Bladder volume correction factors measured with 3D ultrasound and BladderScan

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Introduction: *The aim of this study was to investigate conventional 3D ultrasound and portable BladderScan volume measurements and implement correction factors to ensure accurate volume metrics.*

Materials and methods: *Healthy participants without urinary urgency were recruited for a prospective hydration study in which three consecutive voids were analyzed for two separate visits. Just before and after voiding, 3D ultrasound and BladderScan volumes were measured. Estimated voided volumes were calculated as the volume immediately prior to void minus any post void residual and were compared to actual voided volumes measured using a graduated container. Percent errors were calculated, and an algebraic method was implemented to create correction factors for 3D ultrasound and BladderScan.*

Results: *Sixteen individuals completed the study, and six voids were recorded for each participant. A total of 96 volume measurements ranging from 0 mL to 1050 mL with an average of 394 ± 26 mL were analyzed. Both 3D ultrasound and BladderScan significantly underestimated voided volumes with averages of 296 ± 22 and 362 ± 27, respectively. Average percent error for the 3D ultrasound group was 30.1% (pre-correction) and 20.7% (post-correction) ($p < 0.01$) and 22.4% (pre-correction) and 21.8% (post-correction) for the BladderScan group ($p = 0.20$). The voided volume correction factors for 3D ultrasound and BladderScan were 1.30 and 1.06, respectively.*

Conclusion: *BladderScan and 3D ultrasound typically underestimate voided volumes. Correction factors enabled more accurate measurements of voided volumes for both 3D ultrasound and BladderScan. Accurate volume measurements will be valuable for the development of non-invasive urodynamics techniques.*

Key Words: urinary bladder, ultrasonography, medical imaging

Introduction

Accurate measurement of bladder volume during filling is critical for diagnosis and treatment of all forms of voiding dysfunction. The real-time measurement of bladder volume is a central component of multi-channel urodynamics which remains the gold standard tool for diagnosis. However, urodynamics requires urethral catheterization which is uncomfortable, expensive and exposes the patient to potential complications such as infections, urethral trauma and scarring.[1-3] In addition, the invasive nature of urodynamics as well as the artificial setting and the supra-physiologic fill rates can lead to significant artifacts and challenges in interpretation. This was shown in a study by Erdem et al[4] where many subjects achieved International Continence Society defined verbal sensory thresholds[5] with only "sham" filling.

Furthermore, accurate knowledge of bladder volume is necessary for treatment of patients with

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overactive or underactive bladders.[6] For example, symptoms of urinary frequency and urgency may be caused by incomplete bladder emptying as opposed to reduced bladder capacity. In this regard, bladder volume is directly correlated with bladder function, which can be affected by numerous factors including blood flow, pressure, and compliance.[7,8]

Because detailed knowledge of filling volumes is so important in both diagnosis and treatment of voiding dysfunction, and because of the inherent limitations of invasive urodynamics testing, there is a pressing need to develop non-invasive ultrasound-based assessments of real-time filling volume. New ultrasound technologies are being developed which may ultimately lead to non-invasive methods able to produce comparable data to urodynamics.[8] However, successful implementation of these technologies that could ultimately serve as adjuncts to, or replacements for, urodynamics will likely require detailed studies confirming their diagnostic accuracy. Two currently available non-invasive methods for real-time bladder volume assessment include conventional 3D ultrasound and portable-ultrasound-based BladderScan. Therefore, the purpose of this study was to compare the accuracy of these methods and create correction factors to improve measurement accuracy during oral hydration studies. For this study, we chose to study healthy, asymptomatic volunteers because a previous 3D ultrasound investigation showed that individuals with overactive bladder may have abnormal bladder shapes that might affect volume assessments.[9]

Materials and methods

Recruitment

The prospective study was approved by the Institutional Review Board. All participants were healthy volunteers who had no known medical conditions or were on any medications that could affect bladder function. The assessment of "healthy" was based on an intake history detailing all medical conditions and active medications. Participants were recruited using approved printed flyers or electronic flyers posted on social media. All participants completed the International Consultation on Incontinence Modular Questionnaire for Overactive Bladder (ICIQ-OAB)[10] which assesses the severity of four common symptoms of overactive bladder including frequency (Q3a), nocturia (Q4a), urgency (Q5a), and urge incontinence (Q6a) on a scale of 0 (never), 1 (occasionally), 2 (sometimes), 3 (most of the time), or 4 (all of the time). To be included, participants were required to score ≤ 1 on all questions. Participants' medical history, demographics, and BMI were also recorded.

