

Portable Bladder Ultrasound

An Evidence-Based Analysis

April 2006



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The Medical Advisory Secretariat is part of the Ontario Ministry of Health and Long-Term Care. The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of health services and new health technologies in Ontario to the Ministry of Health and Long-Term Care and to the healthcare system. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

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Executive Summary

Objective

The aim of this review was to assess the clinical utility of portable bladder ultrasound.

Clinical Need: Target Population and Condition

Data from the National Population Health Survey indicate prevalence rates of urinary incontinence are 2.5% in women and 1.4 % in men in the general population. Prevalence of urinary incontinence is higher in women than men and prevalence increases with age.

Identified risk factors for urinary incontinence include female gender, increasing age, urinary tract infections (UTI), poor mobility, dementia, smoking, obesity, consuming alcohol and caffeine beverages, physical activity, pregnancy, childbirth, forceps and vacuum-assisted births, episiotomy, abdominal resection for colorectal cancer, and hormone replacement therapy.

For the purposes of this review, incontinence populations will be stratified into the following; the elderly, urology patients, postoperative patients, rehabilitation settings, and neurogenic bladder populations.

Urinary incontinence is defined as any involuntary leakage of urine. Incontinence can be classified into diagnostic clinical types that are useful in planning evaluation and treatment. The major types of incontinence are stress (physical exertion), urge (overactive bladder), mixed (combined urge and stress urinary incontinence), reflex (neurological impairment of the central nervous system), overflow (leakage due to full bladder), continuous (urinary tract abnormalities), congenital incontinence, and transient incontinence (temporary incontinence).

Postvoid residual (PVR) urine volume, which is the amount of urine in the bladder immediately after urination, represents an important component in continence assessment and bladder management to provide quantitative feedback to the patient and continence care team regarding the effectiveness of the voiding technique. Although there is no standardized definition of normal PVR urine volume, measurements greater than 100 mL to 150 mL are considered an indication for urinary retention, requiring intermittent catheterization, whereas a PVR urine volume of 100 mL to 150 mL or less is generally considered an acceptable result of bladder training.

Urinary retention has been associated with poor outcomes including UTI, bladder overdistension, and higher hospital mortality rates. The standard method of determining PVR urine volumes is intermittent catheterization, which is associated with increased risk of UTI, urethral trauma and discomfort.

The Technology Being Reviewed

Portable bladder ultrasound products are transportable ultrasound devices that use automated technology to register bladder volume digitally, including PVR volume, and provide three-dimensional images of the bladder. The main clinical use of portable bladder ultrasound is as a diagnostic aid. Health care professionals (primarily nurses) administer the device to measure PVR volume and prevent unnecessary catheterization. An adjunctive use of the bladder ultrasound device is to visualize the placement and removal of catheters. Also, portable bladder ultrasound products may improve the diagnosis and differentiation of urological problems and their management and treatment, including the establishment of voiding schedules, study of bladder biofeedback, fewer UTIs, and monitoring of potential urinary

incontinence after surgery or trauma.

Review Strategy

To determine the effectiveness and clinical utility of portable bladder ultrasound as reported in the published literature, the Medical Advisory Secretariat used its standard search strategy to retrieve international health technology assessments and English-language journal articles from selected databases. Nonsystematic reviews, nonhuman studies, case reports, letters, editorials, and comments were excluded.

Summary of Findings

Of the 4 included studies that examined the clinical utility of portable bladder ultrasound in the elderly population, all found the device to be acceptable. One study reported that the device underestimated catheterized bladder volume

In patients with urology problems, 2 of the 3 studies concerning portable bladder ultrasound found the device acceptable to use. However, one study did not find the device as accurate for small PVR volume as for catheterization and another found that the device overestimated catheterized bladder volume. In the remaining study, the authors reported that when the device's hand-held ultrasound transducers (scanheads) were aimed improperly, bladders were missed, or lateral borders of bladders were missed resulting in partial bladder volume measurements and underestimation of PVR measurements. They concluded that caution should be used in interpreting PVR volume measured by portable bladder ultrasound machines and that catheterization may be the preferred assessment modality if an accurate PVR measurement is necessary.

All 3 studies with post-operative populations found portable bladder ultrasound use to be reasonably acceptable. Two studies reported that the device overestimated catheter-derived bladder volumes, one by 7% and the other by 21 mL. The third study reported the opposite, that the device underestimated catheter bladder volume by 39 mL but that the results remained acceptable

In rehabilitation settings, 2 studies found portable bladder ultrasound to underestimate catheter-derived bladder volumes; yet, both authors concluded that the mean errors were within acceptable limits.

In patients with neurogenic bladder problems, 2 studies found portable bladder ultrasound to be an acceptable alternative to catheterization despite the fact that it was not as accurate as catheterization for obtaining bladder volumes.

Lastly, examinations concerning avoidance of negative health outcomes showed that, after use of the portable bladder ultrasound, unnecessary catheterizations and UTIs were decreased. Unnecessary catheterizations avoided ranged from 16% to 47% in the selected articles. Reductions in UTI ranged from 38% to 72%.

In sum, all but one study advocated the use of portable bladder ultrasound as an alternative to catheterization.

Economic Analysis

An economic analysis estimating the budget-impact of BladderScan in complex continuing care facilities was completed. The analysis results indicated a \$192,499 (Cdn) cost-savings per year per facility and a cost-savings of \$2,887,485 (Cdn) for all 15 CCC facilities. No economic analysis was completed for

long-term care and acute care facilities due to lack of data.

Considerations for Policy Development

Rapid diffusion of portable bladder ultrasound technology is expected. Recently, the IC5 project on improving continence care in Ontario's complex continuing care centres piloted portable bladder ultrasound at 12 sites. Preliminary results were promising.

Many physicians and health care facilities already have portable bladder ultrasound devices. However, portable bladder ultrasound devices for PVR measurement are not in use at most health care facilities in Ontario and Canada. The Verathon Corporation (Bothell, Wisconsin, United States), which patents BladderScan, is the sole licensed manufacturer of the portable bladder ultrasound in Canada. Field monopoly may influence the rising costs of portable bladder ultrasound, particularly when faced with rapid expansion of the technology.

Several thousand residents of Ontario would benefit from portable bladder ultrasound. The number of residents of Ontario that would benefit from the technology is difficult to quantify, because the incidence and prevalence of incontinence are grossly under-reported. However, long-term care and complex continuing care institutions would benefit greatly from portable bladder ultrasound, as would numerous rehabilitation units, postsurgical care units, and urology clinics.

The cost of the portable bladder ultrasound devices ranges from \$17,698.90 to \$19,565.95 (Cdn) (total purchase price per unit as quoted by the manufacturer). Additional training packages, batteries and battery chargers, software, gel pads, and yearly warranties are additional costs. Studies indicate that portable bladder ultrasound is a cost-effective technology, because it avoids costs associated with catheterization equipment, saves nursing time, and reduces catheter-related complications and UTIs.

The use of portable bladder ultrasound device will affect the patient directly in terms of health outcomes. Its use avoids the trauma related to the urinary tract that catheterization inflicts, and does not result in UTIs. In addition, patients prefer it, because it preserves dignity and reduces discomfort.

Abbreviations

CI	Confidence interval
CCC	Complex continuing care
LTC	Long-term care
PVR	Postvoid residual
RCT	Randomized controlled trial
UI	Urinary incontinence
UR	Urinary retention
UTI	Urinary tract infection

Objective

The aim of this review was to assess the clinical utility of portable bladder ultrasound.

Background

Clinical Need: Target Population and Condition

Urinary incontinence (UI) is defined as any involuntary leakage of urine (1) and is classified into diagnostic clinical types that are useful in evaluation, planning, and treatment. The 8 major types of incontinence are stress (physical exertion), urge (overactive bladder), mixed (combined urge and stress UI), reflex (neurological impairment of the central nervous system), overflow (leakage due to full bladder), continuous (urinary tract abnormalities), congenital (inherited abnormalities), and transient (temporary impairment). (2;3)

Data from the National Population Health Survey indicate prevalence rates of UI in the general population are 2.5% in women and 1.4 % in men. (4) Prevalence of UI is higher in women than men and prevalence increases with age. (4) Identified risk factors for UI include female gender, increasing age, urinary tract infections (UTIs), poor mobility, dementia, smoking, obesity, consuming alcohol and caffeine beverages, physical activity, pregnancy, childbirth, forceps- and vacuum-assisted births, episiotomy, abdominal resection for colorectal cancer, and hormone replacement therapy. (2;3)

The elements of UI assessment include information from a focused history and physical examination, a urinalysis test, study of postvoid residual (PVR) urine volume, and void description diary. (3) Treatment for UI can be divided into behavioral management, pharmacotherapy, corrective surgery, and therapeutic device use. (3)

Postvoid residual urine volume, which is the amount of urine in the bladder immediately after urination, represents an important component in continence assessment and bladder management to provide quantitative feedback to the patient and continence care team regarding the effectiveness of the voiding technique. (5) Although there is no standardized definition of normal PVR urine volume, measurements greater than 100 mL to 150 mL are considered an indication for intermittent catheterization, whereas a PVR urine volume of 100 mL to 150 mL or less is generally considered an acceptable result of bladder training.

Urinary Retention

Urinary retention (UR) has been associated with poor outcomes including UTI, bladder overdistension, and higher hospital mortality rates. (6;7) Bladder overdistension after surgery under general anesthesia is probably the most common cause of acute UR. (8) In patients with neurogenic bladder problems, UR may occur due to the loss of function in muscles and nerves in the urinary system. Urinary retention can be silent and, especially in elderly patients, symptoms of acute UR involving lower abdominal function may be masked by analgesic use or may not be perceived due to cognitive impairments. Therefore, clinical examination of the abdomen is a notoriously unreliable method of detecting UR.

The definition of UR based on the PVR urine volume depends on the population being studied or the clinically relevant condition. Smith and Albazzaz (7) have defined UR in a study of outcomes in elderly

women undergoing surgery for proximal hip fracture as a PVR urine volume of greater than 300 mL. While most authors accept a figure of between 100 mL and 150 mL as being within the normal range, Diokno (9) maintains that one cannot establish a "normal" or "pathologic" value. Clinically significant volumes may vary between a lower limit of 50 mL and an upper limit of 300 mL. (10;11) The PVR urine volume may vary widely in elderly patients and may reflect impairments such as lower urinary tract obstruction, poor contractility, detrusor hyperactivity with impaired contractility, or a combination of these. (12)

More research is required to define pathologic UR better and to quantify PVR urine volumes. According to an extensive literature review, (13) clinically significant postvoid volumes vary from 50 mL to 300 mL. Although studies on varied populations have yielded no consensus regarding normal and abnormal PVR measurements, most authors in the studies reviewed by the Medical Advisory Secretariat accept volumes between 100 mL and 150 mL as normal.

While not all urethral catheterizations are necessary, many catheterizations can be avoided, especially ones performed to evaluate UR. Urinary retention can be assessed noninvasively by portable bladder ultrasound. (11;13;14) The implementation of bladder ultrasound protocols that are based on evidence will help caregivers determine when catheterization is necessary.

Intermittent catheterization remains the gold standard for precise measurement of PVR volumes. Catheterization, especially after hip fracture, after stroke, or in the presence of cognitive impairment, can be challenging for nursing staff and uncomfortable for people with these conditions. Portable bladder ultrasound offers a noninvasive, painless method of estimating PVR urine volume and eliminates the risk of introducing urinary infection or causing urethral trauma by catheterization. Previous research, in various settings, supports portable handheld ultrasound scanners as noninvasive, cost-effective, reliable, and accurate for measuring PVR urine. (11;12;15-18)

Issues to consider when choosing an alternate approach to assessing, treating, or supporting bladder function other than bladder catheterizations include patients' comfort, complications or adverse effects, and costs. Patients report that catheterization is uncomfortable and humiliating. (Personal Communication, January 2005) Costs for supplies and personnel increase with repeated catheterization because each catheter is an expense and demands on nursing time rise. (19) Furthermore, because indwelling urinary catheters are used for bladder drainage often during hospital care, urinary tract infections are a common complication that can extend hospital stays and increase expenditures.

Urinary tract infections account for about 40% of all hospital-acquired (nosocomial) infections. (20) About 80% of the UTIs (32% of all nosocomial infections) are associated with urinary catheterizations, both indwelling and intermittent. Such urinary infections prolong hospital stays, are expensive to treat, and cause patients to experience conditions ranging from unpleasant symptoms to life-threatening infections and shock. When used in patients who are acutely ill, the risk of a catheter-associated infection may be higher and hence pose a greater threat to life. To reduce catheter-associated UTIs and other complications, the first step is to avoid unnecessary catheterizations; the second step is to remove the catheter that has been inserted as soon as possible.

Portable bladder ultrasound as an alternative to urinary catheterization has been evaluated in several populations. (14;16) It has been found to have an acceptable level of accuracy and may be considered an appropriate and acceptable alternative to intermittent catheterization.

Elderly Patients in Long-Term Care Settings

Although the precise impact of normal aging on bladder function remains undefined, a number of

physiologic changes have been described in elderly men and women. Bladder capacity, urethral compliance, maximal urethral closing pressure, and flow rates all appear to decline in healthy continent women. (12) While urethral resistance increases in older men, postvoid residual volumes and involuntary detrusor contractions increase in both genders. (12)

None of these factors, alone or even in combination, result in incontinence. Nevertheless, any of these may contribute toward the loss of continence in an otherwise vulnerable individual.

The vast majority of older people remain functionally mobile even at an advanced age. Nevertheless, speed, range, and flexibility of locomotion are all reduced even in ostensibly healthy older people. Such changes may, for example, have an impact a person's ability to reach the bathroom following onset of urgency. Moreover, changes in visual perception and fine motor coordination may influence the removal of clothes and positioning in the bathroom.

Also, daily fluid excretion patterns change. Older people excrete much more of their ingested fluids at night. Sleep patterns are altered in aging, with increased episodes of nocturnal awakening resulting in increased nocturia. The risk of incontinence and falls at night is increased due to changes in abilities to accommodate to low lighting and rapid postural movements. As well, neuropsychological and perceptual changes associated with transition from sleep to wakefulness may be problematic.

