

“On the Other Hand . . .”: The Evidence Does Not Support the Use of Hand-carried Ultrasound by Hospitalists

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In the right hands, ultrasound is a safe and helpful diagnostic imaging tool. However, evidence supporting the use of hand-carried ultrasound (HCU) by hospitalist physicians has not kept pace with expanding application of these devices. In spite of its strategic point-of-care benefit, use of this technology by hospitalists may not ultimately translate into improved efficiency and better clinical outcomes. Optimal levels of training in image acquisition and interpretation remain to be established. Novelty, availability, and the results of a few small studies lacking patient-centered outcomes remain insufficient grounds to justify the expanded clinical utilization of these medical imaging devices by nonspecialists. *Journal of Hospital Medicine* 2010;5:168–171. © 2010 Society of Hospital Medicine.

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Ultrasound, one of the most reliable diagnostic technologies in medicine, has a unique long-term safety profile across a wide spectrum of applications. In line with the trend toward the miniaturization of many other technologies, increasingly sophisticated “hand-held” or “hand-carried” ultrasound (HCU) devices have become widely available. To date, the U.S. Food and Drug Administration (FDA) has approved more than 10 new-generation portable (1.0–4.5 kg) ultrasound devices, and a recent industry report projected that the HCU market will see revenues in excess of \$1 billion by 2011.¹

Although cardiovascular assessment remains its primary use, hospitalist physicians are increasingly turning to this technology for the localization of fluid and other abnormalities prior to paracentesis and thoracentesis. While there are other potential uses (eg, managing acute scrotal pain, diagnosing meniscal tears, measuring carotid intimal thickness), the higher-quality studies of hospitalist-physicians’ use of HCU have focused on cardiovascular assessment. HCU confers a number of potential workflow-related advantages, including coordinated point-of-care evaluation at short notice when formal ultrasound may be unavailable, as well as circumvention of the need to call on radiology or cardiology specialists.² Even for experienced cardiologists, heart failure can be difficult to identify using any modality, and the clinical diagnosis of cardiovascular disease by hospital physicians has been documented as poor.^{3,4} Thus, the addition of HCU to the palette of diagnostic and teaching tools available to frontline physicians potentially offers improvements over stethoscope-assisted physical examination alone (including visual inspection, palpation, and auscultation), which has remained essentially unaltered for 150 years.^{5–7}

Evidence Base for HCU Use by Hospitalists

The few primary studies on HCU use by hospitalists have focused on the potential utility of this technology as a valuable adjunct to the physical exam for the detection of cardiovascular disease (eg, asymptomatic left ventricular [LV] dysfunction, cardiomegaly, pericardial effusion) in the ambulatory or acute care setting.^{8,9} Operation of HCU by hospitalists is not clearly indicated for the evaluation of valvular disease (eg, aortic and mitral regurgitation), in part due to the limited Doppler capabilities of the smaller devices.^{9–11} The risk of a gradual erosion of physical exam skills accompanying expansion of HCU use by hospitalists could itself become a potential disadvantage of a premature replacement of the stethoscope, since the results obtained by hospitalists performing a standard physical exam have been shown to be better than those obtained with HCU.^{8,9}

The lack of large, multicenter studies of HCU use by hospitalists leaves many questions unanswered, including whether or not the relatively low initial cost of an HCU device (\$9,000–\$50,000) vs. that of a full-sized hospital ultrasound system (\$250,000) will eventually translate into overall cost-effectiveness or actual patient-centered benefit.¹⁰ While cautious advocates have insisted that HCU provides additive information in conjunction with the physical exam, this approach is not meant to serve as a substitute for standard echocardiography in patients requiring full evaluation in inpatient settings relevant for hospitalists.^{11–14} Referral for additional testing or specialist opinions—and the associated costs incurred—cannot necessarily be circumvented by hospitalist-operated HCU.

A major problem with the HCU literature in general is its lack of standardization between—and within—studies, which renders it nearly impossible to generalize findings

about important clinical outcomes, patient satisfaction, quality-of-life, symptoms, physical functioning, and morbidity and mortality. There are a preponderance of underpowered, methodologically inconsistent, single-center case series that do not evaluate diagnostic accuracy in terms of patient outcomes. For example, although one study did find a modest (22–29%) reduction in department workload with HCU, the authors omitted important information regarding blinding, and no power calculations were reported; thus, it was not possible to ascertain whether or not the reported results were due to the intervention or to chance.¹⁵ There clearly remains a need to “convincingly demonstrate that patient care, shortening of length of stay, long-term prognosis, or potential financial savings could occur” with use of these devices by hospitalists.⁵ The process of device acquisition and resource allocation is, at least in part, based on accumulated evidence from studies that have ill-defined relevant outcomes (eg, left ventricular function). However, even if such outcomes were to be more closely examined, medical decision-making would still suffer from discrepant findings due to numerous differences in study design, including parameters involving patient population and selection, setting (eg, echocardiography laboratory vs. critical care unit), provider background, and specific device(s) used.

Training Issues

Hospitalist proficiency across HCU imaging skills (ie, acquisition, measurement, interpretation) has been found to be inconsistent.⁹ Endorsement and expansion of hospitalist use of HCU may to some extent reflect an overgeneralization from disparate comparative studies showing moderate success obtained with HCU (vs. physical exam) by other practitioner groups such as medical students and fellows with limited experience.^{16,17} Whereas in 2005, Hellmann et al.¹⁸ concluded that medical residents with minimal training can learn to perform some of the basic functions of HCU with reasonable accuracy, Martin et al.^{8,9} (in 2007 and 2009) reported conflicting results from a study of hospitalists trained at the same institution.

