NICE advice

BladderScan BVI 9400 3D portable ultrasound scanner for measuring bladder volume

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Summary

BladderScan BVI 9400 is a portable 3D ultrasound device that measures bladder volume non-invasively to help assess urinary retention and post-void residual bladder volume. Four published prospective cohort studies (3 full papers, 1 abstract) were identified, involving 239 children and young people in secondary or tertiary care settings. These studies showed heterogeneity in the outcome measures and statistical analyses. The reproducibility and accuracy of the results were also varied. The study reported in the abstract contained several limitations and potential biases. The average cost of a BladderScan BVI 9400 system is between £6000 and £8000, excluding VAT.

Product summary and likely place in therapy	Effectiveness and safety
• BladderScan BVI 9400 is a portable 3D ultrasound device designed for non-invasive bladder volume measurement to help diagnose and assess urological conditions. • It would be used in place of either urinary catheterisation or ultrasound (including other portable bladder ultrasound scanners) in children or adults.	• Four prospective cohort studies carried out in children and young people (0–19 years; total n=239) are summarised in this briefing. • No studies in adults met the inclusion criteria for this briefing. • Two studies assessed intra-operator reproducibility. One study reported no difference between repeated BladderScan BVI 9400 measurements taken by the same observer. Another study reported 'poor' intra-observer reproducibility. • Three studies compared the accuracy of the BladderScan BVI 9400 with catheterisation or real-time ultrasound. One study reported poor accuracy, and 2 studies reported moderate to high accuracy. • One study assessed success rates of suprapubic aspiration when guided by the BladderScan BVI 9400, finding that they were lower than those observed in previous studies using real-time ultrasound.

Technical and patient factors	Cost and resource use
• The BladderScan BVI 9400 uses ultrasound to construct a picture of a 'slice' through the abdomen. Algorithms are used to estimate bladder volume from these ultrasound data. • The manufacturer states that BladderScan BVI 9400 does not need to be operated by a sonographer and can be used by a healthcare professional after relevant training. • Three models of the BladderScan are currently marketed in the UK. The BVI 9400 model, which is indicated for use in adults and children, is the focus of this briefing. • BladderScan BVI 9400 uses bespoke 'NeuralHarmonics' algorithms to derive an estimate of bladder volume from the ultrasound data. Compared with predecessor systems, algorithms have been refined to distinguish between the bladder and the uterus.	• The average cost of a BladderScan BVI 9400 system is between £6000 and £8000, excluding VAT. • No evidence on cost consequences and resource use was available.

Introduction

The urinary bladder is a hollow, muscular, expandable organ in the pelvis of adults, and in the lower abdomen of children younger than 6 years old. The bladder stores urine, so that urination can be infrequent and voluntary. When the bladder muscles contract, 2 sphincters (valves) open and the urine flows out of the body through the urethra. Bladder function is controlled by the interaction between the central nervous system and the organs of the lower urinary tract (bladder, urethra and pelvic floor muscles). If this control is damaged bladder function can be affected. Common bladder function problems include urinary incontinence (UI) and urinary retention (UR).

UI is when urine passes from the body without the person having control over it. Prevalence in the UK general population is estimated to range from 14% to 69% in women aged 15 years or older (Hunskaar et al. 2005). The Leicestershire MRC Incontinence Study found that 34.2% of women reported having occasional UI (see NICE's guideline on the management of urinary incontinence in

women). The prevalence of UI in men aged 18 to 64 years is 3%, and increases to 7% to 10% in men older than 65 years (Royal College of Physicians 1995). Nocturnal enuresis (involuntary urination during sleep) is the most common form of UI in children. In a review of the best available evidence, Buckley et al. (2010) reported a night-time UI prevalence of 6.8% to 16.4% in 7-year-old children, and a daytime UI prevalence of 3.2% to 9.0% in the same age group. It is important to note that this review does not clearly distinguish pathophysiological causes of UI from late toilet training.

UR occurs when the bladder does not empty properly. There are 2 main causes of UR; blockage in the flow of urine through the urethra, and weak bladder muscles. It is 10 times more common in men than in women, and is most prevalent in men older than 70, mainly because the prostate gland increases in size with age (Kuppusamy et al. 2011). In England, acute UR has an annual incidence of approximately 3/1000 men (Cathcart et al. 2006). In women, the incidence of UR can increase after childbirth (Mulder et al. 2012). Postpartum UR occurs in 10% to 15% of women (Chaurasia et al. 2013). UR often happens immediately after surgery. The combination of intravenous fluid therapy and anaesthesia may result in a full bladder with impaired nerve function, causing UR.