Finally, physiological responses to medication change in old age, whether people are healthy or ill. Healthy older men and women can show altered responsiveness to some medications and a greater risk of adverse reactions. Anticholinergic medications represent a particular risk, especially for xerostomia (dryness of the mouth), constipation, UR, and impaired cognition. One reason the risk increases proportional to age is that the percentage of body mass that is fat tissue tends to rise and lean body mass decreases. Thus, the pharmacokinetics of distributed volumes of drugs in elderly patients show that lipid-soluble drugs tend to accumulate and water-soluble compounds tend to decrease. Reduced renal clearance of water-soluble medications requires dose adjustments in many, if not all, older people. Therefore, both water- and lipid-soluble medication dosages must be closely monitored in elderly patients.

Urinary incontinence affects about one-half of nursing home residents; ranging from a 40% to 70% prevalence rate. Among the more than 64,000 residents living in long-term care (LTC) facilities in Ontario in 2004, about 80% reported constant incontinence and almost 9% reported occasional incontinence. (21) More than 65% of LTC residents required daily care toileting. (21) With the prevalence of UR in LTC residents at about 9%, urinary retention in the elderly has been associated with poor outcomes including UTIs, bladder overdistension, and higher hospital mortality rates. (6;7) Symptoms of UR can be silent or masked in elderly patients by cognitive impairments or analgesics. In one study involving elderly women undergoing hip fracture surgery, the variably defined PVR was found to be as high as 300 mL or more. (7) Lower urinary tract obstruction, poor contractility, detrusor hyperactivity with impaired contractility, or a combination of these 3 problems may be signaled by PVR urine volume measurements. (12)

As part of an investigation of incontinence in the elderly, Ouslander (16) has listed criteria for referral of elderly patients with incontinence for urodynamic evaluations by urologists or gynecologists. A PVR urine volume of greater than 100 mL is one suggested indication for referral.

Neurogenic Population

Neurogenic bladder is a urinary problem in which abnormal emptying of the bladder occurs with subsequent retention or incontinence of urine. Depending on the type of neurological disorder causing the problem, the bladder may empty spontaneously (incontinence) or may not empty at all (retention with

overflow leakage). Causes of neurogenic bladders include spinal cord injury, brain trauma, diabetes, heavy metal poisoning, acute infection, or genetic nerve problems. The prevalence of the population with neurogenic bladders is difficult to estimate, similar to other incontinence-related statistics. Symptoms of neurogenic bladder may include UI, UR, kidney damage, kidney stones, UTI, absent or incomplete bladder emptying, urinary frequency and urgency, overflow incontinence, and loss of bladder sensation. Long-term consequences, particularly upper urinary tract damage and renal failure, can contribute to premature death. (22) Recommended options for treating neurogenic bladder depend on several factors, especially the cause of the nerve damage, type of voiding dysfunction that results, patient's medical profile, and severity of symptoms. Treatment options range from medication therapies, catheterization strategies to artificial sphincter surgeries. Intermittent catheterization is an important component of clinical management of neurogenic bladders to prevent infection resulting from incomplete or absent bladder emptying. However, intermittent catheterizations introduce high risks of UTI.

Postsurgical Urinary Retention With Incontinence

Bladder overdistension (bladder muscle contraction after prolonged expansion) after surgery using general anesthesia is the most commonly known cause of acute UR. (23) The incidence of postsurgical UR varies with, sex, age, preoperative medication and urinary tract history, and type of surgery and anesthesia. (24) The prevalence of postsurgical UR ranges from 4% to 80%, depending on the definition used and the type of surgery performed. (25) One study in a population of postoperative gynecologic patients found a UR prevalence of 9%. (25) Patients with postsurgical UR risk permanent damage to the bladder's detrusor muscle.

Patients often receive intermittent or indwelling catheterizations prior to surgery and general anesthesia administration to eliminate the risk of UR. Intermittent catheterizations are used to provide relief to people who have experienced previous episodes of acute UR by inserting and removing the urinary catheters within a short span of time, such as the time it takes for the bladder to empty once. Alternatively, indwelling bladder catheters maintain a continuous outflow by gravity drainage of urine. Indwelling catheters are used often for patients during hospital stays, especially for people undergoing surgical procedures that cause delays in regaining bladder sensation. Patients who are to undergo pelvic abdominal surgeries may receive indwelling urinary catheters to empty their bladders before surgery and to protect them by ensuring increased space in the pelvic cavities during surgery. However, intermittent and indwelling catheterizations aimed to prevent UR may serve to increase the risk of UTI.

As stated in the section on UR, the most common complication of catheterization is UTI, which accounts for about 40% of hospital-acquired (nosocomial) infections. (20) Almost 80% of these (32% of all nosocomial infections) are associated with urinary catheters. Such infections cause unpleasant symptoms in patients, become expensive to treat, and prolong hospital stays. Sometimes the UTI may threaten life by causing septic shock. The risks of catheter-associated infections may be higher in patients who are acutely ill and hence pose greater threats to life.

Existing Treatments Other Than Technology Being Reviewed

Catheters

A catheter is a soft, thin, flexible tube that is inserted through the urethra to drain urine from the bladder. Postvoid residual is the removal of urine remaining in the bladder after the person has urinated through the placement of a catheter and functions to measure the extent of PVR (one-time or intermittent catheterization) and to decrease the build-up of urine in the bladder (indwelling catheterization). Large urine build-up is one cause of bladder infections, UI, and permanent damage to urinary system, especially

the bladder and kidneys.

Common problems associated with one-time, intermittent, and indwelling catheter management include:

- bacteria introduction into the urethra and bladder, resulting in urinary tract inflammation, UTI, and generalized fever;
- bypassing of the catheter, which is a leakage of urine around the catheter;
- blocking of the catheter caused by accumulation of sediment or bacteria or by catheter tube kinking;
- discomfort or pain in the urethra felt by the patient;
- bladder spasms felt as discomfort or pain by patients or causing interrupted and decreased urine flow
- interruption of sexual activity;
- injury to the urethra caused by catheter insertion or dwelling friction;
- narrowing of the urethra caused by scar tissue resulting from catheter insertion or dwelling friction;
- injury to the bladder caused by incorrect insertion of the catheter or by catheter dwelling friction; and
- bladder stones, usually resulting after years of catheter dwelling.

Intermittent Catheterization

The standard method of determining PVR urine volumes is intermittent catheterization, often referred to as in-and-out catheterization. After inserting the catheter and draining the bladder, the catheter is removed. Intermittent catheterization is considered to be the most accurate and available means of assessing bladder emptying.

The intermittent method is considered safer than leaving a catheter system intact to drain urine over a prolonged period and insertion of the catheter several times daily may decrease bladder overdistension. Besides intermittent catheterization's high association with increased risk of urinary infection and urethral trauma, discomfort for the patient is a frequent complaint. In men, discomfort during catheterization may be due to prostatic enlargement, urethral stricture, and bladder neck contracture; in postmenopausal women, discomfort may result from atrophic urethritis. (16)

Indwelling Catheter

An indwelling catheter is a closed sterile system inserted into the urethra to allow the bladder to drain over a long period and often is identified as Foley catheterization. An indwelling catheter is held in place with an inflatable balloon at the end of the catheter, which is filled with sterile water after it is inserted to hold the tip of the catheter in place in the bladder. The catheter tubing exits the bladder through the internal urinary system and external genitalia and is secured to the remainder of the closed drainage system. The urine drains into a collecting bag and can be drained through an outlet device. Laboratory tests can be conducted on urine to assess infection, blood, muscle breakdown, crystals, electrolytes, and kidney function.

Indwelling catheter systems may be used for people with circumstances such as failure of other UI treatments, impaired or painful movements, and presence of skin irritations or pressure ulcers.

Risks with an indwelling urinary catheter include these:

- bacterial infection associated with catheter placement;
- balloon failure to inflate after insertion;
- balloon opening or breakage during catheter insertion causing bleeding, damage, or urethral rupture;
- balloon deflation caused by valve leakage over time;

- bleeding urethra caused by tissue irritation resulting from catheter friction;
- blockage of urine flow caused by accumulation of sediment or bacteria, kinking of catheter tubing, or improper placement; and
- potential for long-term and permanent scarring of the urethra.

X-ray

Although an X-ray using contrast dye may be used to determine bladder volume and PVR, this method is seldom used because it entails invasive risks from dye injection and exposure to radiation. Trained operators are required to administer the X-ray and contrast dye, to perform the calculations that indicate bladder volume and PVR, and to interpret the findings and determine a diagnosis. Also, patients must fast prior to an X-ray with contrast dye and must endure the increased discomfort and risk of an invasive procedure.

Ultrasound

Large Stationary Ultrasound

As an alternative to catheterizations and contrast-dye X-rays, urine volume measured by ultrasound technology has been developed as a convenient, noninvasive method of measuring bladder volume, primarily PVR urine volume. PVR volume measured by ultrasound is associated with less discomfort and risk of infection or trauma than catheterization and lacks the hazards of radiation exposure from X-rays or complications associated with the use of a contrast medium.

The major drawbacks of larger stationary ultrasound machines include the constraints of transport, scheduling, and trained sonographer availability. Measuring PVR with portable ultrasound devices may help alleviate the barriers presented by large stationary ultrasound machines.

Portable Ultrasound

The main benefit of portable bladder ultrasound is its portability. However, the major drawback is the lack of a real-time estimation of bladder volume and PVR. Estimating bladder urine volume and PVR using portable ultrasound requires additional time and training for operator calculations, which limits the utility of the portable ultrasound particularly in high volume settings. High-volume settings include those in which urine volume estimates are required several times daily and where large proportions of patients have UI, such as long-term care facilities and complex continuing care environments.

New Technology Being Reviewed

Portable bladder ultrasound devices use automated technology to register bladder volume digitally, including PVR, and to provide three-dimensional images of the bladder. The predominant clinical use of portable bladder ultrasound is as a diagnostic aid. Health professionals (primarily nurses) administer the device to measure PVR and to prevent unnecessary catheterization. An adjunctive use of the bladder ultrasound device is to visualize the placement and removal of catheters. Also, portable bladder ultrasound products may improve the diagnosis and differentiation of urological problems and their management and treatment, including the establishment of voiding schedules, study of bladder

biofeedback, reduction of UTIs, and monitoring of potential UI after surgery or trauma.

Portable bladder ultrasound devices are accurate, reliable, cost-effective, and noninvasive. (11;14-16) The use of a bladder ultrasound device is appropriate when conditions such as these exist: urinary frequency, absent or decreased urine output, bladder distention, or inability to void after catheter removal and during the early stages of intermittent catheterization programs. (17) McCliment et al. (26) discussed the use of bladder ultrasound devices to help manage incontinence in patients who reside in long-term care facilities. By monitoring fluid intake habits and using the ultrasound scanner for 3 days, staff members customized “continence care schedules” for each patient. This method helped patients recognize the sensations associated with bladder volumes and was used to establish voiding patterns. Also, McCliment and colleagues reported that bladder ultrasound devices were useful to assess the patency of indwelling catheters, because minimal amounts of urine should be present in the bladder if an indwelling catheter is in place. When urine output from an indwelling catheter decreased, or when a patient had signs of UR with a catheter in place, the bladder scan device was used to determine bladder volume. High urine volumes suggested that the catheter was occluded or positioned improperly.

Portable bladder ultrasound devices are easy to use and well tolerated by patients. (10) Smith et al. (10) offer step-by-step instructions for use of the BVI 3000, as one example of the bladder ultrasound. First, the machine is turned on and the operator indicates whether the patient is male or female. After explaining the procedure, the operator applies ultrasound gel to the hand-held transducer. Next, with the patient lying supine, the transducer is pointed toward the bladder and positioned 1 inch above the symphysis pubis bone. The head of the person icon on the transducer and the head of the patient should be pointing in the same direction. Finally, the transducer button is depressed to activate the bladder scan. The device signals when the scan is complete; and, a picture of the bladder and an estimated volume (for portable ultrasound machines that can provide volume calculations) appears on the screen. Several sequential scans can be done to obtain the best three-dimensional picture and the most accurate assessment of bladder volume.

History

Since ultrasound machines were introduced in the 1950s, they have been used to estimate various organ volumes. Early studies of ultrasound measurement of PVR urine volume used large stationary ultrasound machines, but they required separate calculation methods of total bladder volumes and PVR urine volumes, their costs were high to purchase and maintain, and patients needed to be transported to them. Portable ultrasound machines permit ultrasonography to be done at the patient’s bedside and some portable machines can calculate bladder and PVR volumes. Further, the cost of a small portable ultrasound machine can be reasonable, particularly in settings where multiple scans are required.

Description

Developments in the technology of portable ultrasound machines in the past several decades have led to advances in the noninvasive measurement of total bladder volume and PVR urine volume. New portable bladder ultrasound devices are designed specifically to measure residual urine volumes with a measuring frequency of 2 MHz and scanning depth reaching about 20 cm.

Portable bladder volume ultrasound machines consist of two main parts, a hand-held ultrasound transducer (scanhead) and a base unit with a display screen. (5) The transducer is placed on the patient’s abdomen (suprapubic area) and aimed toward the bladder. The scanhead touches the ultrasound conducting gel applied to the patient’s abdominal skin at the suprapubic region and the base unit is attached through a length of electrical wiring to the scan head.

The base unit’s LCD screen contains an aiming circle that projects onto the scanned bladder image to

assist the device operator. Most portable ultrasound units automatically display a two-dimensional image of the bladder and calculate the bladder volume on the device display screen. One newer device displays both a three-dimensional image of the bladder area and automatic calculations of bladder and PVR volume measurements. In addition to the other features, some models also display an ultrasound-estimated bladder weight.

Benefits and Adverse Events

Ultrasound measurement of urine volumes compares favourably to manual palpation, which is imprecise, and to catheterization, which is the gold standard but is invasive and risk-laden. Ultrasound technology safely avoids trauma to the urinary tract and infection risks to the patient and attendant associated with catheterization. Using a portable bladder ultrasound device also eliminates the need to calculate bladder volumes manually from formulae, which reduces error introduction risks, and may avoid unnecessary catheterizations. Additionally, noninvasive biofeedback, toileting trials, and self-contenance programs may be implemented based on portable bladder ultrasound measurements of urine volume and PVR. Lastly, as portable bladder ultrasound is a noninvasive transportable device, patient transfer is not necessary, and patient comfort and dignity are improved. Savings realized in nurses' time, catheterization equipment, laundering, and medical imaging serve to offset the costs associated with implementing portable bladder ultrasound.

