Portable bladder ultrasound scanners

This Evidence Note reviews the best available published evidence relating to whether or not the use of portable bladder ultrasound scanners (PBUS) can reduce the need for urinary catheterisation and hence avoid catheter associated urinary tract infections (CAUTIs). The note examines the accuracy of PBUS and also their impact on health outcomes such as urinary tract infections (UTIs). It further examines evidence around implementing bladder scanning protocols in healthcare facilities. The management and/or monitoring of catheterisations by healthcare professionals were not considered.

Health technology description

There are two methods for assessing post-void residual (PVR) urine volume: sterile catheterisation (direct measurement of urine volume) and bladder ultrasound (indirect estimation of urine volume)\(^1\). Bladder ultrasound scanning offers a non-invasive alternative to catheterisation. The scanner is used, primarily as a diagnostic aid, to non-invasively identify incomplete bladder emptying and determine bladder volume\(^2,3\) in adults and children with urinary problems of varying aetiologies, such as\(^4\):

- postoperative patients at risk of urinary retention (UR);
- patients with UTIs, urinary incontinence (UI), enlarged prostate, urethral stricture, neurogenic bladder and other lower urinary tract dysfunctions; and
- patients with conditions that interfere with voiding, such as spinal cord injuries, stroke and diabetes.

Due to its non-invasive nature, the use of ultrasound technology may reduce the risk of urethral trauma and urinary infection associated with catheterisation. Stationary and portable ultrasound machines are available in both 3-dimensional (3D) and 2-dimensional (2D) versions. The PBUS offer potential benefits that the stationery machines do not due to their portability and ease of use\(^2,5\) which permits the use of the

**Key points**

- Portable bladder ultrasound scanners are of sufficient clinical accuracy in estimating PVR urine volume in most patients.
- Studies however report conflicting results regarding the use of the device in children aged less than 36 months and postnatal women.
- There was insufficient evidence available to conclude that any of the models of PBUS compared demonstrated superior clinical accuracy.
- Evidence suggests that adopting standard protocols, including staff training and identifying appropriate patients, for the use of PBUS is associated with reduced risk of unnecessary catheterisation, reduced UTIs and fewer adverse events, as well as improved patient satisfaction, when compared with catheterisation.
- No relevant economic evidence was identified, thus it was not possible to comment on the cost effectiveness of PBUS.
- Further research is required on the accuracy and suitability of newer PBUS so that NHS purchasing can be evidence based.
device in community settings outside of the hospital environment.

The portable, battery-powered, ultrasound scanner utilises automated technology to digitally register bladder volume, including PVR urine volume, while providing images of the bladder area\(^2,6-8\). It consists of a base component with a display screen and a hand-held ultrasound transducer (scan head) which is usually positioned on the patient’s abdomen and pointed towards the bladder. The base component employs ultrasound technology, through electrical connection to the scan head, to automatically create an image of the bladder and calculate bladder and PVR measurements\(^2,9\). Use and interpretation of results of PBUS can be complex, particularly in patients who are morbidly obese\(^2\), have irregular bladder shapes or in postnatal women (immediately after childbirth) as the device records the volume of cystic structures within the pelvis\(^10\) and so interpretation of results requires specific knowledge and high levels of clinical competence\(^11\). Some authors have however suggested that although training is required to interpret results, only minimal technical skills are required to use the device\(^3\).

In the past, the BladderScan\textsuperscript{®} series, manufactured by Verathon Medical, were the most common PBUS\(^6,12\). However, a number of alternatives have recently been launched on the United Kingdom (UK) market. These include the Bardscan\textsuperscript{®}, Cubescan\textsuperscript{®} and different Sonosite\textsuperscript{®} models. Some of these portable scanners, like the Bardscan\textsuperscript{®} and Cubescan\textsuperscript{®} provide real-time ultrasound imaging. There are however other scanners that provide only numeric bladder volumes with no image of the bladder shape.

**Epidemiology**

As detailed above, PBUS may find application in a number of bladder problems of varying aetiologies. Often the problem can manifest as either UI, UR or in women more commonly as recurrent UTIs.

UI is defined as any involuntary urinary leakage\(^13\) that may occur due to a number of abnormalities in the lower urinary tract function or as a result of other illnesses\(^14\). Risk factors for UI include age, female gender, obesity, lower urinary tract symptoms, functional and cognitive impairment, pregnancy, childbirth, diet, smoking, genetics and family history\(^2,14\). UI is under-diagnosed\(^14\). The Leicestershire Medical Research Council (MRC) Incontinence Study\(^15\) reported that 33.6\% of individuals over 40 years of age have significant urinary symptoms. Of these, 6.2\% found the condition bothersome while 2.4\% found it both bothersome and socially disabling\(^15\). Data from Information Statistics Division (ISD) Scotland estimate the prevalence of current UI in adults as 9\%\(^16\).

UR is defined as the inability to pass urine despite persistent effort\(^17\). The definition of UR, based on PVR urine volume, is influenced by the population and clinical condition of interest\(^2\). There is no clear consensus regarding what constitutes a normal or abnormal residual volume; clinically significant volumes could vary between a lower limit of 50 ml and upper limit of 300 ml\(^2,14,18\).