Hydration protocol

This study analyzed bladder volume data from three consecutive voids as part of a hydration study to assess bladder sensation. The identical protocol was repeated after 1 week at the same time of day and after consuming similar foods and beverages which were recorded on a food and beverage diary on the day of each study. Therefore, a total of six voids were analyzed for each participant. Voiding occurred on presentation (preliminary void: variable bladder volume) and then two more times after reaching sensory capacity, defined as reaching 100% sensation on our previously described sensation meter.[11,12] Voiding occurred into graduated 1000 mL collection devices, and the obtained volumes were used as controls.

3D ultrasound

3D bladder images were acquired trans-abdominally at sensory capacity and immediately after voiding using a GE Voluson E8 system (Madison, WI, USA) with a 3D convex 4-8.5 MHz transducer. All images were obtained by trained personnel, saved and analyzed on GE's 4D View software (Version 14, GE Healthcare). Using the Virtual Organ Computer-aided Analysis (VOCAL), 3D images were manually traced by trained research assistants in six planes that were 30° apart. The VOCAL software automatically combined these cross-sections into a continuous rendered volume, Figure 1. Smaller step sizes were found to have similar results in measurements when compared to the 30° step size, based on prior analysis and by past

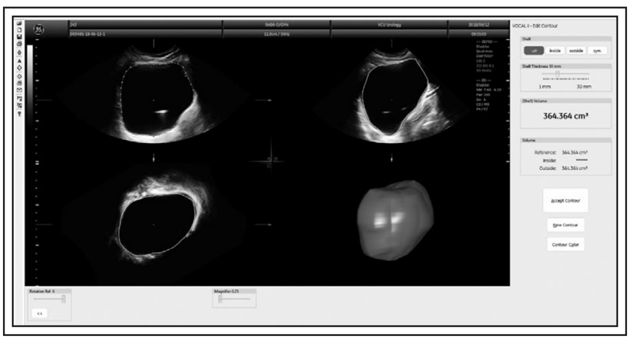

Figure 1. 3D volume measurements developed through VOCAL tracing. The 3D bladder image is presented in three planes: transverse (top left), sagittal (top right), and coronal (bottom left). The transverse plane is traced using VOCAL, which produces an automatic perimeter for the sagittal and coronal planes, to confirm accuracy. The bottom right image is a 3D model of the bladder constructed by the software through the combination of the three planes.

studies.[13] The 3D bladder volumes were obtained from the software's display of the constructed volume and following previously published methods.[14,15]

BladderScan

BladderScan volumes were measured using a Verathon BladderScan BVI 9400 System (Verathon, Bothell, WA, USA) with NeuralHarmonics technology. The portable BladderScan probe was placed trans-abdominally on the participant at the same location the conventional ultrasound probe had been placed to obtain a bladder image which was automatically converted into a bladder volume. To ensure accuracy, three bladder scans were acquired and averaged at sensory capacity and immediately after voiding. BladderScan images were acquired sequentially, immediately following acquisition of 3D ultrasound images.

Correction factors

Because the graduated container volumes were used as control values, a unity line in which all X values = all Y values was constructed using these volumes. All volume measurements for BladderScan and 3D ultrasound were calculated as the pre-void (sensory capacity) measurement minus the post-void measurement. Average volumes were calculated using each of the three methods, Figure 2a, and 3D ultrasound and BladderScan measurements were plotted against the graduated container volumes (unity lines in Figures 3 and 4). A regression line going through the origin was created in Microsoft Excel with the form Y = mX where m is the slope of the line. To adjust for differences, a correction factor was created by taking the inverse of the slope (1/m). This correction factor was then multiplied to each value to create a corrected regression line. Percent errors were calculated by comparing the measured volume to the reference voided volume.