Investigations into bladder function problems typically include measuring the amount of urine left in the bladder after the person has urinated (known as bladder volume assessment). Bladder volume is usually assessed by urinary catheterisation after the person has completely emptied their bladder. Catheterisation is an invasive procedure that involves inserting a tube into the bladder either through the urethra or, less commonly, through a small opening in the lower abdomen, so that urine can drain out of the bladder. Catheterisation is used for diagnostic purposes to measure the post-void residual (PVR) volume of urine in the bladder, and as a treatment to fully drain the bladder. Catheterisation can be intermittent or indwelling. Intermittent catheterisation is when the tube is left open-ended and is removed immediately after all of the urine has been drained out of the bladder. Indwelling catheterisation is when the tube is attached to a drainage bag and left in place over a longer period of time, for example days or weeks.

Urinary catheterisation carries a risk of urethral trauma and urinary tract infection (UTI). UTIs account for an estimated 40% of all hospital-acquired infections (NHS Quality Improvement Scotland 2010). About 80% of these UTIs are associated with catheterisation. These infections increase inpatient length of stay and cost of treatment and, in rare situations, may be life-threatening.

Every year, over 1 million catheterisations are done in NHS hospitals (Nazarko 2010). Studies have shown that about 25% of these are unnecessary (Fakih et al. 2010; Rothfield et al. 2010). Catheterisations may be carried out unnecessarily because of a lack of guidelines on the indications for catheter placement (Bhatia et al. 2010).

Ultrasound scanners can be used to estimate the volume of urine in a bladder non-invasively, and avoid unnecessary catheterisation. Extensive specialist training is needed for conventional ultrasound scanning and it therefore tends to be carried out by sonographers or doctors. An alternative, and increasingly common option, is portable bladder ultrasound scanning (PBUS). PBUS does not need to be done by people with extensive technical training because it automatically provides quantitative measurements of bladder volume.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of healthcare professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The BladderScan BVI 9400 is CE marked as a Class IIa medical technology. The CE mark was received in November 2011 and is held by the manufacturer, Verathon (USA).

Description

The BladderScan BVI 9400 (Verathon) is a portable (21.9 cm × 33.6 cm; 2.36 kg) 3D ultrasound device that measures bladder volume to assess urinary retention and post-void residual (PVR) bladder volume, to help to diagnose urological conditions and post-operative recovery without needing urinary catheterisation.

The BladderScan BVI 9400, like other portable bladder ultrasound scanning technologies, works by sending high-frequency sound waves into the body from a transducer probe placed on the skin of the abdomen. Some of the sound waves are reflected back towards the probe, which detects these reflected sound waves and passes the information back to the ultrasound machine. The ultrasound machine uses this information to construct a picture of a 2D 'slice' through the body.

There are 3 models of the BladderScan available in the UK (BVI 9400, BVI 6100 and BVI 3000), all of which are claimed to enable more accurate measurements than conventional 2D ultrasound. These were developed from predecessor versions of the technology. The 3000 (portable console with probe attached) and 6100 (handheld probe with built-in display) models are intended for use in adults only. Both models use VMODE software to calculate bladder volume by transforming 2D

slice images into a 3D image, which is displayed on the screen and can also be printed. The BVI 9400 uses updated patented software, NeuralHarmonics, to measure bladder volume. This also transforms 2D slice images into a 3D image and uses neural network algorithms to improve the segmentation accuracy of the structures or organ being targeted. The refined NeuralHarmonics algorithms are designed to:

- detect, segment and measure the bladder geometry and volume
- detect the uterus and distinguish this from measurements of the bladder.

The BVI 9400 model allows the user to set the device to 3 modes: 'small child', 'woman who has not had a hysterectomy', or 'all other patients'. The 'small child' mode (referred to as 'child mode' throughout this briefing) is intended to be used when scanning a person less than 122 cm tall and weighing less than 27 kg, generally boys and girls aged below 8 years.

The BladderScan BVI 9400 has reusable and single-use components. The reusable components are:

- A hand-held probe that sends and receives ultrasound waves, automatically moving its internal transducer 360º to scan 12 planes to produce a 3D image of the bladder. The probe is attached to the console by a detachable cable and has 3 main features:
  - A scan button that is pressed to take a scan.
  - An aiming display that displays directional arrows to ensure the bladder is centred within the scanning cone.
  - A microphone that records the voice of the person operating the system.
- A console with a colour LCD display screen. All operating controls, as well as the printer, are located on the console.
- Lithium-ion battery – a fully charged battery can provide about 30 examinations within a 24-hour period. Charging time offline for an empty battery is 6 hours for a full charge.
- A battery charger or wireless hub with AC power cord.

The single-use components are:

- Thermal paper roll for the printer.
- Acoustic coupling gel.

