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Evaluation of the BladderScan® in estimating bladder volume in paediatric patients

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Abstract *Objective:* To evaluate the reliability of estimates of bladder volume (BV) in children with the BladderScan BVI 9400 (BS) compared with the volume obtained at catheterization (CV).
Materials and methods: BV was measured using the BS in 50 children (age range 6 weeks—14 years) who required urinary catheter placement during surgery or urodynamic studies. BS measurements were taken prior to catheter insertion. BV was compared with CV.
Results: BS volumes ranged from 0 to 513 mL (mean = 79 mL, median = 34 mL) and CV from 0 to 500 mL (mean = 81 mL, median = 31 mL). There was high correlation between the BS and CV measures (rho = 0.96). The mean difference between BS and CV volumes was −2.1 mL (SD 21). Where the CV $\leq$ 100 mL the BS volumes ranged from 0 to 84 mL (mean = 74 mL, median = 30 mL) and the CV from 0 to 88 mL (mean = 76 mL, median = 25 mL) (rho = 0.89). The mean difference = 0.5 mL (95% limits of agreement $\pm$ 23 mL). In a small sample of 12 children <36 months, correlation between BS and CV volumes was not as strong with rho = 0.82.
Conclusions: Overall the BladderScan showed a high correlation with catheter volume and there was good clinical agreement between the measures.

Introduction

Urethral catheterization is regarded as the "gold standard" for accurately measuring bladder urine volumes in patients. A key component for assessing children with voiding dysfunction is the measurement of bladder volume and post-void residual volumes and the need to repeat this assessment regularly in order to monitor progress. Despite its accuracy urethral catheterization is an invasive procedure with some risks and a major disadvantage of it is the discomfort and distress in children with a sensate urethra. This limits the usefulness of urethral catheterization to routinely monitor bladder function [1,2].

Ultrasonography (USS) is a proven, non-invasive, alternative method for assessing bladder volume and residual

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volumes. However, conventional ultrasound machines tend to be large and usually require attendance at a radiology department and the availability of an ultrasonographer [1,2]. The increasing availability of automated portable ultrasound scanners has enabled patients to have their bladder assessment undertaken in the outpatient setting. These portable bladder scanners are quick to use, enabling serial examinations at the one outpatient visit. However, there is ongoing concern about the reliability of the portable bladder scanners in estimating bladder volume in paediatrics and there is conflicting results from several studies evaluating their reliability [1–5].

Several publications have demonstrated that USS scanning with volumetric bladder estimate prior to catheterization improves the yield of catheter specimen urine collections and suprapubic aspirate [6–10].

Studies utilizing earlier BladderScan BVI models have been inconclusive about the reliability in estimating bladder volumes in children. Several studies have compared standard USS with automated BladderScan models [1,5,11]. One study compared two automated devices with standard three-dimensional scanning. This study was conducted in healthy participants 18 years or older and relied on voided volumes to confirm the accuracy of the three devices. The study found the BladderScan BVI 3000 to have greater accuracy than the Bardscan, but both were less accurate than standard scanning [11]. Two studies involved comparing the BVI 2500 with standard USS. Both studies found a high correlation between the two methods, but Bland–Altman [12] analysis showed poor clinical agreement. The BVI 2500 in both studies tended to overestimate bladder volume when compared with standard USS [1,5].

One study of 40 children found that bladder volume estimates with the BVI 2500 had a good correlation with catheter volumes (coefficient of correlation = 0.93) for volumes of 0–300 mL, but only "reasonable" correlation overall (coefficient of correlation = 0.76) [2], whereas another with the BladderScan BVI 6200 found poor correlation between initial catheter drainage volumes and sterile volumes introduced via the catheter for purposes of the study [3]. In a small number of neonatal patients with complex renal tract pathology the BladderScan BVI 3000 was found to have poor correlation with catheter volumes [13], whereas another study utilizing the BVI 3000 found it to have a good correlation with bladder volumes in patients with post-operative urinary retention (i.e. high volume bladders) if the patients were over 3 years of age but tended to underestimate the volume in those less than 3 years. Studies involving the BVI 6200 and BVI 3000 tended to underestimate bladder volumes compared with catheterisation [3,4,14].

The BladderScan BVI 9400 (Verathon) is the latest model and due to its recent introduction there is limited data on its accuracy in the paediatric clinical setting. The purpose of this study was to evaluate the accuracy of BVI 9400 in estimating bladder volumes in the paediatric population.

Materials and methods

Our study was conducted in a tertiary paediatric hospital by the department of surgery and urology. Both National (CEN/11/03/012) and Institutional ethics approval was obtained and data were collected between April and September 2011.

Children who were under the care of the two paediatric urologists and were scheduled for urodynamics or surgery, where urethral catheterization would occur, were eligible for enrolment in the study. Written informed consent was obtained from each participant's parent or legal guardian.