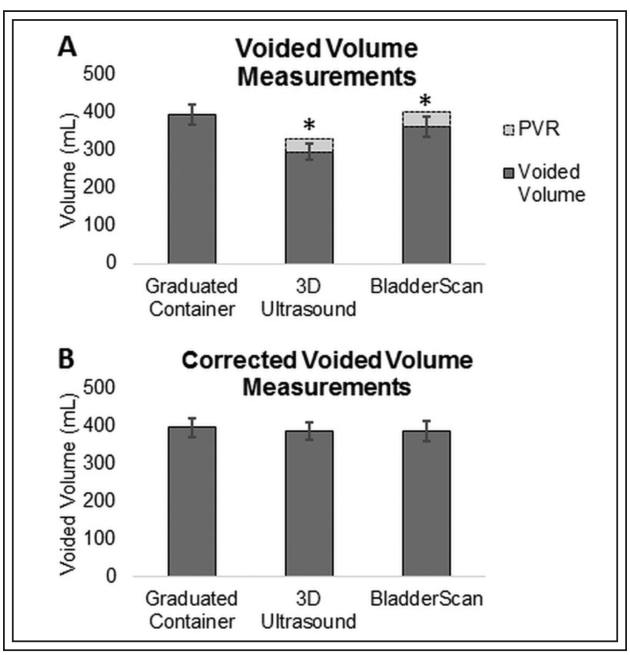

Figure 2. A) Comparison of averaged voided volumes (dark gray, n = 96) from the graduated container, 3D ultrasound and BladderScan (*p < 0.001). For the 3D ultrasound and BladderScan methods, voided volumes were calculated by subtracting post-void residual volumes (light gray) from pre-void volumes (dark gray + light gray). **B)** Comparison of averaged corrected volumes (n = 96) from the graduated container, 3D ultrasound and BladderScan.

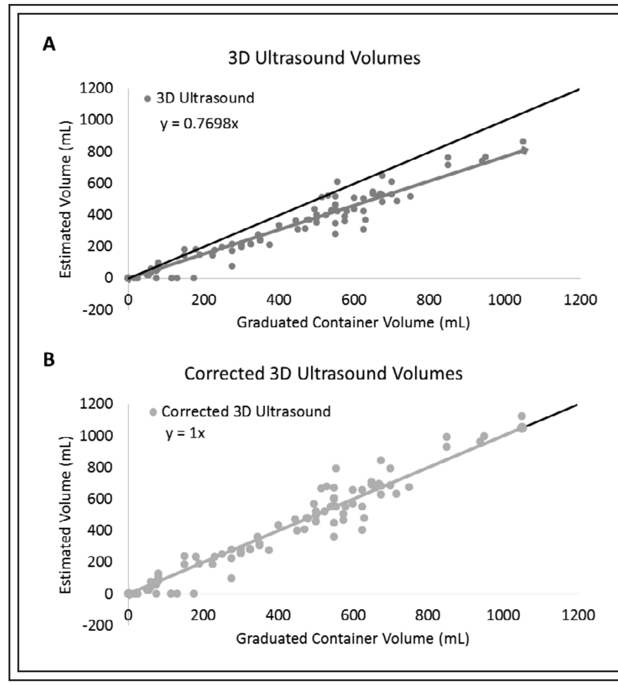

Figure 3. A) Volumes measured by 3D ultrasound (gray dots) and corresponding regression line (gray line) compared to controls obtained from the graduated container (black line with slope = unity). **B)** 3D ultrasound data after the application of a correction factor of 1.30 (1/original slope) over the range of volumes (gray dots) and the corresponding regression line (gray line) with a slope of unity.