Setting and intended use

The BladderScan BVI 9400 is intended for adults and children needing bladder volume measurements in primary and secondary care settings, including both urology and surgical wards. It is not intended for use on unborn babies or pregnant women. The BladderScan BVI 9400 does not need to be operated by a sonographer. Therefore, any healthcare professional, including healthcare assistants and nurses, can use the device, after training provided by the manufacturer.

Current NHS options

Diagnostic testing for urinary retention (UR) can include:

- Urine dipstick to exclude any current infections or existing conditions such as diabetes.
- Urine microbiology and cytology if indicated by a history of urinary tract infection (UTI) or haematuria.
- If incomplete voiding is suspected or there are symptoms of recurrent UTI, post-void residual (PVR) volume is measured. Ultrasound bladder scanning may be used for this if available.

No specific national guidelines for assessment of PVR volume in UR were found, however the UK Bladder and Bowel Foundation suggests that healthcare professionals may recommend various tests for UR, including:

- Immediate catheterisation of people with acute UR and urinalyses to screen for haematuria and UTI, by dipstick testing or microscopic examination of the sediment.
- Uroflowmetry to assess the flow rate of urination.
- Urodynamic testing, which can include catheterised or ultrasound measurement of PVR volume.
- Renal ultrasonography for people with abnormal renal function.
- Cystoscopy to examine the inside of the bladder.

The NICE guideline on the management of lower urinary tract symptoms in men states that men with lower urinary tract symptoms who are having specialist assessment should be offered PVR volume measurement.

According to NICE's guideline on the management of urinary incontinence in women, if incomplete bladder voiding is suspected or there are symptoms of recurrent UTIs, PVR volume should be measured. If available, ultrasound bladder scanning should be used rather than catheterisation because this is more acceptable to people and has a lower incidence of adverse events.

NHS Choices (2014) states that if overflow urinary incontinence (UI) is suspected in a person in a primary care setting, PVR volume may be measured. Overflow UI, also called chronic UR, is often caused by a blockage to the urethra, such as a bladder stone. The bladder may fill up as usual, but because it does not empty properly during voiding (because of the obstruction or muscle or nerve damage) the remaining urine leaks out. Measurement is usually carried out by bladder ultrasound, but occasionally by urinary catheterisation.

When assessing lower urinary tract dysfunction in a person with neurological disease, the NICE guideline on urinary incontinence in neurological disease suggests an option of measuring the PVR volume by ultrasound, preferably using a portable scanner, and potentially taking further measurements to find out how bladder emptying varies at different times and in different situations.

The NICE guideline on urinary tract infection in under 16s states that catheter samples or suprapubic aspiration (SPA) should be used for children with UTI symptoms if it is not practical to collect urine by non-invasive methods. Before SPA is tried, ultrasound guidance should be used to show that urine is in the bladder.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the BladderScan BVI 9400:

- Bardscan II (Mediwatch [UK])
- Cubescan BioCon-500 and BioCon-700 (Medline)
- SonoSite M-Turbo (FUJIFILM SonoSite).

Costs and use of the technology

The market average cost of the BladderScan BVI 9400 system is between £6000 and £8000, excluding VAT. The estimated average device cost of catheterisation is £2.38 per person, including the average price of a catheter (excluding long-term catheters), a catheter insertion pack, and a drainage bag. The cost can increase to £5.59 per person, if urethral anaesthetic and a stabilisation

device (such as StatLock) are used. Conventional ultrasound scanning of the bladder costs £49 per scan (less than 20 minutes, NHS reference cost 2013/14 code RA23Z).

Likely place in therapy

The BladderScan BVI 9400 would be used in a primary or secondary care setting. The BladderScan BVI 9400 is currently used in the NHS. The BladderScan BVI 9400 would be used as an alternative to catheterisation or ultrasound (including other portable bladder ultrasound scanners) to help diagnose urological conditions and assess post-operative urine retention.

Specialist commentator comments

One specialist commentator highlighted that the BladderScan device does not diagnose urological conditions, but can provide PVR volume measurements to form part of a broader assessment. They added that a diagnosis can only be made after additional testing to determine the underlying cause.

One specialist commentator expressed concern that the BladderScan is unable to distinguish the bladder from other pelvic structures and may, therefore, also register uterine volume, and fluid from cysts and ovaries. The same specialist emphasised the importance of operator training in distinguishing between these different volumes. Another specialist commentator noted that it is difficult to mix up non-bladder and bladder pathologies when using BladderScan.

One specialist commentator noted that postpartum bladder scanning is not recommended because it is not reliable and, in practice, catheterisation provides a more accurate measurement of PVR volume in women after delivery.