The aim of the study was to evaluate the reliability of the BladderScan BVI 9400 in estimating bladder volume in children compared to the volume obtained by catheterisation. A previous study ($n = 40$) found a correlation of at least 0.76 between the BladderScan BVI 2500 and catheterization in children [2].

Therefore it was calculated that a sample size of 50 would provide a 95% CI of approximately ± 0.12 for that correlation. For a paired t test this would have a $>90\%$ power to detect an average difference of 10 mL between methods (assuming the SD of the differences is 20 mL). With the Bland–Altman agreement analysis this sample size would give levels of agreement with 95% CI of approximately ± 10 mL (approx. 0.5 times the SD of the differences). Data analysis was undertaken using the StatsDirect Ver.2.7.8 software (StatsDirect Ltd, Altrincham, UK).

For the children having surgery, the BS was done following anaesthetic induction (GA) and prior to catheter insertion ($n = 45$). The children having urodynamic studies underwent BS measurement prior to the urodynamic catheter being inserted ($n = 14$). We found no difference in the BS ability to produce "on target" scans between the children under GA or awake. A second BS measurement was obtained at the end of the urodynamic study prior to removal of the catheter and emptying the bladder. The urodynamic catheters used were 8-Fr non-balloon catheters and did not interfere with the BS.

A total of 59 BS measurements were done. The majority of the BS ($n = 38$) were performed by one of the paediatric urologists, 14 were performed by the nurse specialist on patients not going to theatre, and the remainder by the second paediatric urologist.

The BladderScan BVI 9400 measures ultrasonic reflections on multiple planes producing a three-dimensional image whereby it calculates the bladder volume. The BVI 9400 provides distinct scan modes for men, women, and small children (<27 kg). The BVI 9400 enables repeated scans to be taken rapidly. The scans were performed until they were "on target" indicated by eight flashing arrows on the probe and the bladder outline was shown in the cross-hairs on the console screen. For this study three "on target" scans were obtained for each participant and the average of these used as the BS volume. There was good agreement within the sets of three repeat BladderScan readings. The intraclass correlation coefficient was 0.97, and the average absolute difference between repeated measures was 14 mL (range 0–172 mL).

Results

Fifty children, 12 females and 38 males were enrolled in the study, with nine presenting twice during the study period. Nine of the sets of readings were excluded due to technical or clinical issues. These were (a) inability to obtain three BS which were all 'on target' ($n = 2$), (b) difficulty with urethral instrumentation resulting in inaccurate CV measurements ($n = 5$), and (c) two children with large irregular bladders where it was not possible to achieve an accurate BS or CV measurement.

The remaining 50 sets of measurements were used for comparison. The age range was 6 weeks—14 years (mean age = 6.2, median = 5).

The BS and CV measures were compared by correlation coefficient (Table 1 and Fig. 1), and using a Bland—Altman plot (Fig. 2).

The BS volumes ranged from 0 to 513 mL (mean = 79, median = 34) and the CV from 0 to 500 mL (mean = 81, median = 31). There was high correlation between the BS and CV measures (non-parametric correlation, rho = 0.96). The mean difference between the BS and CV volumes was −2.1 mL SD = 21). All results are based on the average of each participant's results. There was no material difference between these results and those based on the manufacturer recommended highest measured volume (rho = 0.96, mean difference = 9.1 mL).

As we were primarily interested in the ability of the BladderScan to estimate residual volumes, we re-analysed the data using only the measures where CV was 100 mL or less (Table 2 and Fig. 3).

For this group BS volumes ranged from 0 to 84 mL (mean = 74 mL, median = 30 mL) and the CV from 0 to 88 mL (mean = 76 mL, median = 25 mL). There was good clinical agreement with very little bias (0.5 mL) and 95% limits of agreement of ±23 mL and a good correlation between BS and CV measures (rho = 0.89).

We also decided to re-analyse the data for the 12 patients less than 36 months (6 weeks—2 years, mean = 1.03 years, median = 0.96 months) (Table 3 and Fig. 4). BS volumes ranged from 0 to 39 mL (mean = 14 mL, median = 13 mL) and the CV from 0 to 40 mL (mean = 16 mL, median = 14 mL). Correlation between BS and CV volumes was not as strong with rho = 0.82. The mean difference between the BS and CV volumes was −2.6 mL with 95% limits of agreement of ±16 mL.