Table 1: Advantages of Using Portable Bladder Ultrasound

-
- Noninvasive and more comfortable, thus readily accepted by patients
 - Less risk compared with catheterization (infection and trauma risks)
 - Risk free compared with X-ray with contrast dye (radiation and reaction to medium risks)
 - Easy to use, thus readily acceptable by staff
 - Faster than in-and-out catheterization
 - Less risk compared with manual calculation (error introduction risk)
-

Clinical applications of portable bladder ultrasound are as follows:

- Bladder scanning is indicated as a component of all continence assessments.
- Bladder scanning can be combined with a patient's symptom profile to assess the need for mechanical bladder emptying strategies, such as intermittent self-catheterization, vibration, or other methods.
- Bladder scanning can provide biofeedback to patients with urgency and help with bladder retraining by demonstrating the sizes of volumes causing symptoms.
- Bladder scanning can help check residual urine volumes, which may indicate an obstructive voiding pattern.
- Bladder scanning can be used to identify the levels of bladder sensation related to bladder volumes.
- Bladder scanning can be used to evaluate the ability and degree of a patient to void during a trial void after the removal of an indwelling catheter.
- Bladder scanning can assess the degree of retention and whether further investigation or intervention is necessary.
- Bladder scanning can assess and monitor clients on anticholinergic medication to ensure the medication has not induced a voiding problem.

Although there are no contraindications for using portable bladder ultrasound devices, informed consent must be obtained and health care workers must be trained on the use of the device. Potential adverse

effects of portable bladder ultrasound use include skin irritation, an allergic reaction to the ultrasound gel and padding, and pressure sore formation at the site of sensor placement. (22) Additional precautions to take before using a portable bladder ultrasound on a patient include recognizing that a patient with UI may find gentle pressure from the probe uncomfortable and ensuring that the machine's battery has been charged but is not left on charge during the procedure. Morbid obesity, severe abdominal scarring, ovarian cysts, fluid-filled structures in the pelvis greater than 2 cm, pregnancy, muscle spasms, abdominal herniation, and abdominal breathing may interfere with bladder ultrasound scanning and prevent accurate measurements. (5;22)

Regulatory Status

Several portable bladder ultrasound devices are licensed for use in Canada (Appendix 1). The Verathon Corporation (Bothell, Washington, United States) is the only company licensed to sell portable ultrasound machines with automated bladder volume measurements in Canada. BardScan (27) and Bladder Manager (28) are 2 other portable ultrasound devices from different manufacturers that provide an automated readout of bladder volume; however, they are not licensed by Health Canada.

Ontario Health Insurance Plan Funding

Physicians may bill for measurement of PVR urine volumes under the Ontario Schedule of Benefits and a portable bladder ultrasound measurement may be performed in the physician's office using ultrasound or catheterization. Also, because they are measurement and treatment tools, catheterization and portable bladder ultrasound use are within the scope of practice of nurses. However, Ontario Health Insurance Plan billing does not apply to nurses; therefore, the costs of performing PVR measurement is represented in their hourly wage or salary.

Current Use

Nurses and physicians use portable bladder ultrasound in many facilities. Urologists, gerontologists, and gynecologists are the physician specialties most likely to use portable bladder ultrasound. Nurses in postoperative units, obstetric-gynecology units, long-term care, home care, rehabilitative units, complex continuing care, and general practice use portable bladder ultrasound. Portable bladder ultrasound instruments are often purchased through operating budgets of individual institutions and departments.

During the Improving Continence Care in Complex Continuing Care IC5 project, aimed at improving continence care in complex continuing care facilities in Ontario, 12 institutions purchased portable bladder ultrasound instruments for implementation and evaluation in continence care nursing practice (Personal Communication, February 2006).

Literature Review on Effectiveness

Objective

The aim of this review was to assess the clinical utility of portable bladder ultrasound.

The questions asked were as follows:

- What is the sensitivity and specificity of portable bladder ultrasound in measuring PVR?
 - In what populations?

- What is the utility of portable bladder ultrasound in prevention?
 - Catheterizations avoided
 - Urinary tract infections avoided
 - Discontinued catheter use
 - Reducing catheter-related damage to the urinary tract
 - Reducing incontinence episodes as an outcome of bladder training and prompted voiding (bladder/voiding training/rehabilitation technique for incontinence)
- What are the harms of portable bladder ultrasound?
- What is the effect of portable bladder ultrasound use on quality of life?
- What is the nursing preference for portable bladder ultrasound use?

Methods

The Medical Advisory Secretariat completed a computer-aided search limited to English-language studies in humans. Case reports, letters, editorials, nonsystematic reviews, and comments were excluded (Appendix 2). Inclusion and exclusion criteria were applied to the results (see below). Each article was critically appraised for quality using Jaeschke's criteria (29) and Greenhalgh's criteria (30) for evaluating diagnostic studies (Appendix 3).

Inclusion Criteria

- English-language articles
- Journal articles that reported primary data on the effectiveness or cost-effectiveness of data obtained in a clinical setting
- Journal articles that reported an analysis of primary data maintained in registries or databases
- Study design and methods that were described clearly
- Systematic reviews, randomized controlled trials (RCTs), non-RCTs, or cohort studies, all of which had to have had at least 20 patients; and cost-effectiveness studies
- Relevant populations (i.e., not healthy volunteers)
- Devices licensed by Health Canada

Exclusion Criteria

- Duplicate publications (publications superseded by another publication by the same investigator group with the same objective and data)
- Non-English-language articles
- Nonsystematic reviews, letters, and editorials
- Animal and in-vitro studies
- Case reports
- Studies that did not examine the outcomes of interest
- Subjects not within the population of interest (i.e., healthy volunteers) or studies that did not describe the population of interest

Intervention

- Use of portable bladder ultrasound

Comparators

- Urinary catheterization
- No use of portable bladder ultrasound for voiding trials and prompted voiding
- Incontinence episodes

Literature Search

- Cochrane database of systematic reviews
- ACP Journal Club
- DARE
- INAHTA
- EMBASE
- MEDLINE
- Reference sections from reviews and extracted articles

Outcomes of Interest

- Sensitivity and specificity of portable bladder ultrasound
- Effect of portable bladder ultrasound use in diagnosis between different types of UI
- Effect of portable bladder ultrasound use in diagnosis between different types of UR
- Effect of portable bladder ultrasound use in diagnosis between different types of neurogenic bladder
- Effect of portable bladder ultrasound use in diagnosis between different types of urine volume measurements, especially bladder volume and PVR urine volume
- Effect of portable bladder ultrasound use with catheterizations avoided
- Effect of portable bladder ultrasound use with discontinued catheter use
- Effect of portable bladder ultrasound use with UTIs avoided
- Effect of portable bladder ultrasound use with catheter-related damage to urinary tract
- Effect of portable bladder ultrasound use with self-toileting outcomes of bladder training
- Effect of portable bladder ultrasound use with incontinence episodes avoided
- Effect of portable bladder ultrasound use with voiding trials, voiding schedules, and biofeedback outcomes
- Effect of portable bladder ultrasound use in different settings of practice and residence
- Effect of portable bladder ultrasound use in different populations of patients by age, sex, and type of diagnosis and medical or surgical intervention
- Effect of portable bladder ultrasound use on quality of life
- Effect of portable bladder ultrasound use with nursing preference
- Harms of portable bladder ultrasound

Results of Literature Review

Table 2: Quality of Evidence of Included Studies*

Study Design	Level of Evidence	Number of Eligible Studies
Large RCT,* systematic reviews of RCT, health technology assessments	1	0
Large RCT unpublished but reported to an international scientific meeting	1(g)	0
Small RCT	2	0
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	17
Non-RCT with historical controls	3b	0
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	0
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

*RCT refers to randomized controlled trial; g, grey literature.

After scanning the literature search results, 17 articles were considered relevant to the Medical Advisory Secretariat review. Articles were found concerning the clinical utility of portable bladder ultrasound in patients who were elderly with urologic, rehabilitation, postsurgical, and neurogenic bladder conditions. All candidate articles included data on reduced or avoided urinary catheterizations plus subsequent UTI occurrences with implementation of portable bladder ultrasound. There were no RCTs found in the literature review on portable bladder ultrasound. Several of the investigation questions (diagnosis between different types of UI, UR, neurogenic bladder, urine volume measurements; discontinued catheter use, self-toileting outcomes of bladder training, incontinence episodes avoided, nursing preference of bladder ultrasound use) were not addressed by studies found in the literature review and were not included in the Medical Advisory Secretariat analysis.

Summary of Existing Health Technology Assessments

In 1996, the Alberta Heritage Foundation for Medical Research completed a health technology assessment on the use of bladder ultrasound scanning for the measurement of PVR in comparison to intermittent catheterization in patients with neurological disorders following stroke or spinal cord injury. (5) Based on the 4 diagnostic studies reviewed, the Alberta Heritage Foundation for Medical Research concluded that bladder ultrasound was not as accurate as intermittent catheterization in measuring PVR; however, bladder ultrasound was effective in measuring clinically relevant levels of PVR. The health technology assessment concluded that bladder ultrasound was much easier and faster to perform than catheterization but requires standardized training protocols for care staff.

Summary of Controlled Diagnostic Experiments/ Prospective Clinical Series

Geriatric Medicine Patients and Long-Term Care Facility Patients

A community-based study by Ouslander et al. (16) assessed the clinical utility of portable bladder ultrasound in 201 consecutive incontinent people residing in long-term care facilities who were participating in a larger clinical trial. PVR measurements were obtained using the portable bladder

ultrasound model BVI 2000 (n = 140) or the BVI 2500 (n = 61) over a period of 3 years from 3 trained staff members, and then compared with the gold standard, in-and-out catheterization. The accuracy of the portable bladder ultrasound was determined by comparing the volumes obtained via catheterization and measured by bladder ultrasound.

When the BVI 2500 was developed, the newer device replaced the BVI 2000 and the 2 machines' results were shown to be highly correlated (range $r^2 = 0.87$ to 0.90). The ultrasound demonstrated excellent test-retest (range $r^2 = 0.97$ to 0.98) and inter-rater reliability (range $r^2 = 0.92$ to 0.94). For low PVR (n = 118), the device was highly sensitive ($r^2 = 0.90$ for PVR < 50 mL and $r^2 = 0.95$ for PVR < 100 mL) and moderately specific ($r^2 = 0.71$ for PVR < 50 mL and $r^2 = .63$ for PVR < 100 mL). For high PVR, or volumes of more than 200 mL (n = 26), the ultrasound had a sensitivity of 0.69 and a specificity of 0.99. Thus, portable bladder ultrasound was highly sensitive and moderately specific for low volumes of PVR and was moderately specific and highly specific for high PVR volumes (more than 200 mL) (Table 3). Due to the low sensitivity of portable bladder ultrasound (0.69) in high PVR, repeated measurements may be needed in some people to confirm or exclude high PVR. Investigators concluded that the portable ultrasound device may join in-and-out catheterization as being useful in long-term care settings to measure PVR.

Table 3: Accuracy of Portable Bladder Ultrasound for Various Postvoid Residual Levels in Incontinent Nursing Home Residents*

Postvoid Residual From Intermittent Catheterization	Sensitivity	Specificity
< 50 mL (n = 70)	0.90	0.71
< 100 mL (n = 118)	0.95	0.63
> 100 mL (n = 68)	0.63	0.95
> 150 mL (n = 37)	0.59	0.97
> 200 mL (n = 26)	0.69	0.99

*Ouslander et al. (16)

A prospective study in the geriatric medicine department of a Singapore hospital (n = 80), investigated the clinical utility of portable bladder ultrasound (using the BVI 2500 machine). (31) One hundred portable bladder ultrasound measurements were made first by 1 investigator and then compared with corresponding catheterization volumes taken by hospital medical staff (doctor or nurse) blinded to the ultrasound measurements. In the first 20 cases, one portable bladder ultrasound reading was taken. In the subsequent 80 cases, 2 portable bladder ultrasound PVR measurements were performed to investigate if the accuracy of the portable bladder ultrasound could be improved. PVR volumes ranged from 5 to 1150 mL. Accuracy in PVR volumes greater than 100 mL was 89% and accuracy in PVR volumes greater than 200 mL was 86%. The Kappa values for agreement between single ultrasound measures of PVR volumes greater than 100 mL or 200 mL were 0.78 and 0.76, respectively. In the 80 cases of dual ultrasound readings, the absolute errors were +54 mL (standard deviation [SD], 81) and +55 mL (SD, 86), respectively, indicating that 2 PVR measurements did not result in measurement improvements. The Pearson co-efficient of variation for pairs of portable bladder ultrasound and catheterized PVR measurements was 0.96. Analysis of the 100 portable bladder ultrasound measurements revealed no statistically significant findings regarding increased accuracy as experience with the portable bladder ultrasound device increased ($P = .21$). Study investigators concluded that portable bladder ultrasound was reasonably accurate and its routine use was recommended for the measurement of PVR.

Patients With Urologic Conditions

In one study among older outpatients with urologic conditions ($n = 249$) in the United States, 2 independent observers prospectively evaluated patients first by measurement with the portable bladder ultrasound (BVI 2500 device) and then, for comparison, by in-and-out catheterization. (11) Portable bladder ultrasound and catheter volumes were correlated closely ($r^2 = 0.90$, $P < .001$) across the range of 0 to 1015 cc. On average, the portable bladder ultrasound underestimated catheter volume by 10 cc in men and 20 cc in women. Using the threshold of 100 cc or greater, the portable bladder ultrasound BVI 2500 had a sensitivity of 97%, a specificity of 91%, and an overall accuracy of 94%. To test inter-device variability, the 1994 BVI 2500 model was used in 81 accuracy studies and the 1995 BVI 2500+ model was used in 101 studies. The accuracy of the 2 machines was compared with no significant differences found. Inter-rater reliability tests between the 2 observers, a licensed physician and a graduate physician, were performed, which showed them to have achieved similar volume determinations ($r^2 = 0.90$, $P < .001$). In 11 patients had portable bladder ultrasound readings of 0, corresponding catheter volumes ranged from 0 to 55 cc with a mean volume of 21.5 cc. In the 17 patients with portable bladder ultrasound readings between 0 and 50 cc, catheter volumes ranged from 10 to 94 cc, with a mean of 37.4 cc. Therefore, in null or very low bladder volume outputs, portable bladder ultrasound readings may reflect either accurate or underestimated bladder volume readings. Lastly, patient characteristics (age, sex, height, weight, diagnosis, uterine presence or prostate size, and user experience) were analyzed and found to not impact the accuracy of the portable bladder ultrasound. Study investigators concluded that portable bladder ultrasound was an accurate and reliable device for bladder volume measurement in adult outpatients.