One specialist commentator suggested that the BladderScan device could be beneficial for people with multiple sclerosis or spinal injuries. These conditions can disrupt spinal nerve pathways and result in impaired bladder function and incomplete emptying of the bladder. The specialist commentator suggested that the most important investigation on which to base any planned management strategies is measurement of PVR volume, which can be carried out with portable bladder ultrasound scanning.

According to 1 specialist commentator, the scanner is easy to use, and reliable, in children. The commentator noted that the BladderScan devices are used nationally in paediatric urology departments. They explained that the difficulty in assessing PVR volume in young children relates to their small bladder volumes and less developed ability to start voids. The commentator added

that it is not acceptable practice in UK paediatric units to use a catheter to formally assess PVR volume.

The lack of studies carried out in adult populations was noted by 1 specialist commentator.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance, NICE aims to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Portable bladder ultrasound scanning may be used to assess PVR volume in people with chronic neurological conditions such as cerebral palsy or spinal dysraphism.

Bladder care is an important aspect of management in the postpartum period. Postpartum voiding dysfunction occurs in a significant number of women after giving birth. Standard bladder scanners may measure uterine debris as bladder volume. The NeuralHarmonics technology within the BladderScan BVI 9400 potentially allows more accurate non-invasive bladder volume measurement in women who have recently given birth, because it can differentiate more accurately between the bladder and the uterus.

The BladderScan BVI 9400 is not intended for use on unborn babies or pregnant women. Pregnancy is a protected characteristic under the Equality Act 2010.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency (MHRA) website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. There were

77 adverse events identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE) from 2007 to the present. One report related to the BladderScan BVI 3000 model, 29 reports did not clearly state the model, and the remaining 17 were on the BladderScan BVI 9400model (FDA 2013). All adverse events were listed as device malfunctions, including device lock-up and false readings (for example, reporting zero when the bladder was not empty). None were reported to result in patient harm.

Clinical evidence

Of 18 papers identified, 13 were excluded from further assessment because they reported an intervention or outcomes that were not relevant to this briefing (for example, if a study investigated device repeatability but not accuracy), included an overlapping study population, had a small sample size (fewer than 10 people) or were not clinical studies. Studies were only included if they used the BladderScan BVI 9400. No studies in adults met the inclusion criteria for this briefing. Three fully published studies and 1 abstract in paediatric populations are summarised in this briefing.

The Bevan et al. (2011) study was set in Australia. The reproducibility and accuracy of the BladderScan BVI 9400 was compared with conventional real-time ultrasound (RTUS; ACUSON S2000, Siemens) for measuring bladder volume in 61 healthy children aged 0 to 24 months. Children were scanned with both the BladderScan and RTUS on 2 separate occasions, 1 hour apart. The BladderScan readings were done by 2 senior paediatric doctors. On each occasion 6 BladderScan measurements were taken for each child, 3 by each doctor. In 36 children, the measurements were repeated using a second BladderScan BVI 9400 machine in case of machine variability. The BladderScan measurements were immediately followed by RTUS measurement. All RTUS measurements were done by a single senior paediatric sonographer who was blinded to the BladderScan measurements. The BladderScan and RTUS measurements were compared by Bland−Altman analysis to determine the reproducibility and the limits of clinical agreement (as a measure of accuracy). The authors describe 'poor' reproducibility within the repeated BladderScan measurements at each time point for both BladderScan BVI 9400 devices used. BladderScan measurements ranged from 10 ml to 86 ml. The overall reproducibility coefficient within BladderScan readings was 20 ml, indicating that 95% of repeated BladderScan measurements were within 20 ml of each other. The authors report 'poor' accuracy when comparing the BladderScan measurements to RTUS. By Bland−Altman analysis, the 95% limits of agreement between BladderScan and RTUS were −31 to +19 ml, indicating that 95% of BladderScan readings were between −31 and +19 ml of the corresponding RTUS measurement. The authors concluded that the BladderScan BVI 9400 does not appear to be a reliable method for

assessing bladder volumes in children aged 0 to 24 months. Details of the study are shown in table1.

The Buntsma et al. (2012) study was set in Australia. The success rate of suprapubic aspiration (SPA) was determined for 60 children aged 0 to 24 months when assisted by BladderScan BVI 9400. There was no comparator measurement. The children had presented to A&E needing urine collection by SPA. The audit showed an overall success rate of 53% (32/60; 95% confidence interval 41–66%), which the authors describe as low. The BladderScan-assisted SPA success rate was higher in children with readings ≥20 ml (70%). The authors also note that this rate is lower than previous success rates reported in studies using RTUS. (See table 2 for details.)