Discussion

Urethral catheterization is usually distressing and uncomfortable for children with a normal sensate urethra and parents are reluctant to allow repeated catheterizations. The development and availability of portable bladder ultrasound scanners (PBUS) offers a non-invasive alternative to catheterization. They can be used as a diagnostic aid to help determine bladder volume and effectiveness of bladder emptying. PBUS have improved the management of paediatric patients in the emergency department where they have been introduced. With young children presenting to emergency departments, it is often necessary to obtain a catheter urine specimen (CSU) in order to rule out a urinary tract infection. PBUS have been shown to greatly improve the success rate of first time CSU by ensuring there is sufficient urine in the bladder for a urinalysis and culture before catheterization [6—10]. Another area where the PBUS can be useful in reducing unnecessary catheterisation is in determining urinary retention in post-operative children [4].

Post-void residual urine measurements are a key management tool for children with dysfunctional voiding. In our institution this has been undertaken by the radiology department following referral from the urologist, and usually

Table 1 Correlation and mean difference for BladderScan BVI 9400 (BS) and volume obtained at catheterization (CV) ($n = 50$).

		95% CI
Non-parametric correlation (rho)	0.96	(0.92—0.97)
Parametric correlation (r)	0.98	(0.97—0.99)
Mean difference (mL)	−2.1	(−8.2 to 4.1)

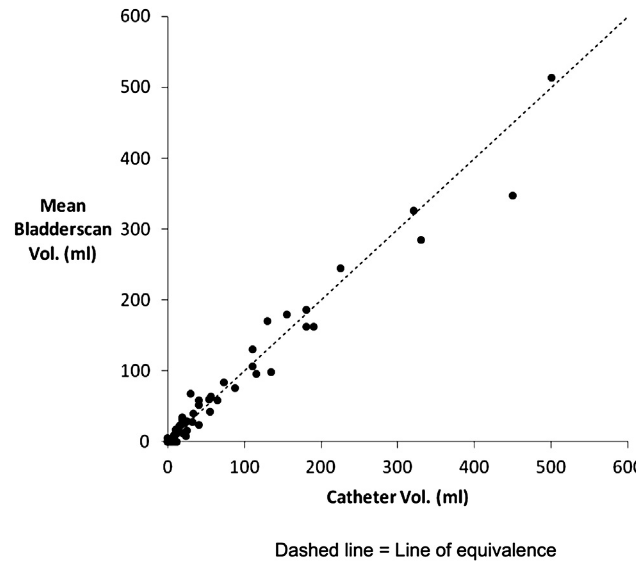

Figure 1 Scanned volume versus catheter volumes with line of equivalence shown.

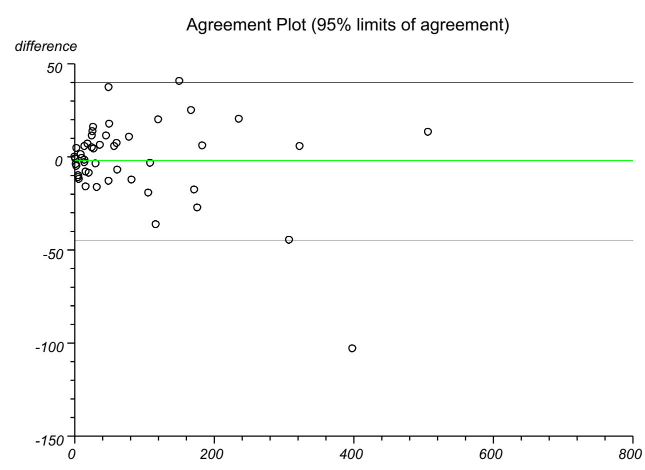

Figure 2 Bland—Altman analyses of BladderScan BVI 9400 (BS) and volume obtained at catheterization (CV) ($n = 50$). Mean of BS and CV (x-axis) plotted against difference of BS minus CV (y-axis) with 95% limit of agreement and mean difference (bias) indicated by the horizontal lines.

Table 2 Correlation and mean difference for BladderScan BVI 9400 (BS) and volume obtained at catheterization (CV) ≤100 mL ($n = 36$).

		95% CI
Non-parametric correlation (rho)	0.89	(0.79–0.94)
Parametric correlation (r)	0.89	(0.64–0.92)
Mean difference (mL)	0.5	(−3.3 to 4.3)

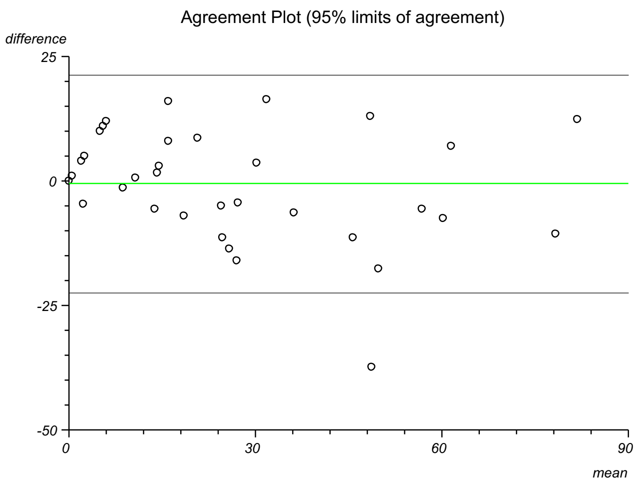

Figure 3 Bland–Altman analyses of BladderScan BVI 9400 (BS) and volume obtained at catheterization (CV) ≤100 mL ($n = 36$). Mean of BS and CV (x-axis) plotted against difference of BS minus CV (y-axis) with 95% limit of agreement and mean difference (bias) indicated by the horizontal lines.