A prospective study by Huang et al. (32) investigated the accuracy of portable bladder ultrasound compared to traditional stationary ultrasound device in the measurement of PVR. Sixty-four patients (37 men, 27 women) with voiding dysfunctions referred for PVR measurements from April to September 2001 were included in the study. Patients' diagnoses included spinal cord injury ($n = 23$), stroke ($n = 32$), traumatic brain injury ($n = 6$) and other conditions ($n = 3$). In sequence, PVR measurements were taken by the portable bladder ultrasound (BVI 3000), stationary ultrasound, and then the gold standard in-and-out catheterization. Three examiners performed the 3 measurements separately and were shielded from knowing one another's results. The mean operating time was 44.9 ± 18.8 seconds for portable bladder ultrasound, 103.7 ± 34.1 seconds for stationary ultrasound, and 277.2 ± 89.0 seconds for catheterization. The mean absolute errors were 34.4 mL (69.5%, $P < .05$) for portable bladder ultrasound and 21.9 mL (16.6%, $P < .05$) for the stationary ultrasound, when correcting for examination interval time (1 mL/minute). (Table 4) Portable bladder ultrasounds and stationary ultrasounds had sensitivities of 80% and 87%, respectively, and specificities of 90% and 100%, respectively. In a subgroup analysis, based on bladder volume (mL) determined by catheterization, there was a significant increase in accuracy with the portable bladder ultrasound device from Group I (less than or equal to 100 mL bladder PVR volume) with a percentage error of $66.1 \pm 76.2\%$ to Group II (101–300 mL bladder PVR volume) with a percentage error of $20.2 \pm 18.7\%$. With regards to Group III (301–500 mL PVR) and Group IV (> 500 mL PVR), there was insufficient power to detect any significant differences. (Table 5) The authors concluded that portable ultrasounds might not provide measurements of PVR as accurate as stationary portable bladder ultrasounds, particularly with small bladder volumes.

Table 4: Comparison of Mean Absolute Error and Mean Percentage Error of Portable Bladder Ultrasound and Stationary Ultrasonography*

Ultrasound Equipment	Portable Bladder Ultrasound	Stationary Ultrasound	P
Mean absolute error	34.4 ± 38.2	21.9 ± 25.0	< .05
Mean percentage error	36.0 ± 52.4	13.1 ± 10.5	< .005

*Huang et al. (32)

Table 5: Subgroup Comparison of Different Bladder Volume Levels*

Bladder Volume Group	n	Catheterized Bladder Volume (mL)	Stationary Ultrasound		Portable Bladder Ultrasound	
			Absolute Error (mL)	Percentage Error (%)	Absolute Error (mL)	Percentage Error (%)
≤ 100 mL	23	61.4 ± 24.5	7.9 ± 7.8	12.9 ± 7.8	25.4 ± 25.8	66.1 ± 76.2
101–300 mL	32	169.0 ± 47.2	25.3 ± 20.5	14.8 ± 11.5	29.8 ± 28.9	20.2 ± 18.7
301–500 mL	7	414.3 ± 61.4	30.9 ± 22.6	6.9 ± 4.0	75.4 ± 72.9	16.8 ± 13.9
> 500 mL	2	850.0 ± 70.7	99.5 ± 65.8	10.1 ± 5.5	69.0 ± 52.3	7.7 ± 5.7

*Huang et al. (32)

Goode et al. (33) assessed the clinical utility of BladderScan (BVI 2500) in 95 women, ages 32–92, who sought treatment for UI in community settings. Study participants underwent an interview, physical examination, pre- and post void portable bladder ultrasound, and urethral catheterization for PVR. Initial ultrasound volume for PVR was significantly correlated with catheterized volume ($r^2 = 0.60$, $P < .001$) and was significantly larger than the mean catheterized volume (mean difference 17 mL; $P < .0001$; 95% confidence interval (CI) 8–25 mL). Nine participants had elevated PVR volumes greater than or equal to 100 mL by catheterization. By portable bladder ultrasound, 6 of the 9 patients' PVR measurements were more than or equal to 100 mL, for a sensitivity of 66.7%. Specificity of the portable bladder ultrasound device for PVR more than or equal to 100 mL was 96.5%. The authors concluded that the portable bladder ultrasound was quick, easy to use, reasonably sensitive, and very specific for determining elevated PVR.

A study by Alnaif and Drutz (34) examined the accuracy of portable bladder ultrasound (BVI 2500) in a population of 80 women undergoing urine flow studies (uroflowmetry) in a urodynamic unit in Toronto, Ontario. Ultrasound PVR measurements were performed immediately prior to urinary catheterization. Catheterized PVR was considered the gold standard and the portable bladder ultrasound reading was considered accurate if it was within 25% of the PVR obtained from catheterization. Readings from bladder volumes below 50 mL correlated poorly with actual PVR derived from catheterization (60.6% correlation). Ultrasound readings of '000' were obtained 35 times (44%), corresponding to volumes obtained by catheterizations that ranged from 5 to 170 mL. Of the 35 null portable bladder ultrasound readings, 85% ($n = 29$) had corresponding catheter measurement volumes of less than 50 mL, but 3% ($n = 1$) of the null portable bladder ultrasound readings had catheter-measured PVR volumes greater than or equal to 100 mL, which is considered a clinically significant indicator for catheterization. In further analysis, women with null portable bladder ultrasound readings did not differ significantly from other patients in the study with respect to BMI and height, which are hypothesized to affect portable bladder ultrasound accuracy. The large variability in differences between volumes derived by catheterization and portable bladder ultrasound PVR was found to be statistically significant according to the Wilcoxon signed-rank test ($P < .001$). Of the portable bladder ultrasound measurements, 39% ($n = 30$) were within 25% of the actual catheterized PVR.

With accuracy defined as a less than 25% or less than 20 mL difference between catheterized and portable

bladder ultrasound PVR volumes for ultrasound readings of '000', the portable bladder ultrasound had 60.6% accuracy in PVR less than 50 mL (n = 33), 27% accuracy in detecting PVR of 50 to 150 mL (n = 36), and 10% accuracy in detecting residuals more than 150 mL (n = 10) (Table 6). The authors concluded that misaimed scanheads caused bladders to be missed and produced partial bladder volume measurements and PVR underestimates when lateral borders were missed. They concluded that caution should be used in interpreting PVR from portable bladder ultrasound machines and that catheterization may be the preferred assessment modality if an accurate PVR measurement is necessary.

Table 6: Accuracy of Portable Bladder Ultrasound in Detecting Postvoid Residual at Different Postvoid Residual Volumes Within 25% of Catheterized Volume*

Postvoid Residual Volume	N	Accuracy, %
< 50 mL	33	60.60
50–150 mL	36	27.00
> 150 mL	10	10.00

*Alnaif and Drutz (34)

Postoperative and Acute Care Patients

In a validation trial of portable bladder ultrasound (BVI 2500), Brouwer et al. (35) investigators used a sample of 60 healthy volunteers and 50 patients (aged 18–80 years) scheduled to undergo surgeries requiring anesthesia and catheterization. The results from the 60 healthy volunteers were excluded from this Medical Advisory Secretariat review. For the surgical sample, ultrasound measurements were recorded before and after the induction of anesthesia and then followed by catheterizations for measurement of true urinary volumes. The portable bladder ultrasound measurements of bladder volumes underestimated true bladder volumes by 7% across the total volume range of 17 mL to 970 mL. Underestimation of PVR was greater in females than in males ($P < .02$). The correlation of portable bladder ultrasound volume to catheter volume was $r^2 = 0.94$ in awake patients ($P < .01$) and $r^2 = 0.95$ in anesthetized patients ($P < .01$). Bland-Altman analysis indicated a bias of 19 mL in patients with a precision of 80 mL for portable bladder ultrasound. An evaluation of body length and weight by BMI found no significant differences in PVR measurements in male or female surgical patients ($P < .05$).

Rosseland et al. (24) compared BladderScan BVI 2500+ readings in comparison to catheterized PVR volumes in 36 patients who underwent spinal anesthesia and were monitored in one post-anesthesia care unit. The 13 nurses working in the postanesthesia care unit were given 5 to 10 minutes of training on the operation of portable bladder ultrasound. Portable bladder ultrasound measurements of bladder volumes were compared with catheter obtained volumes. The mean difference between portable bladder ultrasound and catheterization estimates was -21.5 mL (95% CI, -147–104 mL) using Bland-Altman statistical techniques. Hence, on average, portable bladder ultrasound measurements underestimated bladder volumes by 21.5 mL. Study investigators concluded that there was good agreement between portable bladder ultrasound and catheter estimates of bladder volumes.

The use of portable bladder ultrasound (BVI 2500) was studied in a sample of 40 women undergoing laparoscopy consecutively. (36) Patients in the study were given the opportunity to void preoperatively. Following the induction of general anesthesia, PVR estimates were obtained using portable bladder ultrasound. The same operator performed all scans. If estimated bladder volume was more than or equal to 100 mL, urinary catheterization was performed prior to surgery and true PVR volume was recorded. Of the 40 women, 14 had findings of estimated PVR greater than 100 mL (range 101–445 mL), as obtained by portable bladder ultrasound and were catheterized. The true PVR obtained by catheterization had a range of 47 to 370 mL. In 5 women, PVR was less than 100 mL. In all but 1 woman, scanning

overestimated the PVR. Using Bland-Altman methods, the mean overestimated volume was 39 mL (95% CI, -13–85 mL). Investigators concluded that use of portable bladder ultrasound may eliminate unnecessary catheterizations and felt that a mean error of 39 mL was acceptable if recorded bladder volume was over 100 mL. However, due to study design limitations, portable bladder ultrasound measurements in estimated volumes less than 100 mL were assumed accurate and no true PVR volumes were obtained from catheterizations.

Slappendel et al. (8) sought to determine if the use of portable bladder ultrasound to measure bladder volume reduced the number of catheterizations used and the incidence of UTI. This study was of patients (n = 4,116 total) who underwent elective orthopedic surgery at a hospital in the Netherlands in 2 different periods associated with pre-portable bladder ultrasound use (n = 1,920) and during portable bladder ultrasound use (n = 2,196). Portable bladder ultrasound was used prospectively in an attempt to reduce the need for urinary catheterizations and the incidence of UTIs after orthopedic surgery. Over a 4-month period before portable bladder ultrasound use in which 1,920 patients were studied, catheterization was performed if there was no spontaneous voiding by 8 hours after surgery. Thirty-one percent of these patients were catheterized and 18 patients developed UTIs. In a subsequent 4-month period during which portable bladder ultrasound was used, 2,196 patients were studied and catheterization was performed 8 hours after surgery only if the bladder volume exceeded 800 mL as determined by portable bladder ultrasound measurement. The rate of catheterization decreased to 16% and 5 patients developed UTIs. Reductions in the number of patients catheterized and the number of UTIs were found to be statistically significant using the Wilcoxon signed rank test ($P < .05$) (Table 7).

The authors concluded that measuring bladder volumes by portable bladder ultrasound reduced the need for urinary catheterizations and the likelihood of UTIs. However, there were limitations to the study. Catheterization guidelines at the institution had changed from the pre-portable bladder ultrasound period to more stringent guidelines for catheterization when portable bladder ultrasound was introduced into the hospital. Fewer patients underwent surgery with anesthesia post-portable bladder ultrasound introduction, which may have decreased the risk of UR and UTI by a small amount.

Table 7: Results From a Study in an Orthopedic Surgery Unit Before and After Introducing Bladder Scan*

	Period Before Portable Bladder Ultrasound Measurement	Period With Portable Bladder Ultrasound Measurement
Number of patients	1,920	2,196
Number of catheters used	602	349
Percentage of patients who were catheterized	31	16†
Number of urinary tract infections	18	5†

*Slappendel et al. (8)

† $P < .05$.

In a study by Moore and Edwards, (37) investigators described the implementation of portable bladder ultrasound and rates of UTI reduction and then reported the expenditures and cost-savings attributable to portable bladder ultrasound. Over a 12-month period, 2 hospital units in a Maryland facility were selected to have bedside assessments of bladder volumes by portable bladder ultrasound in place of intermittent catheterization. Over the 12-month study period, 805 portable bladder ultrasound procedures were performed. Only 22% of the patients scanned with the device required catheterization and the hospital had a 50% decrease in UTIs. Additionally, investigators found the portable bladder ultrasound device to be more accurate with smaller bladder volumes correlating to the amount of urine drained via catheterization. The cost of each UTI incidence was estimated at \$680 (US) and the cost to perform each

catheterization ranged from \$5.25 to \$16.35 (US) (excluding practitioner's wages). Given the savings realized from a reduction in treating UTI, Moore and Edwards (37) suggested that 1 portable bladder device needed to be used 200 times in order to recover the purchase cost (list price purchased at \$8,300 [US]). However, a formal economic analysis was not included in the study and cost analysis was based on author opinion.

Rehabilitation Patients

Borrie et al. (13) examined UR in patients who resided in geriatric rehabilitation unit ($n = 167$) and assessed the prevalence and risk factors of UR, including an investigation of portable bladder ultrasound (BVI 2500) validity. The prevalence of UR was defined as PVR greater than or equal to 150 mL in 2 consecutive measurements. Estimates were confirmed by in-and-out catheterization for true volumes of PVR for the 19 residents who had a PVR greater than 150 mL. Individuals who did not have 2 consecutive PVR measurements of greater than 150 mL were not catheterized. In the frail elderly population, UR prevalence was 11% with the risk of UR greater for patients who were older, on anticholinergic medications, with histories of long-term diabetes, or with fecal impactions. Scan volumes underestimated catheterization volumes by 80.8 ± 111.3 mL ($P < .001$). The correlation between paired scan and catheter volumes of more than or equal to 150 mL was 0.87. The results suggest that the BladderScan BVI 2500+ ultrasound scanner, when used by trained nursing staff, provides conservative and valid estimates of PVR more than or equal to 150 mL in people undergoing geriatric rehabilitation.

