Portable Ultrasound Devices

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Clinical Question: What are the current and potential future roles for portable ultrasound in primary care settings?

Background

Ultrasound technology has become progressively more portable since the 1970s, and now includes 'hand-held' devices designed to complement clinical examination by non-radiologist clinicians. Such devices are marketed for use in a range of environments and have been described as 'modern stethoscopes' [1]. This Horizon Scanning Report focusses on portable ultrasound by non-radiologists with limited training and potentially relevant to primary care.

Clinical areas and current literature

Uses of portable ultrasound described in the literature fall into a number of categories, of which the current report will focus on the following clinical areas most relevant to primary care where evidence has been found:

- musculoskeletal uses
- screening for abdominal aortic aneurysm
- measurement of bladder volume
- screening/measurement of carotid artery stenosis
- diagnosis of suspected deep vein thrombosis and assessment of the venous circulation.

(Echocardiography will be considered in a separate report).

Musculoskeletal uses

Several studies evaluated the use of handheld ultrasound for shoulder disorders, largely to detect partial or complete rotator cuff tears. The only studies we identified involved orthopaedic surgeons rather than general practitioners (GPs). Jeyam et al studied the office-based use of portable ultrasound in 64 patients with acute or chronic shoulder pain [2]. They found agreement between the surgeon's findings and that of arthroscopy in 59 cases (92% sensitivity), with 100% specificity for detection of a full thickness tear. In a similarly designed study, Al-Shawi et al compared portable ultrasound with either magnetic resonance imaging (MRI) or operative findings in a sample of 143 patients, 78 of whom had a full thickness tear [3]. They reported 96.2% sensitivity and 95.4% specificity for detection of this pathology. One study introduced portable ultrasound at an orthopaedic clinic, operated by a surgeon who had received 15 hours of training. The 146 patients who received ultrasound were significantly less likely to have MRI (9.7% with ultrasonography vs 14.4% without; $p = 0.03$) although equally likely to undergo surgery (33.6% with ultrasonography vs 22.1% without, $p = 0.77$). No ultrasonography-examined patients had an incorrect diagnosis at surgery [4]. Another study assigned 77 patients attending a shoulder clinic to 2 groups, where patients were either assessed and had ultrasonography performed by a surgeon as outpatients (n=37), or were assessed and referred for departmental ultrasonography where appropriate (n=40) [5]. Patients receiving portable ultrasound completed their clinical episodes significantly quicker than those that were referred ($p<0.02$) and the savings in departmental imaging and follow-up appointments to discuss results and management amounted to nearly £200 per patient. The study concluded that the use of a portable ultrasonography device by an orthopaedic surgeon can significantly reduce the time to treatment and the financial cost for patients with rotator cuff tears.

Portable ultrasound has been used to exclude effusion in acutely swollen joints in an emergency department (ED). In a retrospective study, 54 patients were identified who had presented with pain, erythema and swelling of the knee, elbow, ankle or metatarsophalangeal joint and had received portable ultrasound by an ED doctor trained in sonography [6]. Following sonography, joint aspiration was considered necessary in only 20 out of 39 patients in whom it was initially planned. However the cases selected for this study needed to have undergone ultrasound and might not be representative of all patients with all such joint abnormalities.

Hand-held ultrasound has been used to exclude meniscal tears. Shetty et al [7] investigated 35 patients who subsequently underwent knee arthroscopy and reported fairly high sensitivity (86.4%, comparable with MRI) but lower specificity (69.2%) for meniscal tear detection using portable ultrasound. The low specificity would risk unnecessary arthroscopies if ultrasound were used alone to screen patients, but the high sensitivity suggests that need for MRI might be reduced if only those screening positive underwent the more expensive MRI examination to confirm.

In a study of 212 children and young adults with 348 suspected fractures (actual fracture prevalence 24%), Wieberg et al reported an overall sensitivity of 73% and specificity 92% for fracture detection using ultrasound by paediatric emergency physicians who had received a 1h training session [8]. Reviewing other literature in this area, this group concluded that ultrasound is more useful for 'ruling in' than 'ruling out' fracture, and may have a place in settings with limited access to X-rays.

Detection of Abdominal aortic aneurysm (AAA)

AAA is common in older men particularly but occurs in both sexes. It is readily detected by ultrasound, including portable devices. Four similarly designed studies of AAA screening in an outpatient clinic [9,10], a vascular surgery clinic [11] and an echocardiography laboratory [12], respectively, using portable ultrasound by physicians for patients at risk of vascular disease all report high agreement with traditional ultrasonography (with sensitivity 89-93% and specificity 94-99%) and recommend its use as an extension of clinical examination in vascular patients. A recent systematic review of emergency department bedside ultrasonography for diagnosing suspected AAA reported pooled operating characteristics of ED US for the detection of AAA of sensitivity 99% (95% confidence interval [CI] = 96% to 100%) and specificity 98% (95% CI = 97% to 99%) [13].