necessitates another visit by the child and family for the ultrasound scan. Last year our surgical and urology department decided to investigate the purchase of a portable bladder scanner for use in the outpatient setting in order to streamline the number of visits children with dysfunctional voiding required. The availability of a suitable bladder scanner to measure residual urines in the outpatient clinic would reduce the number of hospital attendances.

A review of the literature found that previous studies had shown them to be effective in determining the timing of catheterization for CSU and whether catheterization was required post-operatively. However, there was less convincing evidence in the literature as to whether portable bladder scanners were as accurate as conventional ultrasound or catheterization.

In our study we found the BVI 9400 to have a high correlation with catheter volumes with good clinical agreement. Anecdotally during our study we found the BVI 9400 to have a higher accuracy with smaller bladder volumes. This was borne out when we analysed the results where the catheter volume was ≤100 ml that there was a high correlation and good clinical agreement with smaller bladder volumes.

Table 3 Correlation and mean difference for BladderScan BVI 9400 (BS) and volume obtained at catheterization (CV) ≤36 months ($n = 12$).

		95% CI
Non-parametric correlation (rho)	0.82	(0.39–0.94)
Parametric correlation (r)	0.79	(0.45–0.95)
Mean difference (mL)	−2.6	(−7.7 to 2.4)

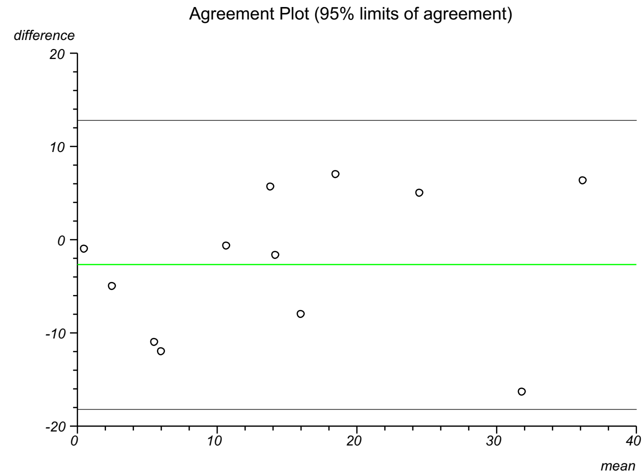

Figure 4 Bland–Altman analyses of BladderScan BVI 9400 (BS) and volume obtained at catheterization (CV) ≤36 months ($n = 12$). Mean of BS and CV (x-axis) plotted against difference of BS minus CV (y-axis) with 95% limit of agreement and mean difference (bias) indicated by the horizontal lines.

Several previous studies [1,4,13] have highlighted that portable bladder scanners tend to be unreliable in children less than 36 months. Two of these [1,4] analysed their data for children less than 36 months of age separately, so we looked at the data we had for children <36 months who were eligible for enrolment during our study period. Our study was not specifically focused on children less than 36 months of age group but 12 patients under 36 months of age were enrolled. Our results showed an improvement in the accuracy of the BVI 9400 in this age group, compared with the previous two studies where the BVI 2000 [1] and BVI 3000 [4] were used. A limitation of our study is the small cohort of patients less than 36 months compared with the previous two studies. We had only 12 patients less than 36 months compared with 41 [1] and 22 [4] patients. Therefore, a robust study to measure the accuracy of the BladderScan in this age group would be beneficial.

A further limitation of our study could be that we did not radiologically verify complete bladder emptying with the catheterization. However catheterization was carried out by experienced personal so we would expect reliable drainage in the majority of cases.

Conclusion

Overall the BladderScan BVI 9400 showed a high correlation with catheter volume and there was good clinical agreement between the measures. Despite this, it should still be used with caution in children <36 months. The BVI 9400 in conjunction with an uroflowmetry monitor can provide a reasonably comprehensive assessment for children with dysfunctional voiding problems. The BVI 9400 is quick and easy to use and allows for serial measurements and can be undertaken tin the outpatient setting.

Conflict of interest

We thank Verathon Medical (Australia) for unconditionally loaning the department the BladderScan BVI 9400 for the duration of the study. The study was undertaken independently of Verathon, who were not involved in any capacity in the study design, collection or analysis of the data.

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