Lewis et al. (17) conducted an observational study ($n = 86$) on portable bladder ultrasound (BVI 2500) implementation at a rehabilitation facility. Investigators measured PVR volume as part of a standard assessment of a patient's bladder function to determine patient needs with regards to bladder emptying ability. A secondary objective of portable bladder ultrasound implementation was its effect on the rate of urinary catheterization. Facility staff members were trained to use portable bladder ultrasound to measure PVR. The percentage of patients with orders for catheterization decreased from 80% to 60% following the implementation of the ultrasound program. Sixty-eight measurements (79%) of post void residual volumes done by bladder ultrasound found volumes of 100 mL or less, and catheterizations were avoided for these patients. The investigators concluded that volumes found in 48 of 72 post void residual catheterizations were too low to justify catheterizations.

In a geriatric unit and an acute rehabilitation unit, Resnick et al. (12) evaluated the effectiveness of portable bladder ultrasound (BVI 2000) in the assessment and treatment of UI and in the training of older adults ($n = 16$) to regain bladder function after the removal of an indwelling urinary catheter. All participants in the study were over 65 years of age. Over a 3-month period, the 16 patients in the study had 95 scans performed. The patients' bladders were scanned after each spontaneous void or every 8 hours until PVR was 300 mL or less. Individuals with residual urine volumes of greater than 300 mL were catheterized. Of the 95 scans performed, 50 resulted in a patient being catheterized, and 8 patients were catheterized because of PVR volumes greater than 300 mL. Consequently, 45 scans (47%) resulted in a patient not being catheterized because of the scan. Study investigators also reported a decrease in UTI rates. Urinary tract infections were present in 50% of patients at admission and in 12% at discharge. No study protocol was in place to examine the effect of portable bladder ultrasound on UTI rates. The nurses, who learned the scanning procedure quickly after an initial demonstration and a single practice assessment, reported informally that the scans were quick and easy to do. The patients reported satisfaction at not having to endure unnecessary catheterizations. Although study authors reported that use of the portable bladder scanner probably reduced hospital costs by decreasing the numbers of catheterizations, UTIs, and nursing time involved, they did not provide direct evidence of cost-savings.

Neurogenic Bladder Patients

Residual urine volumes in men with neurogenic bladder dysfunction ($n = 24$) were assessed repetitively prior to 100 episodes of intermittent catheterization for a total of 400 times using the BVI-2000 portable bladder ultrasound device. (18) By comparing each examiner's first ultrasound measurement of urine volume with the first catheterized urine volume, the mean error of the ultrasound measurements was -26 mL (-11%) and the mean absolute error was 44 mL (22%). The ultrasound measurements detected the presence of residual urine volumes of more than or equal to 100 mL with a sensitivity of 90% and a specificity of 81%. In the subset of catheterization episodes in which the catheterized urine volumes were less than or equal to 200 mL, the mean error of the ultrasound measurements was -15 mL (-9%), the mean absolute error was 37 mL (28%), and the sensitivity and specificity were 77% and 81%, respectively. The investigators found no advantage in using the mean or maximum of 2 repeated ultrasound measurements over using each examiner's first ultrasound measurement alone. Increased examiner experience did not decrease significantly the errors encountered.

Iretton et al. (38) evaluated portable bladder ultrasound (BVI 2000) in a population of patients ($n = 112$) from a hospital spinal cord injury unit, a hospital urology clinic, and a Veterans hospital cystoscopy clinic who required PVR measurements for standard clinical indications. Exclusion criteria included extreme obesity and abdominal scarring. All investigators had completed a minimum of 10 supervised portable bladder ultrasound estimates prior to the study. Every patient had 4 portable bladder ultrasound measurements completed by 2 different investigators within one 10 minute interval and then had their bladders emptied by either cystoscopy or catheterization. The correlation co-efficient between portable bladder ultrasound-estimated PVR and catheterized PVR volumes was $r^2 = 0.79$. Measurements in men were more accurate than in women ($r^2 = 0.82$ versus $r^2 = 0.53$) and in patients with spinal cord injuries in comparison to other patients ($r^2 = 0.75$ versus $r^2 = 0.68$). However, the comparisons were not found to be statistically significant at the 0.05 level. The 2 investigators with the most experience using the device had a better correlation with catheterized volume than other investigators ($r^2 = 0.84$ versus $r^2 = 0.60$). However, the more experienced investigators were both on the spinal cord injury team, which may have biased the results and elevated their correlation with the catheterized volumes. Study investigators concluded that although portable bladder ultrasound design needs improvement, it is an alternative to urethral catheterization for determination of bladder volume in most patients.

Fakhri et al. (39) evaluated the use of portable bladder ultrasound (BVI 3000) in male patients with spinal cord injury patients ($n = 39$) in a Kuwait rehabilitation hospital. Of the patients participating in the trial, 21 patients had strongly reactive (hyperreflexic) bladders, and 18 patients had poorly reactive (hyporeflexic) bladders. For all patients, portable bladder scans were performed immediately prior to catheterizations. The mean difference between portable bladder ultrasound and catheterization PVR volumes was $-29 \text{ mL} \pm 7 \text{ mL}$ in the hyperreflexic bladder group, and $-47 \text{ mL} \pm 11 \text{ mL}$ in the hyporeflexic bladder group. There was no significant difference of PVR volume measured by portable bladder ultrasound and catheterization in both groups of patients ($P > .05$). The investigators concluded that portable bladder ultrasound results are reliable with good correlation to results of urethral catheterization.

Summary of Observational Studies

All studies examining the clinical utility of portable bladder ultrasound in the elderly population found portable bladder ultrasound acceptable, including one study that found portable bladder ultrasound to underestimate catheterized bladder volume. (11;16;31)

Of 3 portable bladder ultrasound studies in urology patient populations, 2 found portable bladder

ultrasound acceptable to use, even though each reported shortcomings of the device. Huang et al. (32) found portable bladder ultrasound measurements to be less accurate than catheterization, particularly for small PVR volumes. Goode et al. (33) reported that portable bladder ultrasound measurements overestimated catheterized bladder volumes. In the third study by Alnaif and Drutz, (34) the authors concluded that bladders were missed if scanheads were misaimed and that partial bladder volumes resulted if lateral borders were missed producing measurements that underestimated PVR volumes. Alnaif and Drutz concluded that caution should be used in interpreting PVR from portable bladder ultrasound machines and that catheterization may be the preferred assessment modality if an accurate PVR measurement is necessary.

Three studies in postoperative populations found portable bladder ultrasound reasonably acceptable. Although 2 studies found that the devices overestimated catheter derived bladder volumes by 7% and 21 mL, (35) and by 39 mL, (36) the third study (24) found the opposite—that the devices overestimated catheter bladder volume by 39 mL.

Two studies in rehabilitation settings found portable bladder ultrasound to underestimate catheter derived bladder volumes; yet, both authors concluded that the mean errors were within acceptable limits. (13;18)

Two studies (38;39) in the neurogenic bladder population also found portable bladder ultrasound to be an acceptable alternative to catheterization despite the fact that it was not as accurate as catheterization for obtaining bladder volumes.

Lastly, in the four studies (8;19;37;40) that examined negative health outcomes avoided, unnecessary catheterizations fell by 20% to 47%, and UTIs were decreased by 38% to 50% after the implementation of portable bladder ultrasound.

Several limitations applied to the studies. There were no RCTs, although randomization may have been appropriate in examining health outcomes, such as reductions in catheterizations and UTI rates. However, randomization would not have been appropriate in studies examining sensitivity and specificity because an appropriate work-up in each individual is required in the diagnostic study design. A majority of studies did not include details of training protocols regarding null portable bladder ultrasound readings and catheterization procedures and some studies did not mention details about training individuals to use the portable bladder ultrasound devices. Additionally, very few studies used blinding techniques to prevent investigators from learning the bladder volume or PVR volume that corresponded to the portable bladder ultrasound and catheterization.

One of the major flaws in the literature was the inappropriate use of statistical methods. Bland and Altman (41) point out that in the comparison of 2 measurement methods measuring the same quantity, the statistical concept of limits of agreement would be more appropriate than the correlation coefficient. The Bland-Altman Test measures how close the agreement is; whereas, correlation coefficients measure the degree of association between the 2 measurement methods. Hence, studies investigating the clinical utility of portable bladder ultrasound should use the Bland-Altman Plot method. (41) Additionally, the majority of the studies provided conclusions regarding the utility and effectiveness of portable bladder ultrasound without previously stating the definitions of the appropriate levels of clinical utility (e.g., sensitivity and specificity) or the reductions of negative health outcomes (e.g., unnecessary catheterization and UTI).

Medical Advisory Secretariat Review

Models of Portable Bladder Ultrasound Devices

There are several models of portable bladder ultrasound in use, but the only products licensed by Health Canada are BladderScan machines manufactured by Verathon Corporation. Two studies addressed the use of different portable bladder ultrasound models. BladderScan models BVI 2000, BVI 2500, and BVI 2500+ were evaluated as newer models of the device and were introduced during the study time periods. The BVI 2000 compared favourably to BVI 2500 in the first study by Ouslander et al., (16) deriving similar results to correlations with catheter volume. In the second study, Marks et al. (11) used BVI 2500 and BVI 2500+ machines and also obtained similar readings to catheter volumes.

In the study by Ouslander et al. (16) portable bladder ultrasound model BVI 2000 was compared with the BVI 2500, a newer model at the time. Study Observer 1 tested 61 pairs on both models on 2 occasions and found a correlation co-efficient of $r^2 = 0.89$ for both tests. Study Observer 2 found a correlation of $r^2 = 0.87$ for the first test on 61 pairs and a correlation of $r^2 = 0.90$ for test 2 using 60 pairs. Both observed results indicate little variation between portable bladder ultrasound models BVI 2000 and BVI 2500.

In a study by Marks et al., (11) portable bladder ultrasound models BVI 2500 and BVI 2500+ were examined in 1994 and 1995, respectively. Using linear regression, the investigators predicted catheter volume from portable bladder ultrasound volume and found the BVI 2500 correlation to scan volume was $r^2 = 0.93$ (SD 42) and BVI 2500+ correlation to scan volume was $r^2 = 0.93$ (SD 40). There were minimal differences between the BVI 2500 and BVI 2500+ in predicting catheter volumes from portable bladder ultrasound volumes.

Inter-Rater Reliability

Inter-rater reliability was evaluated in 3 studies with relatively similar results between raters. Ouslander et al. (16) compared observer 1 to observer 2 in 2 tests, using 143 pairs in the first test with a correlation of $r^2 = 0.92$ and 142 pairs in test 2 with a correlation of $r^2 = 0.94$, thus concluding excellent inter-rater reliability. In a study by Marks et al., (11) a graduate physician and a college student achieved similar volume determinations ($r^2 = 0.90$). Study protocol in Ireton et al. (38) included performing a minimum of 10 supervised portable bladder ultrasound measurements prior to completing any portable bladder ultrasound measurements for the study. The 2 investigators with the most experience had better correlations with catheter volumes ($r^2 = 0.84$ and $r^2 = 0.83$) in comparison to the other investigators ($r^2 = 0.60$). However, some of the variation was potentially accounted for by the fact that the 2 more experienced investigators worked on the spinal cord catheterization team and catheterized men with neurogenic bladders so that the portable bladder ultrasound measurements from these subjects were more closely related to their actual catheter volume measurements than those obtained from other study subjects by less experienced investigators.

Repeated Measures

Five studies included consecutive portable bladder ultrasound measurements in individual patients. They found that repeated measurements did not improve the accuracy of portable bladder ultrasound as correlated to catheterization volume. In the Ireton et al. study, (38) 4 portable bladder ultrasound measurements were completed on each patient by 2 different examiners. Investigators found that the first measurement compared with the mean of 4 measurements taken consecutively did not improve or diminish correlation to catheter volume ($r^2 = 0.79$ to $r^2 = 0.76$). Ouslander et al. (16) completed about 4 measurements on each subject and used the mean of the first 2 measurements when presenting sensitivity and specificity; but, they did not report outcomes across the 4 consecutive PVR measurements made with

portable bladder ultrasound. Ding et al. (31) completed 1 portable bladder ultrasound measurement on the first 20 subjects in their study, and then 2 consecutive portable bladder ultrasound measurements in the subsequent 80 study participants to determine if accuracy could be further improved. The first measurement alone had an absolute error of 54 mL, and when the mean of 2 measurements was taken an absolute error of 55 mL was obtained, indicating no benefit of multiple scans. In a study of 24 men with neurogenic bladders, 400 measurements were made, and authors reported that there was no clear advantage in using the mean or maximum of 2 portable bladder ultrasound measurements over using the examiner's first measurement alone. (18) In a study that took 3 portable bladder ultrasound measurements, investigators used the highest reading rather than mean or random readings, because it provided the highest correlation to catheterized bladder volume ($r^2 = 0.90$, $P < .001$). (11) However, all 3 readings did correlate with catheter volume and with each other (all $r^2 > 0.85$, $P < .001$).

Null Readings

Two studies examined the zero (null) bladder volume measurements made by portable bladder ultrasound. Marks et al. (11) looked at a subgroup of 11 patients with portable bladder ultrasound readings of 0 and catheter volumes ranging from 0 to 55 mL. In the 17 patients where scan volumes were greater than 0 but less than 50 mL, corresponding catheter volumes ranged from 10 to 94 mL. In this study, low portable bladder ultrasound readings, including null readings, were predictive of low catheter volumes. The authors concluded that the underestimated scan volumes may be due either to a bladder's continuing to fill with urine during the delay before catheterization and after portable bladder ultrasound or to the failure of the scan to include all parts of the bladder. (11)

In another study of female urology outpatients, portable bladder ultrasound readings of 0 were obtained 35 times (44%), and corresponding catheter obtained volumes ranged from 5 to 170 mL. (34) Of the 35 null portable bladder ultrasound readings, 85% had a corresponding catheter measurement in volumes of less than 50 mL, but 3% of the null portable bladder ultrasound readings had PVR volumes of over 100 mL, which is considered a clinically significant indicator for catheterization. In further analysis, the findings of measurements in women with null portable bladder ultrasound readings were not found to be significantly different from those in other patients with regards to BMI and height, which are hypothesized to affect portable bladder ultrasound accuracy. The large variability in the difference between catheterized and portable bladder ultrasound PVR was statistically significant according to the Wilcoxon signed-rank test ($P < .001$).

Sensitivity and Specificity

Portable bladder ultrasound is highly sensitive and moderately specific for low volumes of PVR and moderately specific and highly specific for high PVR volumes (Table 8). Reported sensitivities ranged from 0.67 to 0.90, and reported specificities ranged from 0.63 to 0.97.

