart if you think it is a "piece of crap". Now that you have used this device clinically, please take a moment to provide your feedback of its utility.

Please feel free to leave the form blank if you would rather not comment!

Please circle the number that best represents your opinion of each issue.

1. Time it took to learn to use the Signos:

Excessive ... Reasonable

1 2 3 4 5 6 7 8 9 10

2. Image quality of the Signos:

Poor ... Excellent

1 2 3 4 5 6 7 8 9 10

3. Considering size, availability, usability and cost compared to other Ultrasound devices it was:

Not nearly as good ... Different but adequate ... Clearly better

1 2 3 4 5 6 7 8 9 10

4. Based upon your limited experience youroverall assessment of the Signos device is:

Not useful ... Undecided ... A must have

1 2 3 4 5 6 7 8 9 10

Thank you for your honest and unbiased assessment of this device.

Table 1 Phase one and two results

	Excellent	Adequate	Marginal	Poor	Remarking required
Phase one (89 cases)					
Thoracentesis (34 cases)	27 (79%)	4 (12%)	3 9%)	0	2 (6%)
Paracentesis (33 cases)	29 (79%)	3 (9%)	1 (3%)	0	0
Evaluation only (22 cases)	15 (68%)	7 (32%)	0	0	n/a
Phase two (85 cases)					
Thoracentesis (38 cases)	38 (100%)	0	0	0	38 Solo (100%)
Paracentesis (35 cases)	29 (83%)	6 (17%)	0	0	31 Solo (89%)
Evaluation only (12 cases)	12 (100%)	0	0	0	n/a

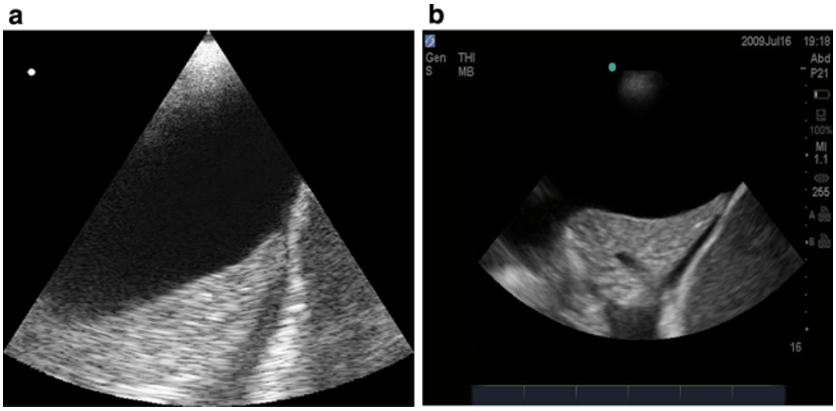

Fig. 2 Thoracentesis comparative images. **a** Signos, **b** Sonosite

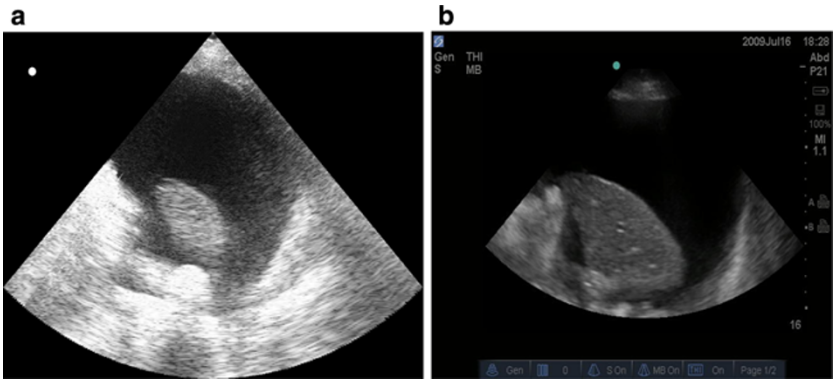

Fig. 3 Paracentesis comparative images. **a** Signos, **b** Sonosite

Results

The results of phases one and two are depicted in Table 1, and comparative images are displayed in Figs. 2 and 3. Phase three captured the experience of five novice trainees on four different parameters. The average responses were as follows: question 1 = 9.1/10, question 2 = 7.6/10, question 3 = 8.1/10, and question 4 = 8.9/10.

There were no major or minor complications from the procedures, and the Signos itself performed without technical difficulty. The portable battery life proved more than sufficient for an entire day of heavy use.

Discussion

Extreme portability is one of the most striking aspects of the Signos. The entire device can fit in the pocket of a white coat or be worn around the neck like a stethoscope, making it ideal for highly mobile practitioners such as proceduralists, hospitalists, intensivists, emergency

physicians, outpatient practitioners, and home care clinicians. The ergonomic layout was highly functional, with the buttons and roller ball well-positioned to allow for right or left-handed single-handed operation.

The results indicated that the image quality proved overall to be adequate. The advanced proceduralist experienced a rapid learning curve for image acquisition and interpretation during phase one, and with practice the image quality became strikingly similar to images obtained with the Sonosite. After the brief learning curve, the Signos was sufficient for procedure completion without further imaging for the vast majority of straight-forward studies. However, for difficult cases with smaller fluid collections or anatomic aberrations, further localization with the Sonosite remained important in both phase one and two.

The novice practitioners in phase three had a generally positive response, although this phase was limited by a small "*n*" and too brief a test period for competency to be assessed [4].

We recognize several limitations of this study. First, this represents the experience of a single, non-blinded operator who subjectively judged each image based on his experience. Further, he is considered to be a master proceduralist (having performed thousands of ultrasound-guided procedures), so the reproducibility of his learning curve and aptitude is uncertain relative to an average user's experience or learning curve with new ultrasound technology. Lastly, this study examined only one aspect of ultrasound as it related to procedure guidance for fluid removal; therefore, extrapolation to other ultrasound applications should be approached with caution.

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Conflict of interest Equipment loan from Signostics.

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