Concern about switching from standard to nonstandard HCU operators is raised by studies in which specialized operators (eg, echocardiography technicians) obtained better results than hospitalists using these devices.^{8,9} In 2004, Borges et al.¹⁹ reported the results of 315 patients referred to specialists at a cardiology clinic for preoperative assessment prior to noncardiac surgery; the results (94.8% and 96.7% agreement with standard echocardiography on the main echocardiographic finding and detection of valve disease, respectively) were attributed to the fact that experienced cardiologists were working under “ideal conditions” using only the most advanced HCU devices with Doppler as well as harmonic imaging capabilities. Likewise, in 2004, Tsutsui et al.²⁰ studied 44 consecutive hospitalized patients who underwent comprehensive echocardiography and bedside HCU. They reported that hemodynamic assessment by

HCU was poor, even when performed by practitioners with relatively high levels of training.²⁰ In 2003, DeCara et al.¹² performed standard echocardiography on 300 adult inpatients referred for imaging, and concluded that “standardized training, competency testing, and quality assurance guidelines need to be established before these devices can be utilized for clinical decision-making by physicians without formal training in echocardiography.” Although there have been numerous calls for training guidelines, it has not yet been determined how much training would be optimal—or even necessary—for professionals of each subspecialty to achieve levels of accuracy that are acceptable. Furthermore, it is well known that skill level declines unless a technique is regularly reinforced with practice, and therefore, recertification or procedure volume standards should be established.

The issue of potential harm needs to be raised, if hospitalists with access to HCU are indeed less accurate in their diagnoses than trained cardiologists interpreting images acquired by an established alternative such as echocardiography. False negatives can lead to delayed treatment, and false positives to unwarranted treatment. Given that the treatment effects of HCU use by hospitalists have not been closely scrutinized, the expansion of such use appears unwarranted, at least until further randomized studies with well-defined outcomes have been conducted. Although the HCU devices themselves have a good safety profile, their potential benefits and harms (eg, possibility of increased nosocomial infection) will ultimately reflect operator skill and their impact on patient management relative to the gold-standard diagnostic modalities for which there is abundant evidence of safety and efficacy.²¹

Premarketing and Postmarketing Concerns

The controversy regarding hospitalist use of HCU exposes gaps in the FDA approval process for medical devices, which are subjected to much less rigorous scrutiny during the premarketing approval process than pharmaceuticals.²² Moreover, the aggressive marketing of newly approved devices (and drugs) can drive medically unwarranted overuse, or “indication creep,” which justifies calls for the establishment of rigorous standards of clinical relevance and practice.^{23,24} While the available literature on HCU operation by hospitalists is focused on cardiovascular indications for the technology, hospital medicine physicians are increasingly using HCU to guide paracentesis and thoracentesis. Given how commonplace the expansion of such practices has become, it is noteworthy that HCU operation by hospitalists has not yet been evaluated and endorsed in larger, controlled trials demonstrating appropriate outcomes.²⁵

Across all fields of medicine, the transition from traditional to newer modalities remains a slippery slope in terms of demonstration of persuasive evidence of patient-centered benefit.²⁶ Fascination with emerging technologies (so-called “gizmo idolatry”) and increased reimbursement potential

threaten to distract patients and their providers from legitimate concerns about how medical device manufacturers and for-profit corporations increasingly influence device acquisition and clinical practice.^{27–31} While we lack strong evidence demonstrating that diagnostic tests such as HCU are beneficial when performed by hospitalists, the expanded use of these “handy” new devices by hospitalists is simultaneously generating increased incidental and equivocal findings, which in turn render it necessary to “go back” and perform secondary verification studies by specialists using older, gold-standard modalities. This vicious cycle, coupled with the current lack of evidence, will continue to degrade confidence in the initiation of either acute or chronic treatment on the basis of HCU results obtained by hospitalist physicians.

Eventually, the increased use of HCU by hospitalists might lead to demonstrations of improved hospital workflow management, but it may just as easily represent another new coupling of technology and practitioner that prematurely becomes the standard of care in the absence of any demonstration of added value. The initially enthusiastic application of pulmonary artery catheters (PACs) serves as a cautionary tale in which the acquisition of additional clinical data did not necessarily lead to improved clinical outcomes: whereas PACs did enhance the clinical understanding of hemodynamics, they were not associated with an overall advantage in terms of mortality, length of hospital stay, or cost.^{32–35} Ultimately, “more” information is not necessarily “better” information. Although new medical technologies can produce extremely useful diagnostic results that aid in the management of critically ill patients, poor data interpretation resulting from lack of targeted training and experience can nullify point-of-care advantages, and perhaps lead to excess morbidity and mortality.¹⁴ In clinical practice, it is generally best to avoid reliance on assumptions of added value in lieu of demonstrations of the same.

Conclusions

Hospital practitioners should not yet put away their stethoscopes. New technologies such as HCU need to be embraced in parallel with accumulating evidence of benefit. In the hands of hospitalists, the smaller HCU devices may very well prove “handy,” but at present, the literature simply does not support the use of HCU by hospitalist physicians.

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