Table 8: Sensitivity and Specificity of Portable Bladder Ultrasound Measured to Catheterization Volume

Study	Portable Bladder Ultrasound	Population	N	Cutoff Value, mL	Sensitivity	Specificity
Ouslander et al., 1994 (16)	BVI 2000 BVI 2500	Elderly people in nursing homes	201	< 50	0.90	0.71
Ouslander et al., 1994 (16)	BVI 2000 BVI 2500	Elderly people in nursing homes	201	< 100	0.95	0.63
Ouslander et al., 1994 (16)	BVI 2000 BVI 2500	Elderly people in nursing homes	201	> 200	0.69	0.69
Marks et al., 1997 (11)	BVI 2500 BVI2500+	Urology patients	249	≥ 100	0.97	0.91
Huang et al., 2004 (32)	BVI 3000	Urology patients	64	≥ 100	0.80	0.87
Goode et al., 2000 (33)	BVI 2500	Urology patients	95	≥ 100	0.67	0.97
Revord et al., 2003 (18)	BVI 2000	Neurogenic bladder patients	24	≥ 100	0.90	0.81
Revord et al., 2003 (18)	BVI 2000	Neurogenic bladder patients	24	≤ 200	0.77	0.81

Mean Error Estimates

The mean error of the difference between the bladder volumes derived from portable bladder ultrasound and that of the catheter was included in several studies (Table 9). Portable bladder ultrasound volumes were found to both over- and underestimate catheter-obtained bladder volumes.

Table 9: Mean Error Differences Between Portable Bladder Ultrasound and Catheterization*

Study	Portable Bladder Ultrasound	Populations	N	Mean Volume Difference Estimate, mL
Marks et al., 1997 (11)	BVI 2500 BVI 2500+	Older urology patients	249	-15.2 ±4
Goode et al., 1990 (33)	BVI 2500	Urology patients	95	17 (95% CI, 8–25)
Rosseland et al., 2002 (24)	BVI 2500+	Postoperative patients	36	-21.5 (95% CI, -147–104)
Moselhi et al., 2001 (36)	BVI 2500	Postoperative patients (females)	40	39 (95% CI, -13–85)
Brouwer et al., 1999 (35)	BVI 2500	Surgical patients	50	-31 ±55 ($P > .05$)
Fakhri et al., 2002 (39)	BVI 3000	Neurogenic bladder patients (with hyperreflexic bladders)	39	-29 ±7 ($P < .05$)
Fakhri et al., 2002 (39)	BVI 3000	Neurogenic bladder patients (with hyporeflexic bladders)	39	-47 ±11 ($P < .05$)
Borrie et al., 2001 (13)	BVI 2500	Rehabilitation patients	167	-80.6 ±111.2 ($P < .001$)

*CI indicates confidence interval.

Subgroup Analysis

Three studies investigating the clinical utility of portable bladder ultrasound found differences regarding accuracy of the device in certain subpopulations. In a study by Marks et al., (11) portable bladder ultrasound volumes underestimated true bladder volumes by 10 mL in men and 20 mL in women. One study concerning patients from a hospital urology clinic, a hospital spinal cord injury unit, and a veterans' hospital cystoscopy clinic, found slight differences in the accuracy of portable bladder ultrasound in bladder measurements of women and patients from spinal cord injury groups. Measurements in men were more accurate than in women ($r^2 = 0.82$ versus $r^2 = 0.53$) and in spinal cord injury patients in comparison to other patients ($r^2 = 0.75$ versus $r^2 = 0.68$). However, there were no studies that showed statistical significance at the 0.05 level. Fakhri et al. (39) evaluated portable bladder ultrasound measurements in 39 male spinal cord injury patients in a Kuwait rehabilitation hospital. They found the mean difference between portable bladder ultrasound and catheterization PVR volumes was $-29 \text{ mL} \pm 7 \text{ mL}$ ($P < .05$) in the hyperreflexic bladder group and $-47 \text{ mL} \pm 11 \text{ mL}$ ($P < .05$) in the hyporeflexic bladder group.

Catheterization and Urinary Tract Infections Avoided

Four studies included outcomes related to health outcomes, specifically the reduction of catheterization and UTI, with the implementation of portable bladder ultrasound (Table 10). Unnecessary catheterizations avoided ranged from 16% to 47% in the selected articles. Reductions in UTI ranged from 38% to 72%. In the study by Slappendel et al., (8) there was a statistically significant reduction in catheterizations and UTIs, due to the pre- and post-study design of the trial. ($P < .05$) Often, a patient is catheterized upon suspicion of UR. The proportion of scanned patients who received catheterization ranged from 16% to 53%, indicating a potential relationship between the implementation of portable bladder ultrasound with reductions in catheterizations and subsequent UTI.

Table 10: Health Outcomes of Portable Bladder Ultrasound Implementation*

Study	Setting	No. of Scans	Catheters Avoided, %	UTI Reduction, %	Patients Catheterized After Scans, %
Resnick et al., 1995 (12)	Geriatric rehabilitation unit	95	47	38	53
Lewis et al., 1995 (17)	Rehabilitation unit	72	20	NR	33
Slappendel et al., 1999 (8)	Orthopedic postsurgical unit	2,196	16 $P < .05$	72 $P < .05$	16
Moore and Edwards, 1997 (37)	Acute care hospital	805	NR	50	22

*UTI indicates urinary tract infection; NR, not reported.

Summary of Medical Advisory Secretariat Review

- Portable bladder ultrasound has acceptable levels of clinical utility. It is not as accurate as catheterization, but it is noninvasive; therefore, there are other benefits.
- Portable bladder ultrasound is highly sensitive and moderately specific for low volumes of PVR, and moderately specific and highly specific for high PVR volumes. Reported sensitivities ranged from 0.67 to 0.90, and reported specificities ranged from 0.63 to 0.97.

- Portable bladder ultrasound has good levels of inter-rater reliability given training and standardization.
- Repeated consecutive measurements do not significantly improve the correlation of a portable bladder ultrasound reading to true bladder volume measurement as derived from catheterization.
- In sub-group analysis, portable bladder ultrasound is less accurate for woman than for men. Patients with spinal cord injuries also showed higher levels of accuracy than did other acute care and rehabilitative patients.
- Unnecessary catheterizations avoided with portable bladder ultrasound ranged from 16% to 47% in the review articles. Reductions in UTI ranged from 38% to 72%. Significant findings in reducing negative health outcomes.

Economic Analysis

Results of Literature Review on Economics

In the literature, bladder ultrasound devices have been estimated to cost from \$8,300 to \$10,000 (US). (10;19;37) Recent studies have outlined cost-benefit analyses used when considering the purchase of a portable bladder ultrasound device by an institution.

In a cost-analysis by Moore and Edwards, (37) UTI incidence was \$680 (US) and the costs to perform each catheterization ranged from \$5.25 to \$16.35 (US) (excluding practitioners' wages). Given the savings realized from a reduction in treating UTI, Moore and Edwards (37) suggested that 1 portable bladder device needed to be used 200 times in order to recover the purchase cost. However, a formal economic analysis was not included in the study, and cost analysis was based on author opinion.

Philips et al. (42) described a facility's attempt to decrease nosocomial UTIs and the associated cost analysis. Prior to implementing their UTI reduction project, they estimated the yearly cost of nosocomial UTIs to be \$1.7 million (US). A portion of this program encouraged the use of a bladder ultrasound protocol after indwelling catheter removal. In the month prior to the introduction of the bladder ultrasound protocol, 118 intermittent catheterizations were performed in the rehabilitation unit. One month after the protocol, only 2 intermittent catheterizations were performed. Supply savings alone were estimated at \$2,784 (US) yearly. If 1,392 catheterizations were avoided yearly, then about 27 nosocomial UTIs may also be avoided; potential savings were estimated at \$45,900 (US) for 1 year.

Frederickson et al. (19) also offered a brief cost analysis of a bladder ultrasound protocol in orthopedic and surgical units. They estimated the BVI 2500 to cost \$8,300 (US) and treatment costs for nosocomial UTIs to be \$680 (US) for each incident. They concluded that the supply cost saved after 2,280 avoided catheterizations would recover the cost of the device in about 2.9 years. However, when considering the cost of UTIs, it would take only 12 avoided infections to recover the cost of the device.

Wooldridge et al. (43) outlined the information required for a comprehensive cost analysis when comparing intermittent catheterizations and bladder ultrasound devices. Data to be considered for intermittent catheterization included the number of catheterizations yearly, number of times a measurement of bladder volume is required, time required for catheterizations, associated labor costs, supply costs, UTI rates, and UTI treatment and medication costs. However, Wooldridge directed this information to long-term care facilities and did not include the costs of extended acute care hospital stays, which would need to be considered. According to Wooldridge, these costs should be compared with the costs associated with bladder ultrasound use that include the number of times a measurement of bladder volume is required, time spent scanning, and labour costs associated with scanning. They also noted that

catheterization labor costs must be calculated using licensed personnel wages. The final step would be to compare approximate savings to the cost of the device. Training to use a scan involves a 10-minute video describing operation that is available online from Verathon Corporation.

Ontario-Based Economic Analysis

Notes & Disclaimer

The Medical Advisory Secretariat uses a standardized costing methodology for all of its economic analyses of technologies. The main cost categories and the associated methodology from the province's perspective are as follows:

Hospital: Ontario Case Costing Initiative (OCCI) cost data is used for all program costs when there are 10 or more hospital separations, or one-third or more of hospital separations in the ministry's data warehouse are for the designated International Classification of Diseases-10 diagnosis codes and Canadian Classification of Health Interventions procedure codes. Where appropriate, costs are adjusted for hospital-specific or peer-specific effects. In cases where the technology under review falls outside the hospitals that report to the OCCI, PAC-10 weights converted into monetary units are used. Adjustments may need to be made to ensure the relevant case mix group is reflective of the diagnosis and procedures under consideration. Due to the difficulties of estimating indirect costs in hospitals associated with a particular diagnosis or procedure, the Medical Advisory Secretariat normally defaults to considering direct treatment costs only. Historical costs have been adjusted upward by 3% per annum, representing a 5% inflation rate assumption less a 2% implicit expectation of efficiency gains by hospitals.

Non-Hospital: These include physician services costs obtained from the Provider Services Branch of the Ontario Ministry of Health and Long-Term Care, device costs from the perspective of local health care institutions, and drug costs from the Ontario Drug Benefit formulary list price.

Discounting: For all cost-effectiveness analyses, discount rates of 5% and 3% are used as per the Canadian Coordinating Office for Health Technology Assessment and the Washington Panel of Cost-Effectiveness, respectively.

Downstream cost savings: All cost avoidance and cost savings are based on assumptions of utilization, care patterns, funding, and other factors. These may or may not be realized by the system or individual institutions.

In cases where a deviation from this standard is used, an explanation has been given as to the reasons, the assumptions and the revised approach.

The economic analysis represents an estimate only, based on assumptions and costing methods that have been explicitly stated above. These estimates will change if different assumptions and costing methods are applied for the purpose of developing implementation plans for the technology.

Bladder scanners in Ontario are funded through global hospital and long-term care facility budgets. This economic analysis focuses on the potential cost savings that would result if the portable bladder ultrasound technology were adopted for the 15 complex continuing care (CCC) facilities within Ontario.

The total cost of a bladder scanner as reported by the manufacturer is \$19,566 (Cdn) per device. This includes a 5-year manufacturer's warranty, scanner insurance, training video, manuals, software upgrades, online viewing and printing of images, online calibration, and 12-month exam storage.

The prevalence of UI is estimated at 2.5% for women and 1.4% in men in the general population. (4)

Economic analysis was not completed in acute care, community and home care, and long-term care

population settings. Data were not available on either catheterization rates or the effectiveness of portable bladder ultrasound on relevant health outcomes in these populations.

Table 11: Urinary Incontinence and Catheter Use in Ontario*

Health sector	Population	Urinary Incontinence Prevalence	Rate of intermittent catheterization	Rate of UTI
Community care access centres	12 million Ontario residents	unknown	unknown (purchased ~ 46,000 intermittent cath in 2004/2005)	unknown
Acute care	~1,000,000 admissions per year	unknown	unknown (UHN purchased 12,700 intermittent cath in 2004/2005)	~35,000 per year (unknown how many associated with catheterization)
Complex continuing care	~30,000 residents in ON	unknown	19-90% -- all types of catheters (unknown no. of intermittent cath)	unknown
Long-term care homes	~65,000 residents in ON	80.5%	2.5% -- all types of catheters (unknown no. of intermittent cath)	2.6% (unknown how many associated with catheterization)

*UTI indicates urinary tract incontinence.

In fiscal year 2003, for all 15 complex continuing care (CCC) facilities in Ontario, the total population of patients was estimated to be 30,360, which averages 2,024 patients per CCC facility per year. (44) The mean length of hospital stay for a patient in a CCC facility was 53 days (Population Health Planning Database Data, Ontario Ministry of Health and Long-term Care, April 2006). The mean daily population of a typical CCC facility was calculated to be 294 patients based on the mean length of hospital stay according to the equation that follows.

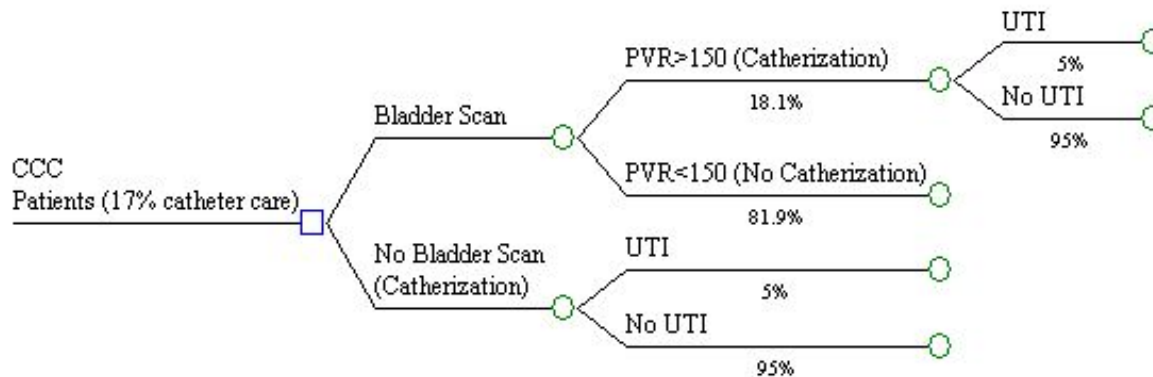
Total number of patients in a CCC facility = (2,024 patients x 53 days)/365 days = 294 patients

Of the 294 patients per CCC facility per day, about 17% (50 patients) would be classified as those that require catheter care (Personal communication, February 2006). Therefore, 50 patients per CCC facility would benefit from the adoption of the bladder scanner.