Statistical analysis

All data are reported as means ± standard error. Percent error values were calculated using Excel software. Statistical comparisons were also made using Excel software with paired students t-tests with $p < 0.05$ considered significant.

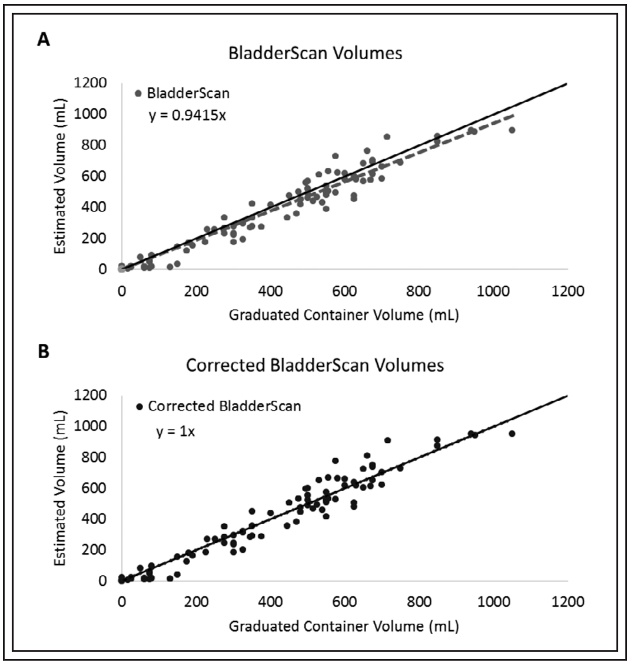

Figure 4. A) Volumes measured by BladderScan (gray dots) and corresponding regression line (dashed line) compared to controls obtained from the graduated container (black line with slope = unity). **B)** BladderScan data after the application of a correction factor of 1.06 (1/original slope) over the range of volumes (black dots) and the corresponding regression line (dashed line) with a slope of unity.

Results

A total of 16 participants, six male and ten female, were recruited for the study, providing a total of 96 voids for volume analysis. Mean age was 24 ± 1.3 with a mean body mass index (BMI) of 23.0 ± 0.8 kg/m^2. ICIq-OAB symptom scores were 0.25 ± 0.11 (3a: frequency), 0.44 ± 0.13 (4a: nocturia), 0.0 ± 0.0 (5a: urgency), and 0.0 ± 0.0 (6a: urge incontinence). When comparing the average of all voided volumes, the graduated container was 394.0 ± 26.3 mL, 3D ultrasound was 296.1 ± 22.2 mL, and BladderScan was 362.1 ± 27.0 mL. Both ultrasound and BladderScan significantly underestimated the actual voided volumes ($p < 0.001$), Figure 2a.

3D ultrasound

All 3D ultrasound values were plotted as a function of graduated container volumes, Figure 3a. The line of regression was visibly lower (slope of 0.770) than actual voided volumes as measured by the graduated container volumes. A correction factor of 1.30 (determined by taking 1/slope) was implemented, Figure 3b.

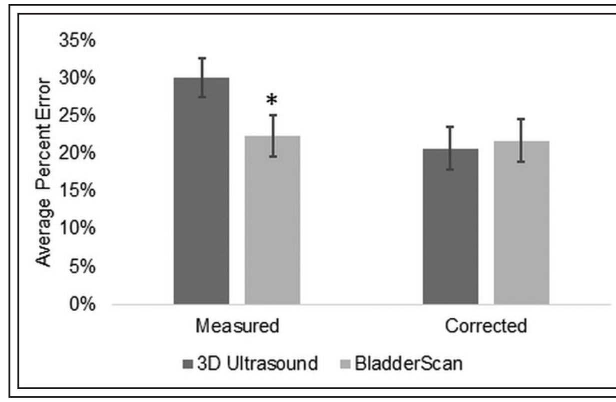

Figure 5. Average percent errors from 3D ultrasound (dark gray) and BladderScan (light gray) using both the measured data (left) and corrected data (right). *$p < 0.01$.