The study by Marciano et al. (2013) was available as an abstract. The study was set in Italy. The authors used the 'child mode' of the BladderScan BVI 9400 to evaluate the accuracy of bladder volume measurement in 59 children who were scheduled for diagnostic evaluation or treatment under general anaesthesia (or deep sedation). There was no comparator measurement in this study. The average age was 7.1 years (range 1–19 years). Bladder volume was measured using BladderScan immediately after bladder emptying. Saline was then infused into the bladder of each child using a transurethral catheter. The bladder volume was measured again after total volumes of 20 ml, 50 ml and 100 ml of saline had been infused. The BladderScan measurement was repeated 3 times by the same operator for each volume infused. No significant differences were found among the repeated BladderScan measurements. Bladder volumes were negligible after bladder emptying. The bladder volumes measured using BladderScan were statistically significantly lower than the amount of saline infused when the children were considered as a single group. However, when the data were stratified according to both the age of the child and the amount infused, only the volumes measured in children aged 1 to 6 years were significantly lower than the amount of saline infused. No significant differences were seen for infusion volumes above 20 ml in the children aged 7 to 12 years or at any volume in the children over 12 years. The authors concluded that the BladderScan BVI 9400 provides an accurate and reliable measure of bladder volume in children, but that use should be limited to children older than 6 years. (See table 3 for details.)

The Rowe et al. (2014) study was set in New Zealand. The 'child mode' of BladderScan BVI 9400 was used to evaluate the accuracy of bladder volume measurement compared with catheterisation in 50 children who were scheduled for urodynamics (assessment of bladder and urethra functioning) or surgery that included urethral catheterisation. The BladderScan volumes ranged from 0 ml to 513 ml (mean=79; median=34) and the catheterised volume from 0 ml to 500 ml (mean=81; median=31). The correlation between the BladderScan and catheterised urine volume was 0.96 (95% confidence interval 0.92 to 0.97); the mean difference between the volumes was −2.0±21 ml. In 12 children aged less than 36 months, the BladderScan volumes ranged from 0 ml to

39 ml (mean=14 ml; median=13 ml) and the catheterised from 0 ml to 40 ml (mean=16 ml, median=14 ml). Correlation between the BladderScan and catheterised volume in children aged less than 36 months was not as strong (rho=0.82) with a mean volume difference of −2.6 ml. The authors concluded that BladderScan BVI 9400 was accurate when compared with catheterised volume but should be used with caution in children under 36 months. (See table 4 for details.)

Recent and ongoing studies

No ongoing or in-development trials using the BladderScan BVI 9400 for bladder volume measurement were identified.

Costs and resource consequences

The BladderScan BVI 9400 can be used instead of diagnostic catheterisation to help diagnose urological conditions non-invasively. It can also be used to assess whether therapeutic catheterisation would otherwise be needed and could, therefore, reduce the number of unnecessary catheterisation procedures. No other additional facilities or technologies are needed alongside the technology. The manufacture recommends training and offers an educational training pack and an in-service session to train staff, both of which are included in the cost of the machine. The manufacturer states that a sonographer is not needed to operate the BladderScan BVI 9400.

No published evidence on the resource consequences of the BladderScan BVI 9000 series was identified.

Strengths and limitations of the evidence

All 4 studies considered in this briefing were prospective cohort studies in children, which limits their generalisability to adults. No randomised controlled trials were identified. The BladderScan BVI 9400 model was used in all 4 studies. All studies were carried out in secondary or tertiary care settings, which may limit their generalisability to the primary care setting. In addition, none of the studies were carried out within an NHS setting or within the UK. Clinical practice and patient characteristics may differ between countries and care must be taken when relating them to the NHS context.

The BladderScan BVI 9400 is intended to be used for both adults and children; however, no clinical evidence investigating the accuracy and reproducibility of this model for the assessment of bladder volume in adults met the inclusion criteria for this briefing. Evidence in adults exists for the previous versions of BladderScan, however no studies have compared previous models to the

current model and, therefore, it is unclear whether results obtained from previous models are generalisable to the 9400 model.

Rowe et al. (2014) was the only study that reported a sample size calculation. Consequently, it is unclear whether the other studies were adequately powered to detect differences in the outcomes.

A potential source of performance bias is the training received to use the device. The manufacturer states that a sonographer is not needed to carry out the scanning, and that the BladderScan should only be used by healthcare professionals who have had training and authorisation by the appropriate healthcare provider. Training of scanner operators was mentioned in the Buntsma et al. (2012) study, but not described in the other studies. Skill levels and scanning methodology may differ among operators.

