Summary

- Several hand-carried ultrasound units have been developed for point-of-care cardiac examination.
- Limited small comparative studies indicate that these devices are more accurate than physical examination. Though their diagnostic performance is generally inferior to standard echocardiography, there appears to be close agreement for some conditions.
- Operator training in the performance and interpretation of tests using these ultrasound devices is vitally important.
- The place of these devices in health care will depend on their compatibility with individual practice, their cost, reimbursement decisions and further technical developments.

The Technology

Echocardiography uses ultrasound to show the structure and function of the heart and related blood vessels. Portable, hand-carried ultrasound units, about the size of a laptop computer, have been developed for point-of-care cardiac assessment at the bedside or in the physician's office to extend the accuracy of the bedside physical examination. These units allow physicians to rapidly assess and document left ventricular function, chamber size, source of murmurs, wall thickness, valve structure and the presence of pericardial effusion.

Recent models of portable ultrasound units for cardiac assessment include the SonoHeart® ELITE (SonoSite Inc., Bothell, Washington), OptiGo™ (Philips Medical Systems, Andover, MA) and Terason 2000™ (Teratech, Burlington, MA). Many other "portable" ultrasound devices are available, but these are either larger units transported on carts, or are designed for other clinical purposes, such as emergency care or obstetrics.

Earlier versions of these machines offered two dimensional (2-D) imaging, however, some newer models have the capability for continuous or pulsed wave Doppler (which shows the speed and volume of the blood flow) and enhanced tissue imaging.

Regulatory Status

The SonoHeart, OptiGo and Terason units are authorized for sale by Health Canada.

Patient Group

The potential patient group is very broad. These units are being marketed as tools for use in routine cardiac examination and vascular assessment. Early studies included the examination of critically ill hospital patients, patients presenting at cardiovascular clinics, screening for aortic aneurysm and left ventricular dysfunction. Other preliminary investigations describe the use of portable units in screening for congestive heart failure, carotid artery stenosis, hypertrophic cardiomyopathy and fetal and newborn cardiac abnormalities.

Current Practice

Physical examination, using techniques such as palpation and auscultation, is the standard approach to evaluate persons with suspected cardiovascular disorders. However, the diagnostic...
accuracy of the physical examination is limited,\textsuperscript{4} and some conditions can only be detected with echocardiography.\textsuperscript{14} Echocardiography can be used to augment the physical exam and obtain important additional information on the condition of the heart. Standard echocardiography (SE) equipment is used widely and has good diagnostic performance in the hands of trained operators. The disadvantages of SE are that the units are larger and more expensive. The equipment may be housed in a laboratory elsewhere in the hospital, and the availability of the service will be limited by the number of units and sonographers - possibly leading to delays in diagnosis and patient management.

The Evidence

Several observational studies have been published. Most of these studies describe the use of earlier versions of hand-carried ultrasound devices, and may not reflect their current technical performance.

Spencer et al. compared the results of physical examinations of 36 patients in a cardiology clinic to those from a prototype hand held device used after the physical exam.\textsuperscript{4} Standard echocardiography was used as the gold standard. Physical examination failed to detect 59% of cardiovascular findings (43% were considered major findings). Physician-performed echocardiography with the hand-carried ultrasound device missed 29% of cardiovascular findings, including 21% of major findings. Point-of-care echocardiography improved detection of cardiovascular pathology compared to physical examination, but missed a significant proportion of findings in comparison to SE. The reasons for this may include inexperience in the performance of echocardiography by cardiologists, limitations with the prototype device and better image quality with SE equipment.

Rugolotto et al. investigated the impact of the use of the OptiGo unit in comparison to standard clinical assessment, in the cardiac assessment of 55 patients admitted for acute cardiac care.\textsuperscript{15} As a result of the bedside ultrasound examination, changes were reported in 53/133 (39.8%) of diagnoses or diagnostic likelihood. Changes in planned therapy were reported in 11 of 53 patients (20.8%). The authors concluded that the bedside echocardiogram was particularly useful in the evaluation of left ventricular function, pericardial effusion and aortic stenosis.

Goodkin et al. compared results from a portable device (SonoHeart) with those from standard echocardiography in 80 critically ill patients in intensive care units, step down units, recovery rooms or emergency rooms.\textsuperscript{3} The portable device missed a clinical finding related to the reason for referral in 31% (n=25) of patients and in 19% (n=15) a clinically important finding, separate from the indication for echocardiography, was also missed. Reasons for missed findings include technical limitations of the hand-held device, such as the lack of spectral Doppler capability, and difficulties with imaging some critically ill individuals. The portable device provided important anatomical information but fell short of SE in this application.