Economic Model

Figure 1 illustrates a typical CCC facility decision analytic model to estimate cost savings.

Figure 1: Economic Model for a Complex Continuing Care Facility*



*CCC indicates complex continuing care; PVR, postvoid residual; UTI, urinary tract infection.

About 17% of the population in an average CCC facility would be classified as those that require daily catheter care (Personal communication, February 2006). Figure 1 summarizes the path taken for an instance of catheter care with and without the adoption of bladder scanner technology.

In the scenario where the bladder scanner is used, a qualified nurse would scan the patient to determine PVR. A patient with a PVR measurement greater than 150mL, which indicates UR, would be catheterized. On the other hand, a patient with a PVR measurement less than 150 mL would not be catheterized, leading to a decrease in “unnecessary catheterizations.” Borrie et al. (13) estimated the probability of a PVR measurement greater than 150 mL to be about 11% per patient while Wu et al. (45) and Tam et al. (46) estimated the probability at 21.5% and 21.8%, respectively. An average of these estimates (18.1%) was used in the economic model for this health technology policy assessment. In the scenario with no bladder scanner adoption, each patient would be catheterized, regardless of UR.

In each instance of catheterization, the probability of UTI is 5%. (47) According to expert opinion, a patient would be scanned about 4 times daily to determine PVR measurements and if catheterization were necessary. Therefore, each scenario would repeat itself 4 times at the end of each path to represent typical daily PVR assessment and catheterization procedures in a CCC facility. For example, in the scenario with the adoption of the bladder scanner, if a patient were to follow the topmost path, the patient would be initially scanned and catheterized (assuming a PVR measurement over 150 mL) and then develop a UTI. Six hours after this assessment, the patient would be scanned again and the progression within that model would depend on the PVR measurement and whether the patient developed a UTI. On the other hand, in the scenario with no bladder scan, the patient would be catheterized every 6 hours; progression within the model would depend on whether the patient developed a UTI in each instance of catheterization.

For each unique path within the economic model, the path probability was determined as well as the total expected cost per facility per day, the expected number of catheterizations per facility per day and expected number of UTIs per facility per day. This was done to estimate expected net costs to a CCC facility and the total number of catheterizations and UTIs avoided due to adopting the portable bladder ultrasound scanner.

Costs

All costs are in Canadian currency unless otherwise noted.

Ontario Case Costing Initiative data were unavailable for the CCI and ICD-10 codes in relation to UI and catheterizations. Since nurses would typically use the bladder scanner for PVR measurements within complex continuing care facilities and due to a lack of physician codes billed, nursing time and cost of catheters were used to cost catheterization procedures. Similarly, nursing time was used to cost each instance that a bladder scan was conducted. The mean time spent by a nurse for a bladder scan was estimated at 0.75 minutes \pm 0.3 minutes while the mean time spent by a nurse on a catheterization was estimated at 4.6 minutes \pm 1.5 minutes. (48)

The mean cost of 10 days of oral antibiotic treatment was used to cost UTIs, which was estimated at \$17.18 per UTI (mean 10-day regime of Bactrim, Amoxil, and Macrobid). The mean cost of a registered nurse in Ontario is \$29.80/hour (Personal Communication, Ontario Nurses Association, April 2006).

Cost Calculations

- Estimated cost for a portable bladder ultrasound scan: \$29.80 per hour*(0.0125 hours) = \$0.37
- Mean cost of a urinary catheter is \$1.50
- Total cost per catheterization is \$1.50 + \$29.80 per hour*(0.0769 hours) = \$3.79

The economic model revealed that about 169 catheterizations and 1 UTI were avoided daily in a typical CCC facility. The total annual expected cost per CCC facility with the portable bladder ultrasound scanner was estimated at \$24 per CCC facility per day while the total annual expected cost per CCC facility without the bladder scanner was estimated at \$679 per CCC facility per day. The difference in costs is mostly attributable to the decrease in the number of catheterizations with the adoption of the portable bladder ultrasound scanner technology.

The total annual cost to a CCC facility (including catheter costs, nurse time, and UTI treatment costs but excluding device costs) was estimated at \$35,770 with the adoption of the bladder scanner technology. Without the adoption of the technology, the cost to a typical CCC facility was estimated at \$247,835.

Budget Impact Analysis

To estimate the total budget impact and cost to the Ministry of Health and Long Term Care, device costs were factored into the above costs.

- Total first year cost **with** bladder scanner per facility: \$55,336 (= \$35,770 + \$19,566)
- Total first year cost **without** bladder scanner per facility: \$247,835
- Net first year cost per facility: \$192,499 in savings
- Net first year cost for 15 CCC facilities = \$2,887,485 in savings

Because the cost of the bladder scanner is a one-time cost to each CCC facility, after the first year, an additional savings of \$19,566 per year would occur.

Existing Guidelines for Use of Technology

The Canadian Urological Association

In June 2005, the Canadian Urological Association (49) voted to adopt guidelines on UI, which specify that "Adult patients with a history of urinary incontinence should undergo a basic evaluation that includes a history, physical examination, evaluation of post void residual volume and urinalysis...Estimation of PVR volume is better done by catheterization or pelvic ultrasound. ...Residual volume (repeat test of high residual volume) of 50 to 100 mL is considered "acceptable" but in any case clinical history and circumstances would have to be analyzed."

The American Urological Association

Optional tests are those that are not required but may aid in the decision-making process. (50) When the initial evaluation suggests a nonprostatic cause for the patient's symptoms, or when the patient selects invasive therapy, the physician may consider additional diagnostic testing if the results of the test(s) are likely to change the patient's management or more precisely predict the benefits and risks of the selected treatment. The 1994 Agency for Health Care Policy and Research guideline suggested that the physician consider performing 1 or more "optional" diagnostic test(s) prior to offering treatment options to the patient. (50) In some cases, additional diagnostic tests may aid in the selection of an invasive treatment that is best for an individual patient (e.g., identification of prostate middle lobe).

Optional: Following the initial evaluation of the patient, urinary flow-rate recording and measurement of PVR may be appropriate. These tests usually are not necessary prior to the institution of watchful waiting or medical therapy. However, they may be helpful in patients with a complex medical history (e.g., neurological or other diseases known to affect bladder function or prior failure of benign prostatic hypertrophy therapy) and in those desiring invasive therapy.

Large PVR volumes (e.g., 350 mL) may indicate bladder dysfunction and predict a slightly less favourable response to treatment. In addition, large PVR volumes may herald progression of disease. Still, residual urine is not a contraindication to watchful waiting or medical therapy. Because of large test-retest variability and a lack of appropriately designed outcome studies, it is not feasible to establish a PVR threshold or "cut-point" for decision making. The Panel considered the use of PVR measurements optional in men undergoing noninvasive therapy based on the observation that the safety of noninvasive therapy has not been documented in patients with residual urine (200 to 300 mL). In some studies, however, residual urine has predicted a high failure rate of watchful waiting. Within the range of residual urine volumes from 0 to 300 mL, the PVR does not predict the response to medical therapy. Although long-term, controlled data are lacking, many patients maintain fairly large amounts of residual urine without evidence of UTI, renal insufficiency, or bothersome symptoms. Therefore, no level of residual urine, in and of itself, mandates invasive therapy.

Policy Development

Policy Implications

Diffusion – International, National, Provincial

Rapid diffusion of portable bladder ultrasound technology is expected. Recently, the IC5 project on improving continence care in Ontario complex continuing care centres piloted portable bladder ultrasound at 12 sites. Preliminary results were promising (Personal Communication, January 2006).

Numerous physicians and health care facilities already have portable bladder ultrasound devices. However, portable bladder ultrasound devices for PVR measurement are not in use in most health care facilities in Ontario and Canada. Additionally, the use of a PVR measurement is not incorporated into all regular continence care procedures. Because of its importance, measurement of PVR volume should be incorporated into the assessment of UI. Once fully diffused and incorporated as a standard in UI assessment and care, the diffusion of portable bladder ultrasound technology is set to increase. The Verathon Corporation, which patents BladderScan, is the sole licensed manufacturer of the portable bladder ultrasound in Canada. Field monopoly may influence the rising costs of portable bladder ultrasound, particularly when faced with rapid expansion of the technology.

Target Population

Several thousand Ontario residents would benefit from portable bladder ultrasound. The number of residents of Ontario that would benefit from the technology is difficult to quantify, because incontinence prevalence and incidence are grossly under-reported. However, long-term care and complex continuing care institutions would benefit greatly from portable bladder ultrasound, as would numerous rehabilitation, postsurgical care units, and urology clinics.

Patient Outcomes – Medical, Clinical

Introduction of the portable bladder ultrasound into various care units would likely be associated with improved UI-related outcomes in patients. As outlined in the evidence-based analysis, using the portable bladder ultrasound device to measure PVR volume will likely result in identifying a clinically significant PVR volume that may avoid unnecessary catheterization and subsequent UTI. Implementation of the portable bladder ultrasound device may result also in saved nursing time for facility staff through avoided catheterizations, which thereby may create additional care time available to patients.

Ethical Considerations

Use of the portable bladder ultrasound device should be restricted to trained health care professionals such as medical doctors and nurses who have undergone training for the use of the device.

Portable bladder ultrasound usage may benefit the patient, because it may avoid catheterizations, which are invasive and can lead to UTI. It may also help to preserve patient dignity.

Financial Impact

The cost of the portable bladder ultrasound devices ranges from \$17,698.90 to \$19,565.95 (Cdn) (total purchase price per unit as quoted by the manufacturer). Additional training packages, batteries and battery

chargers, software, gel pads, and yearly warranties are additional costs. Studies indicate that portable bladder ultrasound is a cost-effective technology, because it avoids costs associated with catheterization equipment, saves nursing time, and reduces catheter-related complications and UTIs. (2;19)

The major costs associated with the implementation of portable bladder ultrasound in a health facility will be the purchase costs of the device. Facility administrators will be affected by the costs of the device from their global budget. Additionally, health care professionals using the device will need to calibrate the machine and send the device for yearly tune-ups depending on the model used. Other costs include those associated with additional warranties, with the time needed for training, and with battery and gel pads costs, which also need to be incorporated into yearly budgets.

System Pressures

The primary system pressures will occur in budgeting and the diffusion of the device. Currently, funding constraints have prevented some facilities and units from purchasing the portable bladder ultrasound machine (Personal Communication, January 2006). In addition, although PVR measurement is included in the physician fee schedule for general assessments in urology settings, it is not in widespread use during urological examinations by family physicians (Personal Communication, January 2006).

There is potential for portable bladder ultrasound use in prompted voiding, a bladder/voiding training/rehabilitation technique for incontinence. Two case reports to date have found success in using portable bladder ultrasound for prompted voiding. (26;51) Given that currently 68% of the more than 30,000 patients in LTC facilities in Ontario require assisted toileting and almost 80% are incontinent, the implications would have an impact on several thousand Ontarians and thus should be considered. The implementation of the device may result in decreased incontinence episodes, potential saved supply costs, and savings to nursing time required for toileting assistance, while increasing patient dignity.

The Canadian Continence Foundation held 7 reactor panels across Canada, including in Ontario's metropolitan, rural, and mid-size areas. Through the reactor panels' discussions on continence care in Canada, several system-level themes emerged. Most notably, access to continence care was a major theme and easily reflects system pressures regarding portable bladder ultrasound implementation in Ontario. Several unmet continence care needs that may affect portable bladder ultrasound implementation include concerns such as access to continence care, provision and availability of instruments plus knowledge of their proper application (e.g., portable bladder ultrasound to assess and manage UR), voiding-diary method, billing practices disincentive to continence care and follow-up, funding as a barrier to services, uninsured specialized health professionals such as continence care nurses and physiotherapists, the shortage in medical specialists, and long waiting lists for referral services.

Stakeholder Analysis

Licensed health care professionals such as nurses and physicians use portable bladder ultrasound devices for patients with UI. Catheterizations and UTIs may be avoided through use of the technology; therefore, healthcare professionals may save time, and cost-savings should be realized. Physician visits may be avoided if PVR volume is measured at the home facility. Follow-up visits to the physicians for damage caused to the urinary tract by catheterizations and UTIs might be avoided, too. Moreover, health care providers prefer noninvasive portable bladder ultrasound to catheterization.

The use of portable bladder ultrasound device will affect the patient directly in terms of health outcomes. Its use avoids the trauma related to the urinary tract that catheterization inflicts, and does not result in UTIs. In addition, patients prefer it, because it preserves dignity and reduces discomfort.

Appendices

Appendix 1: Portable Bladder Ultrasound Devices Licensed by Health Canada*

Licence Number	Class	Licence Name	Device Name
30416	3	PORTABLE BLADDER ULTRASOUND BVI3000: NONINVASIVE BLADDER VOLUME INSTRUMENT	PORTABLE BLADDER ULTRASOUND BVI 3000
60888	2	DIAGNOSTIC ULTRASOUND CHARGER CRADLE	CHARGER CRADLE
60889	2	DIAGNOSTIC ULTRASOUND COMMUNICATION CRADLE	COMMUNICATION CRADLE
61755	3	BVI PORTABLE BLADDER ULTRASOUND	PORTABLE BLADDER ULTRASOUND BVI 6100 SCANNER
			BVI 6200 PORTABLE BLADDER ULTRASOUND
63380	3	BLADDERMASS BVM 6500	PORTABLE BLADDER ULTRASOUND BVM 6500
63850	3	PORTABLE BLADDER ULTRASOUND BVI 6300 - NON INVASIVE BLADDER VOLUME INSTRUMENT	PORTABLE BLADDER ULTRASOUND BVI 6300 SCANNER
65809	3	MOBILE PORTABLE BLADDER ULTRASOUND BVI 6400 - NON INVASIVE BLADDER VOLUME INSTRUMENT	MOBILE PORTABLE BLADDER ULTRASOUND BVI 6400 SCANNER
68889	2	FLOPOINT UROFLOW SYSTEM	FLOPOINT UROFLOW SYSTEM - COMMUNICATION CRADLE
			FLOPOINT UROFLOW SYSTEM - FLOSENSOR
			FLOPOINT UROFLOW SYSTEM - FLOSENSOR CHARGER
			FLOPOINT UROFLOW SYSTEM - MAIN UNIT
			FLOPOINT UROFLOW SYSTEM - SCANPOINT DOCKING STATION
			FLOPOINT UROFLOW SYSTEM - SCANPOINT REMOTE ACQUISITION HANDSET

* All are manufactured by Verathon Corporation (Bothell, Wisconsin, United States).