UTIs are a common complication of urinary catheters that can extend hospital stays. It has been reported that approximately 40\% of all hospital-acquired (nosocomial) infections can be attributed to UTIs and about 80\% of UTIs (32\% of nosocomial infections) are associated with both indwelling and intermittent catheterisation\(^2,19\). Catheterisation is associated with a 5\% risk of urinary infection in long-term care patients\(^5\). CAUTI surveillance is not mandatory in Scotland. The Scottish National Healthcare Associated Infection Prevalence Survey\(^20\), conducted between 2005 and 2006, estimated the percentage of urology patients with catheters as 40.3\%. The greatest proportion of patients catheterised were identified in surgical, medical and elderly specialties\(^20\).

**Clinical effectiveness**

The literature available for PBUS is variable in methodological quality (mostly non-experimental designs involving small numbers of participants and varying requirements for staff training), thus limiting generalisability and the confidence which can be placed in any conclusions drawn.
Accuracy of PBUS

A National Institute for Health and Clinical Excellence (NICE) guideline published in 2006, on the management of UI in women was identified. Based on three studies (with residual urine volumes cut-offs ranging between 50–200 ml) that assessed the accuracy of PBUS compared with catheterisation in men and women, the guideline concluded that the bladder scanner is less invasive with lower adverse effects. The sensitivity (range 67–95%) and specificity (range 63–99%) of ultrasound in detecting PVR volumes were found to be within clinically acceptable limits. However, one study showed a much lower sensitivity at residuals >100 ml. The findings led the guideline to recommend that a bladder scan should be used in preference to catheterisation in the measurement of PVR volumes, on the grounds of acceptability and reduced rate of adverse events. However, due to lack of evidence for what constitutes a clinically significant residual, this recommendation may be limited only to women with signs and symptoms suggestive of voiding dysfunction.

Similar to the NICE guideline, there was general consensus amongst other secondary evidence that although PBUS are not as accurate as catheterisation and require training, they offer acceptable levels of clinical utility and reduced risk of UTIs and improved patient satisfaction due to their non-invasive nature. Results of the studies suggest that the benefits resulting from the use of PBUS outweigh the risks and exceed the benefits of catheterisation. Based on a review of 17 non-randomised controlled trials (RCT) (prospective, observational studies with contemporaneous control), a health technology assessment (HTA) conducted in 2006 by the Ontario Medical Advisory Secretariat reported significant results regarding the negative health outcomes that were avoided due to the use of the PBUS. Catheterisations avoided ranged from 16–47% whilst UTIs were reduced by 38–72%. Subgroup analysis showed that PBUS are less accurate for women than men. Higher levels of accuracy were demonstrated in patients with spinal cord injuries compared with other acute care and rehabilitative patients. There was variability in the type and model of PBUS used in the studies. A recent primary study of 101 women with an indication for PVR measurement concluded that the BladderScan BVI 3000® is an accurate alternative to catheterisation. Results from this ultrasound scanner were highly reproducible and correlated significantly with catheterised volumes, with a mean difference of 12.9 ml (p<0.001).

NB: this literature was not included in the identified secondary evidence.

Accuracy of PBUS in specific population groups

Additional primary literature studies which investigated the clinical utility and user satisfaction of PBUS in specific population groups were also identified.

Assessment of residual urine in postpartum women

Three observational studies, including one UK-based study assessed the reliability of PBUS compared with catheterisation in postpartum women. The residual urine volume indicative of a positive result ranged from 100 ml to 400 ml. Two studies concluded that the BladderScan™ BVI 3000® and BVI 6100® were reliable and non-invasive screening methods for detecting postpartum urinary retention after vaginal delivery and for reducing the number of unnecessary catheterisations, when used by trained nurses. Using a 400 ml threshold, one study estimated the sensitivity and specificity of the BVI 6100® as 76% and 96% respectively. Despite obtaining clinically irrelevant differences in measured volumes, the UK-based study reported that the BVI 3000® is not as accurate as urethral catheterisation for determining residual urine volume in the puerperium. Volumes measured by PBUS were overestimated (by 9 ml) and underestimated (by 33 ml) compared with volumes measured by standard real-time ultrasound and catheterisation respectively.
Assessment of bladder volume in children

Four randomised studies and four non-randomised observational studies, published between 2005 and 2008, evaluated the accuracy of PBUS (different BVI® models and Sonosite 180®) in children in various settings. All four fairly large studies investigating the clinical utility of the Sonosite 180® found that first-attempt urine collection success rates (collection of 2–2.5 ml) in children 36 months or younger were significantly improved by the bladder ultrasound device (range 92–100%) compared with the conventional use of catheters without imaging (range 67–78%). This reduction in unsuccessful urethral catheterisation was also deemed clinically meaningful.