Marciano et al. (2013) was published as an abstract only so has limited detail compared with the other studies. It is not clear whether the bladders were emptied between each infusion of saline or whether additional volumes were added sequentially to give total volumes of 50 ml and 100 ml. It is also not clear whether the investigators were blinded to the volumes of saline infused. The fact that the bladder was infused with saline may be a source of bias, because this is not the same as natural urine production. It is unclear whether this would affect BladderScan readings. Additionally, the underlying conditions of the children were not reported, which may be another potential source of bias. The infusion of saline solution into a child's bladder may carry ethical implications, and it is unclear whether these were addressed in the study.

The 2 studies assessing intra-observer reproducibility of BladderScan measurement reported varied results. Marciano et al. (2013) found no significant intra-observer differences between repeated BladderScan measurements. In contrast, Bevan et al. (2011) reported lower levels of intra-observer reproducibility. There was variation in the statistical analyses used in these studies and so care should be taken when comparing the magnitude of outcome significance between studies.

There was variation in the measures used to show BladderScan accuracy. Two studies looked at the accuracy of the BladderScan compared with known bladder volume (Marciano et al. 2013 using a saline infusion; Rowe at al. 2014 using catheterisation) and 1 investigated accuracy compared with real-time ultrasound (RTUS; Bevan et al. 2011). The remaining study (Bunstma et al. 2012) assessed the success rate of a suprapubic aspiration procedure when aided by the BladderScan. In Buntsma et al. (2012) there was no within-study comparator, but the authors compared results with success rates from conventional RTUS in previous studies. The limitation with this comparison is that the setting was likely to be different between the previous and current studies and therefore there

were likely to be confounding factors. For accuracy studies, the optimal comparator is bladder volume determined using bladder catheterisation, however, this is not possible for ethical reasons in children not already due to undergo procedures involving catheterisation. As mentioned above, it is unclear in the Marciano et al. (2013) study whether the ethical implications of catheterising children to determine bladder volume were addressed.

Age should be taken into account when considering the accuracy or reproducibility of the BladderScan device for children. Bevan et al. (2011) reported that the BladderScan may not be a reliable or accurate method for assessing bladder volume in children aged between 0 months and 24 months. Marciano et al. (2013) reported that although BladderScan produced accurate readings overall, there was less accuracy in children under 6 years, and suggested that use should be limited to children older than 6 years. Rowe et al. (2014) concluded that the BladderScan was accurate when compared with catheterised volume but should be used with caution in children younger than 36 months.

Verathon provided the BladderScan device in the Rowe et al. (2014) study. None of the other studies reported any manufacturer involvement. Manufacturer involvement in the project may have potential for introducing bias in the reporting of outcomes.

Relevance to NICE guidance programmes

The use of the BladderScan is not currently planned into any NICE guidance programme.

NICE has issued the following guidance:

- Lower urinary tract symptoms in men: management (2010) NICE guideline CG97. Date for review: June 2016
- Urinary incontinence in women: management (2013) NICE guideline CG171. Date for review: September 2015
- Urinary incontinence in neurological disease: assessment and management (2012) NICE guideline CG148. Following consultation with stakeholders this guideline has now been placed on the static list
- Bedwetting in under 19s (2010) NICE guideline CG111. Date for review: December 2016
- Urinary tract infection in under 16s: diagnosis and management (2007) NICE guideline CG54. Date for review to be confirmed

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Appendix

Contents

Data tables

Table 1: Overview of the Bevan et al. (2011) study

Table 2: Overview of the Buntsma et al. (2012) study

Table 3: Overview of the Marciano et al. (2013) study

Table 4: Overview of the Rowe et al. (2014) study

Table 1 Overview of the Bevan et al. (2011) study

Study component	Description
Objectives/ hypotheses	To assess the reproducibility and accuracy of the BladderScan BVI 9400 (ABUS), in measuring bladder volume in children aged 0 to 24 months when compared with real-time ultrasound.
Study design	Prospective cohort, single centre.
Setting	The radiology department of a hospital in Australia, between August and October 2009. No follow-up period was reported.
Inclusion/ exclusion criteria	Inclusion: • healthy children aged 0 to 24 months. Exclusion: • children with a history of renal tract abnormality, abdominal surgery or abdominal scar tissue • open skin wounds or wounds to the suprapubic area.
Primary outcomes	Accuracy and reproducibility of bladder volume measurements.
Statistical methods	Bland–Altman limits of agreement for accuracy, Bland–Altman repeatability coefficient for reproducibility.
Patients included	61 children (31 males; mean age±SD=11±6.2 months, range=0–24 months).
Results	The 95% limits of agreement between the BladderScan and real-time ultrasound were −31 to +19 ml. ABUS also detected no values between 0 and 10 ml. The repeatability coefficient within ABUS readings was 20 ml.