Appendix 2: Search Strategy

Bladder Ultrasound Search Strategies

Search date: December 14, 2005

Databases searched: OVID Medline, In Process and Other Non-Indexed Citations, Embase, Cochrane DSR and CENTRAL, INAHTA

Database: Ovid MEDLINE(R) <1966 to November Week 3 2005>

Search Strategy:

-
- 1 (Portable bladder ultrasound or bladder scan or bardscan or bladderscan).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (46)
 - 2 exp BLADDER/us [Ultrasonography] (686)
 - 3 exp Urinary Retention/us [Ultrasonography] (67)
 - 4 exp Urinary Incontinence/us [Ultrasonography] (225)
 - 5 or/2-4 (851)
 - 6 exp Bladder/ or exp Urinary Retention/ or exp Urinary Incontinence/ or exp Urinary Catheterization/ (52802)
 - 7 exp Ultrasonography/ (156634)
 - 8 6 and 7 (988)
 - 9 (mobile or portable or automated or scan? or scanner? or bedside).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (179095)
 - 10 exp Point-of-Care Systems/ (2371)
 - 11 (5 or 8) and (9 or 10) (193)
 - 12 1 or 11 (211)
 - 13 limit 12 to (humans and English language) (171)
 - 14 limit 13 to (meta analysis or review, academic or review, tutorial) (9)
 - 15 (systematic review\$ or meta-analysis or metaanalysis).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (21596)
 - 16 13 and (14 or 15) (9)
 - 17 13 (171)
 - 18 limit 17 to (case reports or comment or editorial or letter or "review" or "review literature" or review, multi-case or "review of reported cases") (31)
 - 19 17 not 18 (140)
 - 20 16 or 19 (149)

Database: EMBASE <1980 to 2005 Week 50>

Search Strategy:

-
- 1 (Portable bladder ultrasound or bladder scan or bardscan or bladderscan).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (37)
 - 2 exp Urine Volume/ (4352)
 - 3 exp Urine Retention/ (5777)
 - 4 exp BLADDER/ (28785)
 - 5 exp Bladder Capacity/ (2007)
 - 6 exp Residual Urine/ (1200)
 - 7 exp Bladder Emptying/ (218)
 - 8 exp Bladder Catheterization/ or exp Urine Incontinence/ or exp Stress Incontinence/ or exp Urge

Incontinence/ (15715)
9 or/2-8 (50086)
10 exp Ultrasound scanner/ (422)
11 9 and 10 (15)
12 exp Ultrasound/ (28612)
13 (mobile or portable or automated or scan? or scanner? or bedside).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (158972)
14 9 and 12 and 13 (64)
15 1 or 11 or 14 (104)
16 limit 15 to (human and English language) (86)
17 exp "Systematic Review"/ (7232)
18 Meta Analysis/ (23734)
19 (systematic review\$ or meta-analysis or metaanalysis).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name] (35159)
20 16 and (17 or 18 or 19) (0)
21 16 (86)
22 limit 21 to (editorial or letter or note or "review") (4)
23 Case Report/ (864093)
24 21 not (22 or 23) (73)

Appendix 3: Diagnostic Study Critical Appraisal Criteria

Reference

Relevant
Validity
Comparison to gold standard of diagnosis?
Blind comparison?
User training or protocol?
Appropriate subjects offered test? (population & sampling)
Gold standard offered regardless of result?
Results
Sample Size (N)
A
B
C
D
Sensitivity ($a/a+c$)
Specificity ($d/b+d$)
Positive predictive value ($a/a+b$)
Negative predictive value ($d/c+d$)
Positive likelihood ratio ($\text{sensitivity}/(1-\text{spec})$)
NLR($1-\text{sens}/\text{spec}$)
Accuracy $(a+D)/(a+b+c+d)$
Pretest probability ($a+c/a+b+c+d$)
Pretest odds ($1-\text{prev}$)
Posttest odds ($\text{pretest odds} \times \text{likelihood ratio}$)
Posttest probability ($\text{posttest odds}/(\text{posttest odds}+1)$) (=PPV)
What were the results?
How accurate were the results? (range, CI)
Normal range derived?
Placed in sequence with other diagnostic tests
Kappa presented if more than 1 outcome assessor
Were likelihood ratios presented or data for their calculation?
External Validity
Patients similar to my patient
Setting similar to my setting
Is test affordable, accurate, available?
Methods of test described to permit replication
Prevalence of disease in patients
Will results of test affect management if patient (cross a treatment threshold)?
Will test results help my patient?

References

1. Abrams P, Cardozo L, Fall M, et al. The standardization of terminology of lower urinary tract function: report from the standardization Subcommittee of the International Continence Society. *Am J Obstet Gynecol* 2002; 187(1): 116-26
2. Yagoda Shagam J. Urinary incontinence and ultrasound imaging. *Radiol Technol* 2004; 75(4): 297-312
3. Gray M. Assessment and management of urinary incontinence. *Nurse Pract* 2005; 30(7): 35-43
4. Finkelstein MM. Medical conditions, medications and urinary incontinence. *Can Fam Pract* 2002; 48: 96-101
5. Corabian P. Bladder ultrasound scanning for the measurement of post-void residual urine volume. 1996. Edmonton: Alberta Heritage Foundation for Medical Research.
6. Simforoosh N, Dadkhah F, Hosseini SY, Asgari MA, Nasser A, Safarinejad MR. Accuracy of residual urine measurement in men: comparison between real-time ultrasonography and catheterization. *J Urol* 1997; 158: 59-61
7. Smith NKG, Albazzaz MK. A prospective study of urinary retention and risk of death after proximal femoral fracture. *Age Ageing* 1996; 25:150-4.
8. Slappendel R, Weber EW. Non-invasive measurement of bladder volume as an indication for bladder catheterization after orthopaedic surgery and its effect on urinary tract infections. *Eur J Anaesthesiol* 1999; 16(8): 503-6
9. Diokno AC. Diagnostic categories of incontinence and the role of urodynamic testing. *J Am Geriatr Soc* 1990; 38:300-5.
10. Smith DA. Gauging bladder volume--without a catheter. *Nursing (Lond)* 1999; 29(12): 52-3
11. Marks LS, Dorey FJ, macairan ML, Park C, DeKernion JB. Three-dimensional ultrasound device for rapid determination of bladder volume. *Adult Urol* 1997; 50(3): 341-8
12. Resnick B. A bladder scan trial in geriatric rehabilitation. *Rehabil Nurs* 2003; 20(4): 194-6
13. Borrie MJ, Campbell K, Arcese ZA, Bray J, Hart P, Labate T et al. Urinary retention in patients in a geriatric rehabilitation unit: prevalence, risk factors, and validity of bladder scan evaluation. *Rehabil Nurs* 2001; 26(5): 187-91
14. Coombes GM, Millard RJ. The accuracy of portable ultrasound scanning in the measurement of residual urine volume. *J Urol* 1994; 152(6 Pt 1): 2083-5
15. Chan H. Noninvasive bladder volume measurement. *J Neurosci Nurs* 1993; 25(5): 309-12
16. Ouslander JG, Simmons S, Tuico E, Nigam JG, Fingold S, Bates-Jensen B et al. Use of a portable ultrasound device to measure post-void residual volume among incontinent nursing home residents. *J Am Geriatr Soc* 1994; 42(11): 1189-92

17. Lewis NA. Implementing a Bladder Ultrasound Program. *Rehabil Nurs* 1995; 20(4):215-7.
18. Revord JP, Opitz JL, Murtaugh P, Harrison J. Determining residual urine volumes using a portable ultrasonographic device. *Arch Phys Med Rehabil* 1993; 74(5): 457-62
19. Frederickson M, Neitzel JJ, Hogan Miller E, Reuter S, Graner T, Heller J. The implementation of bedside bladder ultrasound technology: effects on patient and cost postoperative outcomes in tertiary care. *Orthop Nurs* 2000; 19(3): 79-87
20. Haley RW, Morgan WM, Culver DH, White JW, Emori TG, Mosser J. et al. Update from the SENIC project. Hospital infection control: recent progress and opportunities under prospective payment. *Am J Infect Control* 1985; 13(3):97-108.
21. Guinard S. Long-term care resident profile from 1992 to 2004. 2005. Toronto: Ministry Of Health and Long-Term Care.
22. Anton HA, Chambers K, Clifton J, Tasaka J. Clinical utility of a portable ultrasound device in intermittent catheterization. *Arch Phys Med Rehabil* 1998; 79(2): 172-5
23. Jacobsen SJ, Girman CJ, Roberts RO, Rhodes T, Guess HA, Lieber MM. Natural history of prostatism: risk factors for acute urinary retention. *J Urol* 1997; 158(2):481-7.
24. Rosseland LA, Stubhaug A, Breivik H. Detecting postoperative urinary retention with an ultrasound scanner. *Acta Anaesthesiol Scand* 2002; 46(3): 279-82
25. Bodker B, Lose G. Postoperative urinary retention in gynecologic patients. *Int Urogynecol J* 2003; 14(2): 94-7
26. McCliment JK. Non-invasive method overcomes incontinence. Program retrains residents to recognize the urge to void. *Contemp Longterm Care* 2002; 525(5).
27. Abdel-Fattah M, Barrington JW. The accuracy of Bardscan: a new tool for the measurement of the bladder volume. *J Obstet Gynaecol* 2005; 25(2): 186-8
28. De Ridder D, Van Poppel H, Baert L, Binard J. From time dependent intermittent self-catheterisation to volume dependent self-catheterisation in Multiple Sclerosis using the PCI 5000 BladderManager®. *Spinal Cord* 1997; 35:613-6.
29. Jaeschke R, Guyatt GH, Sackett DL, and the Evidence Based Medicine Working Group. How to use an article about a diagnostic test. *JAMA* 2006; 271(5):389-91.
30. Greenhalgh T. How to read a paper: Papers that report diagnostic or screening tests. *BMJ* 1997;(315):530-3.
31. Ding YY, Sahadevan S, Pang WS, Choo PW. Clinical utility of a portable ultrasound scanner in the measurement of residual urine volume. *Singapore Med J* 1996; 37(4): 365-8
32. Huang YH, Bih LI, Chen SL, Tsai SJ, Teng CH. The accuracy of ultrasonic estimation of bladder volume: a comparison of portable and stationary equipment. *Arch Phys Med Rehabil* 2004; 85(1): 138-41
33. Goode PS, Locher JL, Bryant RL, Roth DL, Burgio KL. Measurement of postvoid residual urine

with portable transabdominal bladder ultrasound scanner with urethral catheterization. *Int Urogynecol J* 2000; 11(5): 296-300

34. Alnaif B, Drutz HP. The accuracy of portable abdominal ultrasound equipment in measuring postvoid residual volume. *Int Urogynecol J* 1999; 10(4): 215-8
35. Brouwer TA, Eindhoven BG, Epema AH, Henning RH. Validation of an ultrasound scanner for determining urinary volumes in surgical patients and volunteers. *J Clin Monit Comput* 1999; 15(6): 379-85
36. Moselhi M, Morgan M. Use of a portable bladder scanner to reduce the incidence of bladder catheterisation prior to laparoscopy. *BJOG* 2001; 108(4): 423-4
37. Moore DA, Edwards K. Using a portable bladder scan to reduce the incidence of nosocomial urinary tract infections. *Medsurg Nurs* 1997; 6(1): 39-43
38. Ireton RC, Krieger JN, Cardenas DD, Williams-Burden B, Kelly E, Souci T et al. Bladder volume determination using a dedicated, portable ultrasound scanner. *J Urol* 1990; 143(5): 909-11
39. Fakhri S, Ahmen MMH, Allam SH, Akbar M, Eyadeh AA. Advantages of using a portable ultrasound bladder scanner to measure the postvoid residual urine volume in spinal cord injury patients. *Kuwait Med J* 2002; 34(4):286-8.
40. Teng CH, Huang YH, Kuo BJ, Bih LI. Application of portable ultrasound scanners in the measurement of post-void residual urine. *J Nurs Res* 2005; 13(3): 216-24
41. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; 1(8476):307-10.
42. Philips JK. Integrating bladder ultrasound into a urinary tract infection reduction project. *Am J Nurs* 2000; 100(3):S3-12.
43. Wooldridge L. Ultrasound technology and bladder dysfunction. *Am J Nurs* 2000; 100(6):S3-11.
44. Canadian Institute for Health Information. Ontario's complex continuing care population: five-year trends in selected clinical characteristics 1999-2000 to 2003-2004. 2005.
45. Wu J, Baguley IJ. Urinary retention in a general rehabilitation unit: prevalence, clinical outcome, and the role of screening. *Arch Phys Med Rehabil* 2005; 86(9): 1772-7
46. Tam C, Wong K, Yip W. Incomplete bladder emptying in elderly wards [abstract]. Bridging basic science and clinical practice. Proceedings of the 35th Annual Meeting of the International Continence Society, Montreal, (Canada); August 28-September 2, 2005. 2005.
47. Stark RP, Maki DG. Bacteriuria in the catheterized patient. What quantitative level of bacteriuria is relevant? *N Engl J Med* 1984; 311: 560-4
48. Frenchman I. Cost of urinary incontinence in two skilled nursing facilities: a prospective study. *Clin Geriatr* 2001; 9(1): 49-52
49. Canadian Urological Association. Urinary incontinence guidelines of the Canadian Urological Association. Draft [report on the Internet]. June 2005. Canadian Urological Association. [cited

2006 Jan. 12]. Available at: http://www.cua.org/guidelines/Incontinence%20Guideline_E.pdf

50. American Urological Association. AUA guidelines on the management of benign prostatic hyperplasia: diagnosis and treatment recommendations [monograph on the Internet]. AUA guidelines on the management of benign prostatic hyperplasia. 1994. [cited 2006 Jan. 15]
Available from:
http://www.auanet.org/timssnet/products/guidelines/main_reports/bph_management/chapt_1_appendix.pdf
51. Newman DK, Palmer MH. Incontinence and PPS: a new era. *Ostomy Wound Manage* 1999; 45(12): 32-50