In the UK, a screening programme for AAA is underway and it is unclear to what extent hand-held ultrasound in primary care settings would contribute to this programme. One study evaluated the accuracy of a portable 3D ultrasound device that automatically measures the maximum diameter of the abdominal aorta without the need for a trained sonographer [14]. Forty-three patients with known AAA (confirmed by CT) and 48 control patients were selected from the UK National Screening programme. For all patients, the aorta was scanned using the hand-held device by a researcher trained to use the device according to the manufacturer and also received a CT. The sensitivity, specificity, positive and negative predictive values were 81%, 72%, 72% and 81%, respectively and the authors concluded that the hand-held device can detect AAA without the need for a trained operator but further technical improvement is required to increase sensitivity. Portable ultrasound use outside the screened populations (currently confined to 65 year old men and older men requesting it) may also improve AAA detection.

Assessment of bladder volume

Accurate measurement of bladder volume can be achieved through catheterisation, but this is invasive, unpleasant for patients, and carries risk of infection. Post-void residual (PVR) volume is measured in the investigation of recurrent urinary tract infection and of urinary incontinence. High PVRs are associated with outflow obstruction and with neuropathic bladder. These are common, treatable disorders carrying significant population morbidity. In a series of 95 women undergoing PVR measurement by portable ultrasound in an outpatient clinic, Goode et al reported a sensitivity of 66.7% and specificity of 96.5% for detection of PVR >100mls, using catheterisation as the gold standard [15]. Al-Shaikh et al assessed 101 women attending a urogynaecology unit [14]. The measurements correlated significantly with catheterisation volumes ($r=0.79$, 95% CI 0.70-0.85, $P<0.001$) and the mean difference between the two techniques was 12.9 ml. Cooperberg et al have reviewed the literature in this area and warn of the risk of over-estimation using portable devices in women when cystic pelvic pathology including ovarian cysts is present [17].

Detection of carotid artery stenosis

Carotid artery disease is a common risk factor for stroke and transient ischaemic attack. Detection of stenosis may occur opportunistically by auscultation, but accurate assessment is usually undertaken

using duplex ultrasound or MRI in the context of an acute event (e.g. stroke or transient ischaemic attack). Portable ultrasound in primary care might assist in the identification of people at risk of stroke, enabling control of vascular risk factors, and in selection of candidates for endarterectomy. A number of studies have demonstrated the use of hand held ultrasound to investigate or screen for carotid artery disease. In the Office Practice Assessment of Carotid Atherosclerosis (OPACA) Study, 10 non-sonographer clinicians (NSCs) were trained in basic carotid anatomy, in the use of a portable ultrasound device (including practical sessions using mock patients), and in the interpretation of images [18]. The NSCs included 3 physicians, 1 physician assistant, 2 registered nurses, 2 medical assistants, 1 emergency medical technician, and 1 nonmedical assistant. Each was certified on completion of training. Eight NSCs then scanned 150 participants to produce 900 images, of which 97% were interpretable. There was a ≥90% agreement on the presence of carotid intima-media thickness (CIMT; defined as right and/or left CIMT ≥75th percentile of the Atherosclerosis Risk in Communities Study), and ≥80% agreement on plaque presence between the hand held measurements and the gold standard in terms of carotid intima-media thickness and plaque detection. Aboyans et al [19] and Kimura et al [20] have also investigated this area with encouraging results. The study of Aboyans et al enrolled 197 consecutive patients with a mean age of 67 years (range 35-94) and a past history of atherosclerotic disease or presence of risk factors. A carotid stenosis >60% was detected in 13 cases (6%). The sensitivity, specificity, positive and negative predictive value of hand-held sonography performed by a vascular physician was 100%, 64%, 17% and 100%, respectively, compared to standard complete carotid duplex ultrasound. In the study by Kimura et al., internal medicine residents, who had received a 1-hour training session on carotid ultrasonography, performed ultrasonography on 10 asymptomatic volunteer patients who had been selected based on findings of no or minimal disease on a previous carotid ultrasound examination. Hand-held screening ultrasound examinations compared to duplex ultrasound resulted in an average sensitivity of 67% (range 42% to 92%), specificity of 73% (range 38% to 100%), and accuracy of 70% (range 55% to 85%). However, Johnson and Stein recently reviewed relevant literature and emphasise both the technical challenge of accurately measuring carotid intima-media thickness by ultrasound and the current lack of evidence that assessing the carotid arteries of asymptomatic individuals improves clinical outcomes [21].

Investigation of suspected deep vein thrombosis (DVT) and the venous circulation

DVT is common and may trigger potentially fatal pulmonary embolism. Whilst traditionally hospital based, detection of DVT might be facilitated by ultrasound in general practice. Patients may be selected for imaging based on a D-dimer blood test (which could also be available in primary care [22]) or based only on clinical suspicion. The ability of non-sonographer clinicians to detect DVT using portable ultrasound and with very brief training has been demonstrated in an emergency department setting [23]. This prospective, cross-sectional study of a convenience sample of ED patients with a suspected lower extremity deep venous thrombosis was conducted at an urban, academic ED. Forty-seven physicians, who had received a 10-minute training session, performed 199 2-point compression ultrasonographic examinations and results were compared to Radiology Department ultrasonography. The sensitivity and specificity of ED 2-point compression ultrasonography for deep venous thrombosis were 100% (95% CI: 92% to 100%) and 99% (95% CI: 96% to 100%), respectively. A recent systematic review on the accuracy of portable ultrasound performed by emergency physicians compared to either colour-flow duplex ultrasound performed

by a radiology department or vascular laboratory, or to angiography, in the diagnosis of DVT, reported a weighted mean sensitivity of 96.1% (95%CI: 90.6-98.5%) and weighted mean specificity of 96.8% (95%CI: 94.6-98.1%) [24].