Conclusions	Study showed poor repeatability and accuracy in bladder volume measurements using BladderScan when compared with real-time ultrasound. The BladderScan method does not appear to be a reliable method for assessing bladder volumes in children aged 0 to 24 months before bladder instrumentation.
Abbreviations: ABUS, automated bladder ultrasound scanner.	

Table 2 Overview of the Buntsma et al. (2012) study

Study component	Description
Objectives/ hypotheses	To determine the success rate of SPA when assisted by the BladderScan BVI 9400 (PBUS; as was standard practice in the A&E of the study hospital).
Study design	Prospective cohort, single centre.
Setting	The A&E of a hospital in Australia. Results were recorded over an 8-month period between August 2009 and March 2010. No follow-up period was reported.
Inclusion/ exclusion criteria	Inclusion: • children aged 0 to 24 months presenting to the ED needing acute urine collection by SPA. Exclusion: none stated.
Primary outcomes	The success rate of SPA. Magnitude of PBUS reading (in ml).
Statistical methods	Descriptive statistics. Chi-square analyses were used to assess proportions (success rates for different BladderScan reading ranges).
Patients included	Children (n=60) aged 0 to 24 months (mean age=5.0 months (range 0 to 18.6 months) presenting to A&E needing acute urine collection by SPA.
Results	The audit showed an overall success rate of 53% (32/60; 95% confidence interval 41%–66%). Success rates were 63%, 32%, 82% and 63% for the BladderScan readings of 0–9 ml (n=8), 10–19 ml (n=25), 20–29 ml (n=11) and ≥30 ml (n=16), respectively, or 39% at <20 ml and 70% at ≥20 ml (p=0.02).

Conclusions	The PBUS-assisted SPA success rate was higher in children with readings ≤20 ml. These rates were lower than previous success rates using RTUS reported in the literature.
Abbreviations: PBUS, portable bladder ultrasound; SPA, suprapubic aspiration; RTUS, real-time ultrasound.	

Table 3 Overview of the Marciano et al. (2013) study

Study component	Description
Objectives/ hypotheses	To evaluate diagnostic accuracy of the child mode on the BladderScan BVI 9400 in paediatric patients.
Study design	Prospective cohort; additional information not specified. BladderScan BVI 9400 was used in children scheduled for diagnostic evaluation or treatment under general anaesthesia or deep sedation. The underlying conditions of the children were not reported. The ethical implications of catheterising children to determine bladder volume were not reported. Bladder volume was evaluated immediately after bladder emptying and after the infusion of 20, 50, and 100 ml of saline solution via transurethral catheter in all patients. Published as an abstract only.
Setting	Acute care setting in Italy. Recruitment period not listed. No follow-up period was reported.
Inclusion/ exclusion criteria	Inclusion and exclusion criteria were not specified.
Primary outcomes	Comparison of BladderScan measures and volume infused via catheter; measure was performed 3 times by the same operator.
Statistical methods	Analysis of variance among the BladderScan evaluation for each volume; measures were compared using Student's t-test with bladder volume obtained via catheter. Patients were stratified into 3 age groups: 0–6, 7–12, and >12 years.

Patients included	n=59; average age 7.1±5 years (range 1–19 years).
Results	No significant differences were found among repeated BladderScan volume measurements. BladderScan measurements according to the volume of saline infused (ml; mean±SD; p-value) All children (average age: 7.1±5 years) • 0 ml: 1.4±8.1; p=0.166 • 20 ml: 15.1±10.1; p=0.0005 • 50 ml: 42.9±13.1; p=0.0003 • 100 ml: 92.9±19.5; p=0.021. 1–6 years (average age: 3±1.6 years) • 0 ml: 0.7±3; p=0.184 • 20 ml: 12.3±8.9; p=0.0001 • 50 ml: 36.9±15; p=0.0005 • 100 ml: 83.5±15.1; p=0.0013. 7–12 years (average age: 8.7±1.2 years) • 0 ml: 0±0; p=0.331 • 20 ml: 15.7±6; p=0.0084 • 50 ml: 46.3±9.9; p=0.134 • 100 ml: 92±17.5; p=0.072. Over 12 years (average age:15±1.9 years) • 0 ml: 5.8±17.1; p=0.260 • 20 ml: 20.8±15.1; p=0.852 • 50 ml: 48.9±9.2; p=0.707 • 100 ml: 106.2±21.3; p=0.355.

Conclusions	The authors concluded that BladderScan BVI 9400 is a reliable and accurate alternative to catheterisation for children older than 6 years.
Abbreviations: SD, standard deviation.	