Greater agreement between the SonoHeart device and SE was found in a study of 114 patients with a variety of cardiac conditions in an outpatient clinic.\textsuperscript{5} Examinations with each method were performed consecutively by different operators and focused on 2-D evaluation of anatomy and function. There was good agreement with SE in evaluation of left ventricular (93%) and right ventricular function (99%), regional wall motion (90%), dimensions of left and right ventricles (both 99%) and dimensions of left and right atria (96% and 99%).

Uses of the technology have also been studied for abdominal aortic aneurysms. A study examined the use of a portable ultrasound in screening for abdominal aortic aneurysm in 125 individuals (aged >70 years) with hypertension.\textsuperscript{6} After SE, an examination was made by a blinded sonographer. Using standard echocardiography as the gold standard, the sensitivity and specificity of the portable device scans were 91% and 96%. The authors conclude that results with the portable device were comparable to a screening strategy with standard echocardiography. Vourvouri et al. also studied screening for abdominal aortic
They tested 100 consecutive hypertensive patients in an outpatient clinic using the SonoHeart device. Standard and hand-carried echocardiography operated by a trained cardiologist, both detected eight aortic aneurysms, with the portable device giving one false positive and one false negative result.

### Adverse Effects

Ultrasound is one of the safest of diagnostic imaging technologies. No evidence of adverse effects from the use of hand-carried ultrasound units has been shown. The implications of missed or incorrect diagnoses due to technical deficiencies of the devices, or to the operator's lack of training and experience with hand-carried ultrasound are not known.

### Administration and Cost

Portable ultrasound machines are intended to be used by cardiologists and other physicians at a patient's bedside, or in a physician's clinic. Appropriate training and certification in echocardiographic examination using these devices is required.

A recent article by ECRI, in the US noted that these units range in price from US$15,000-$35,000, while standard echocardiography systems cost from US$80,000-$250,000. The Canadian price of the OptiGo unit is C$17,622, which includes one day of on-site training. An optional "flash card" for use with the OptiGo can be purchased from computer suppliers (Dave Buchaski, Philips Medical Systems, Edmonton: personal communication, 2002 Jul 9). The SonoHeart ELITE costs C$16,900 for the base unit and $13,000 for the transducer. Additional options that can be purchased separately include the ECG ($600), colour ($2,500) and a package of three additional features (continuous wave Doppler, pulsed wave Doppler and tissue harmonic imaging, $10,500) (Drew Fraser, Northstar Medical, Beaverton, ON: personal communication, 2002 Aug 2). The Terson unit ranges in price from US$25,000-$40,000, depending on the configuration, according to the company's web site.

### Concurrent Developments

Several point-of-care tests for cardiac assessment have been developed recently. These include troponin cardiac marker assays for the diagnosis of myocardial infarction, and B-natriuretic peptide level tests to detect left ventricular dysfunction.

### Rate of Technology Diffusion

At present, echocardiography is mainly performed by sonographers, cardiologists and cardiac anesthesiologists. Introduction of the hand-carried units may expand this group to include other healthcare professionals. It is unknown how this technology is perceived to fit with established practice patterns. Improvements to the devices may extend their scope and make them easier to use. The cost of the units and arrangements for reimbursement will also influence their diffusion. As Schiller comments, the main issues are the rate at which the skills of relatively inexperienced physicians might evolve, and the time that the ultrasound procedure might add to each patient encounter. At present, Canadian hospitals appear to be using hand-carried ultrasound units for emergency and other types of care, rather than for cardiac assessment.

### Implementation Issues

Spencer et al. suggest that examination using portable cardiac ultrasound equipment should be regarded as an extension of the physical cardiac examination, rather than a replacement for it. These portable systems may increase the availability of non-invasive imaging provided that trained staff are available. The American Society of Echocardiography calls for "user-specific" training in the use of hand-carried ultrasound for cardiac assessment. Those responsible for the use of these devices (cardiologists, sonographers or emergency room physicians) must be clearly defined and have adequate training. Protocols should specify appropriate indications for use and circumstances where referral of the patient for follow-up with standard echocardiography is required. Ideally, these should be informed by
data on the diagnostic accuracy of the devices under local conditions.

Some investigators believe this technology may reduce the need for more expensive, standard echocardiographic exams by providing a rapid, bedside diagnosis of certain conditions and identifying those patients who need more comprehensive assessment with standard echocardiography. However, it is possible this technology will be additive to existing diagnostic examinations. An expansion of uses for these hand-carried ultrasound units, such as in community-based screening programs, is likely. It will be important to determine the impact of hand-carried ultrasound units on overall costs, patient management and outcomes.

References