Assessment of varicose veins by portable ultrasound has also been studied, with mixed results. Bradbury et al studied recurrent varicose veins following primary repair and demonstrated the benefit of hand-held ultrasound to complement clinical examination in demonstrating the site of recurrence [25]. This study assessed a consecutive series of 118 patients (148 legs) presenting with recurrent varicose veins who underwent preoperative clinical and hand-held Doppler ultrasonographic examination by a single surgeon. In one-third of cases there was uncertainty about the presence of saphenofemoral incompetence by clinical examination alone, compared with only 6 cases of uncertainty after ultrasound examination. The authors concluded that hand-held Doppler ultrasonographic examination improved the overall accuracy of preoperative assessment of primary and recurring varices. However, Smith et al studied the hand-held ultrasound assessment of varicose veins prior to primary repair in a prospective randomised controlled trial of 149 consecutive patients presenting to a hospital vascular service and reported no improvement in post-surgical outcomes [26]. One prospective single blind study of 943 patients (1218 legs) with varicose veins attending outpatient clinics of vascular surgical units in the UK compared the accuracy of hand-held Doppler as a rapid screening test for selecting patients for duplex imaging [27]. The study showed that Duplex would not have been requested in 62% of limbs and among these hand-held Doppler missed significant reflux in the long saphenous vein in 3% and the short saphenous in 4%. The study concluded that selective use of hand-held Doppler can avoid duplex imaging for many patients, with a low failure rate for detecting correctable venous reflux. However they also observed variations between individuals and units in results of hand-held Doppler and duplex imaging.

Identification of deep cubital fossa veins that are difficult to access for phlebotomy is a common problem in many health care settings. The potential benefits of Doppler in this situation have been discussed [28] but a definitive study in primary care using portable ultrasound imaging has not yet been conducted.

Research questions

While there is a growing literature on the use of point of care ultrasound devices, to date much of the evidence involves small studies, in focussed clinical areas, with undefined training and competencies, and outcomes largely limited to comparative accuracy. There are therefore several major research gaps that need to be filled prior to further implementation of this technology:

1. What are the training needs for primary care clinicians who are not ultrasonographers or radiologists in order to safely use point of care ultrasound devices for specific indications?

2. How do training needs vary between different types of generalist clinicians (GPs vs Nurses) and for different clinical aims (e.g. AAA screening vs diagnostic ultrasound for musculoskeletal abnormalities), and how do competencies need to be assessed to fulfil professional and medical legal standards?

3. What is the impact of point of care ultrasound on subsequent clinical decision making and patient outcomes, and how does this compare with current ultrasound services and other imaging modalities? In particular in comparison to current practice, what is the impact of point of care ultrasound in terms of speed, cost effectiveness and appropriateness of subsequent patient management decisions?

Suggested next steps

The research gaps identified above are sufficiently large that we suggest the following as priority next steps for research. These should all be undertaken before further studies are undertaken on the clinical utility of point of care ultrasound, i.e. impact on clinical decision making or cost effectiveness evaluations.

1) Identification of priority clinical needs for point of care ultrasound in primary care, taking into consideration diagnostic, screening, referral and monitoring needs, and differences among different types of primary care clinician, e.g. GP vs Nurse, GPs with specialised interests/expertise vs regular GPs. In addition this assessment would need to consider current facilitators and barriers to access to imaging in primary care including those identified by relevant guidelines. It would also need to consider modelling the cost implications of any changes to imaging services.

2) Evaluation and comparison of the technical capabilities of point of care ultrasound in comparison to standard devices, including accuracy across multiple conditions with various types of end-users, abilities to record and document findings and integrate with electronic medical records, and need for multiple probes or processing software.

3) Generation of consensus among primary care, secondary care and imaging specialists and their professional bodies in terms of training needs, competency demonstration, medical legal and regulatory approval for potential use of point of care ultrasound devices

4) Further exploratory studies of the role of point of care ultrasound in primary care for teaching and training of medical students and GP trainees.

Expected outcomes

Portable ultrasound in the hands of non-specialists is not yet established but carries potential to complement clinical examination, improve diagnosis and screening, and potentially reduce the need for more formal imaging investigations. However, at present there are major gaps in the evidence base to support these devices, highlighted above, including training needs, comparative accuracy, role within existing imaging and diagnostic services currently offered. Once these are clearer, then studies within priority focussed clinical areas of the clinical utility of such devices are warranted. At present therefore, implementation of point of care ultrasound appears to be premature.

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