Table 4 Overview of the Rowe et al. (2014) study

Study component	Description
Objectives/ hypotheses	To evaluate the accuracy of the BladderScan BVI 9400 using its child mode compared with the volume obtained at catheterisation.
Study design	Prospective cohort study, single centre.
Setting	New Zealand paediatric hospital. Data collection from April to September 2011. No follow-up period was reported.
Inclusion/ exclusion criteria	Inclusion criteria: • written and informed consent from the participant or their guardian • being cared for by 2 paediatric urologists • scheduled for urodynamics or surgery, where urethral catheterisation would be done. No exclusion criteria were listed.
Primary outcomes	Bladder volume measurement obtained at catheterisation compared with the volume obtained by BladderScan BVI 9400.
Statistical methods	Non-parametric correlation between bladder volumes obtained using catheterisation compared with the BladderScan BVI 9400. Sample size of 50 would provide a 95% confidence interval of ±0.12 for correlation coefficients. The sample size would give levels of agreement with 95% CI of approximately ±10 ml for Bland–Altman agreement analysis.

Patients included	n=50; 12 girls and 38 boys, average age of 6.2 years (range 6 weeks to 14 years). The BladderScan was done following anaesthetic induction and before catheter insertion for those having surgery (n=45). For those having urodynamic studies, the BladderScan measurement was done before the urodynamic catheter was inserted (n=14).
Results	Overall, the correlation between the BladderScan and catheterisation volume (n=50) was 0.96 (95% confidence interval 0.92–0.97); the mean difference between the volumes was −2.0±21 ml. Correlation between the BladderScan and catheterisation volume in patients less than 36 months (n=12) was not as strong (rho=0.82) with a mean volume difference of −2.6 ml.
Conclusions	The authors concluded that the BladderScan BVI 9400 showed a high correlation with catheter volume with good clinical agreement between measures overall.
Abbreviations: None.	

Search strategy and evidence selection

Search strategy

For the clinical evidence

Embase 1980 to 2015 Week 11, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; searched 10 March 2015.

1. bladderscan.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

2. portable bladder scan*.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

3. ultrasound bladder scan*.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

4. 1 or 2 or 3

6. limit 5 to yr="2007-Current"

For the economic evidence

Embase 1980 to 2015 Week 11, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present; searched 18 March 2015.

1. bladderscan.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

2. portable bladder scan*.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

3. ultrasound bladder scan*.mp. [mp=ti, ab, sh, hw, tn, ot, dm, mf, dv, kw, nm, kf, px, rx, an, ui]

4. 1 or 2 or 3

5. cost*.mp.

6. economic*.mp.

7. 5 or 6

8. 4 and 7

9. limit 8 to yr="2007-Current"

Cochrane Database of Systematic Reviews: Issue 3 of 12, March 2015; Cochrane Central Register of Controlled Trials: Issue 2 of 12, February 2015; Database of Abstracts of Reviews of Effect: Issue 1 of 4, January 2015; Health Technology Assessment Database: Issue 1 of 4, January 2015; NHS Economic Evaluation Database: Issue 1 of 4, January 2015.

Evidence selection

For the clinical evidence

- Total number of publications reviewed: 88
- Total number of publications considered relevant: 18
- Total number of publications selected for inclusion in this briefing: 4

For the economic evidence

- Total abstracts: 7

- Duplicates: 1
- Abstracts reviewed: 6
- Full papers reviewed: 5
- Studies for review: 0

Exclusion criteria: case studies, editorials, letters, reviews, animal studies, non-English language studies, not using the BladderScan BVI 9000-series.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by King's Technology Evaluation Centre (KiTEC). The Interim process & methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

Project team

King's Technology Evaluation Centre (KiTEC)

Medical Technologies Evaluation Programme, NICE

Peer reviewers and contributors

- Anastasia Chalkidou, Senior Health Technology Assessor, KiTEC
- Kate Goddard, Health Technology Assessor, KiTEC
- Naomi Herz, Health Technology Assessor and Health Economist, KiTEC

- Cornelius Lewis, Director, KiTEC
- Murali Radhakrishnan Kartha, Senior Health Economist, KiTEC
- Stephen Keevil, Director, KiTEC
- Viktoria McMillan, Centre Manager, KiTEC

Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Julia Corbett, Clinical Lead, Continence Service, Central Manchester University Hospitals NHS Foundation Trust
- Julie Hopkins-Budd, Continence Clinical Nurse Specialist, Sandwell and West Birmingham Hospitals NHS Trust
- Irene Karrouze, Lead Continence Nurse, King's College Hospital NHS Foundation Trust
- Feilim Murphy, Consultant Paediatric Urologist, St George's University Hospitals NHS Foundation Trust

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