BladderScan

All BladderScan values were plotted as a function of graduated container volumes, Figure 4a. The line of regression exhibited a lower slope (0.942) than the actual voided volumes. A correction factor of 1.06 (determined by taking 1/slope) was implemented, Figure 4b.

When the averages of all of the corrected volumes for 3D ultrasound and BladderScan were compared, there were no significant differences, Figure 2b. The average percent error for the 3D ultrasound group was 30.1% (pre-correction) and 20.7% (post-correction) ($p < 0.01$). The average percent error for the BladderScan group was 22.4% (pre-correction) and 21.8% (post-correction) ($p = 0.20$). However, accuracy of post-corrected volumes did not differ between the 3D ultrasound and BladderScan methods ($p = 0.78$), Figure 5.

Discussion

This study analyzed a broad range of bladder volumes in healthy volunteers in order to determine the most accurate non-invasive measurement method. The results demonstrate that both modalities significantly underestimated true voided volumes. In addition, BladderScan was found to be more accurate than 3D ultrasound, but correction factors were used to improve measurement accuracy for both techniques.

There is a pressing need for accurate, real-time measures of filling volume as this information will be required in the ongoing development of novel, non-invasive techniques that can supplement or even replace urodynamics. Examples of these novel techniques include ultrasound-based assessments of bladder shape,[9] bladder biomechanics,[8] bladder vibrometry,[16] and wall thickness.[17] These methodologies are starting to provide previously undefined information about the filling phase. In this regard, BladderScan would be ideal for the simple assessment of bladder filling volumes and 3D ultrasound could provide additional anatomic and diagnostic data. Although more accurate volume assessments could be performed by direct catheter instillation of known volumes of saline, the goal of the current investigation was support the on-going development of non-invasive oral hydration studies. Current non-invasive methods of clinically assessing bladder volume include 3D-ultrasound and BladderScan. Ultrasound technology has advanced over the years and now includes software to perform volumetric calculations and is capable of imaging deep tissue.[18,19] BladderScans use the same technology, while remaining less expensive and portable. 3D Ultrasound can be inefficient when determining bladder volume, usually producing significant percent errors.[20] Likewise, BladderScans have been shown to be associated with significant error, especially in determination of post-void residuals.[21,22] However, the current investigation demonstrated that correction factors can be used to improve accuracy for both technologies. The greater accuracy of the BladderScan compared to 3D ultrasound in the present study may have been influenced by the averaging of multiple BladderScan values or the nature of this protocol which involved sequential bladder volume measurements of at five minute intervals throughout filling.

In a similar study, the accuracy of bladder volume measurement based on different bladder shapes was determine using the AvantSonic Bladder Scanner Z5 portable ultrasonographic.[23] In this study, the authors used urodynamic methodologies on patients grouped by the Bladder Deformation Index (BDI) while our study used a non-invasive hydration protocol on healthy participants. Our study also verified conventional 3D ultrasound accuracy in addition to BladderScan accuracy, developing correction factors for both at different voided volumes.

Limitations of the current study include the small sample size and testing only on healthy individuals without urinary urgency. Furthermore, the analysis of data only at the time of voiding could limit applicability over the entire filling phase. In addition, the data were obtained using specific equipment which may not be applicable to other devices. To address the subject number, the study design utilized a repeated measures technique which provided data on six separate voids obtained over two separate study visits. To address the issue of healthy individuals, the goal was to measure bladder voided volume over a broad range, and individuals with overactive bladder would likely have smaller bladder capacities. Finally, the issue of measurement only at the time of voiding was necessary to provide a measurable control (voided volume) for comparison, and measurement was performed at both variable volumes (initial void on presentation) and at sensory capacity.

Conclusion

Overall, this study showed that 3D ultrasound and BladderScan both significantly underestimated actual voided volume, and BladderScan had better accuracy. However, application of correction factors throughout the range of filling volumes demonstrated improved measurement accuracy. The results of this study could be used to enable accurate bladder volume measurements for the development of non-invasive supplements or alternatives to urodynamics. ☐

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