Conflicting findings however were reported in other studies including one RCT, that utilised various BVI® models in children. The studies found that the portable bladder scanner was not reliable in assessing bladder volume in children aged under 36 months. Compared with catheterisation, the BVI 6200® and BVI 3000® underestimated bladder volumes in two studies while the BVI 3000® failed to detect significant volumes in a small study with neonatal cases (n=10). Furthermore, volumes were overestimated in a study comparing the BVI 2500® with standard ultrasound. Nonetheless, reliability was found to be within the acceptable limits in children older than 36 months and those with bladder volumes greater than 20% of the expected bladder capacity for age. The authors of the studies concluded that although the PBUS could be used as a diagnostic aid for assessment of bladder filling (as there is currently no better alternative which reduces the risk of UTIs associated with unnecessary catheterisation), it needs to be used with caution in children less than 36 months, particularly neonates with complex problems, and should not replace current clinical assessment using catheters.

Greater satisfaction and a higher likelihood of using volumetric bladder ultrasound compared with conventional catheterisation were reported by both caregivers and healthcare providers in a prospective RCT. Using a seven-point Likert scale (1='none', 7='a great deal'), caregivers in the catheterisation group rated the children’s discomfort higher (4.4 versus 3.4; p=0.02) and were less satisfied (4.5 versus 6.4; p <0.0001) than those in the ultrasound group. However, another randomised study found no significant difference in caregiver satisfaction between the use of ultrasound and catheterisation in a paediatric population. It is likely that this study was underpowered to detect a difference in satisfaction scores.

Comparative effectiveness of different portable bladder ultrasound scanners

A UK study investigated the accuracy of four commonly used portable bladder scanners (BVI 3000®, BVI 6100®, Sonosite iLook 15® and Bardscan®) in 28 healthy volunteers. Relative to the average of all four scanners, the iLook 15® and Bardscan® under-predicted bladder volumes by 34 ml and 21 ml respectively, while the BVI 3000® and BVI 6100® over-predicted bladder volumes by 17 ml and 38 ml respectively (p<0.05). Volumes obtained from the iLook 15® and Bardscan® were about 50 ml lower than both BVI® models. Although not statistically significant (p=0.051), the BVI 3000® had a slightly greater error variability compared with the other scanners. The authors concluded that no scanner could be classed as being the most accurate. The BVI 6100® was however found to be the fastest and lightest scanner with a markedly less variable error.

Another UK study comparing the BVI 3000®, Bardscan® and another 3D-ultrasound system (HDI 4000®), in a random sequence, concluded that the HDI 4000® is the most accurate of all three scanners. Estimated volumes from all three ultrasound scanners were found to be significantly correlated to voided volumes (p <0.001). The Bardscan® and BVI 3000® underestimated and overestimated respectively, large bladder volumes. Voided volumes were significantly underestimated by 21 ml by the Bardscan® (p=0.008). This finding led the authors to also conclude that the Bardscan® is not as accurate as the BVI 3000® despite having the advantage of producing real-time images.
and instantaneous volume calculation.

Three studies\textsuperscript{25,38,39} that compared BVI® models with catheterisation\textsuperscript{25,38} and other ultrasound devices\textsuperscript{38,39} found the accuracy of the BVI® scanners ‘sufficient’ for clinical practice. In a population of 89 men and women with lower urinary tract symptoms, Choe et al.\textsuperscript{38} found no significant difference in the accuracy and precision in estimating residual volumes between the BME-150A® (S & D Medicare Co., Seoul, Korea) and BVI 3000®. Both devices were found to be clinically acceptable alternatives to urethral catheterisation. The portable 3D (BVI 2500®) and stationary 2D (Vingmed CFM 800®) ultrasound scanners also demonstrated sufficient accuracy for clinical practice in a study involving patients with permanent bladder catheters\textsuperscript{39}.

One study\textsuperscript{40} that assessed the accuracy of the BVI 6100® in measuring volumes ≤ 150 ml concluded that, compared with existing ultrasound methods, the 3D ultrasound device provides significantly greater accuracy for estimating lower bladder volume when appropriate patients are selected and examiner measurement error is reduced.

Successful adaptation of bladder scanning ultrasound programmes that provided staff training in facilities have been reported in a number of studies\textsuperscript{8,24,44-47}. These programmes resulted in easy identification of individuals at risk of developing UTIs\textsuperscript{45}, reduced unnecessary catheterisation\textsuperscript{24,46,47} and reduced UTIs\textsuperscript{46}. Continuous quality assurance and additional training for staff demonstrating inaccurate measurements were however recommended\textsuperscript{44}.

**Safety**

Generally, there are no complications associated with PBUS. One study reported potential adverse effects including skin irritation, allergic reaction to the ultrasound gel and padding and pressure sore formation at the site where the sensor is placed\textsuperscript{2}.

**Cost effectiveness**

No relevant economic evaluations (based on or generalisable to UK costs) were identified.

**Equality and Diversity**

NHS QIS is committed to equality and diversity in respect of the six equality groups defined by age, disability, gender, race, religion/belief and sexual orientation.

The Evidence Note process has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.nhshealthquality.org

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References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network (formally eLibrary) http://www.knowledge.scot.nhs.uk, or by contacting your local library and information service.
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