

### HYPOTHESIS / AIMS OF STUDY

Lower urinary tract symptoms (LUTS) have been universally recognized since the standardization of the urinary tract function terminology by the International Continence Society in 2002.<sup>1</sup> Various assessment methods are utilized, including the assessment of post-void residual volume to determine the type of LUTS. A common manual method of determining bladder volume from two-dimensional (2D) ultrasound images uses the prolate ellipsoid method, which requires three bladder measurements be taken as follows: in the transverse plane, the height (D1) and width (D2) and in the sagittal plane, the diameter (D3). This assessment is done manually by the US operator using on-screen calipers. The formula is  $L \times W \times H \times 0.52$ .<sup>2</sup> This process is repetitive and time-consuming due to many factors.

### STUDY DESIGN, MATERIALS AND METHODS

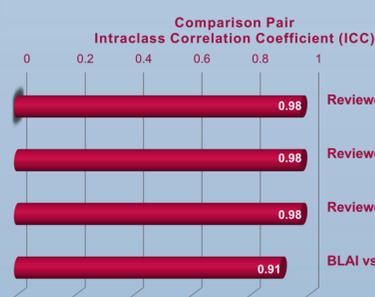
Fifty-eight subjects (18 Males: 40 Females), with a mean age of 31 years (range 21 – 61) and a mean BMI of 26.88 kg/m<sup>2</sup> (range 18 – 45) were recruited for this prospective non-inferior study. Three physical therapists (PTs) with ultrasound imaging experience performed all ultrasound scanning using a Clarius C3HD (curvilinear) and PAHD (phased array) scanner as subjects lay supine with the lower abdomen exposed to access the bladder. Sagittal and transverse images were uploaded to the Clarius Cloud and reviewed blindly by the three reviewers, who independently and manually measured the bladder volume, indicated the bladder view (sagittal or transverse), and traced the bladder wall for each image (Fig.1 A and B). The three blinded PT reviewers measured each bladder volume. The bladder's length, width, and height were measured, and volume was calculated via the prolate ellipsoid method ( $L \times W \times H \times 0.52$ ) (Fig 1. C and D). The absolute percent (%) difference between reviewer pairs was calculated and compared to the absolute percent difference between automatic measurement and mean reviewer measurement using a one-sided t-test and an equivalence margin of 25%.<sup>2</sup> Inter-rater reliability (IRR) was determined via the Intraclass correlation coefficients (ICC) using Bland-Altman plots, while the average Dice similarity coefficient and Jaccard similarity index determined the accuracy of image segmentation measurements.



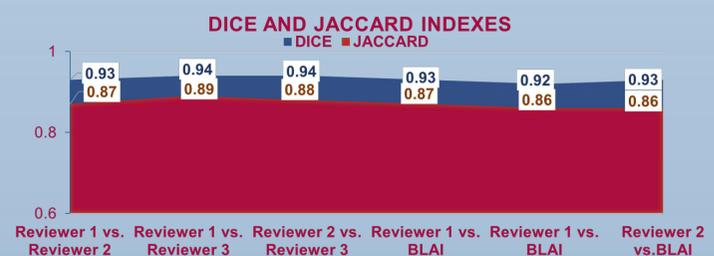
**Figure 1. Transverse and Sagittal images**  
A & B show bladder traces used during machine learning process; C & D show BLAI overlay showing auto placement of calipers to volume. E shows the realtime BLAI process

### RESULTS

The BLAI volume measurement was found to be non-inferior ( $p < .001$ ), with the mean difference between percent differences of the human measurement and BLAI means of  $-0.0228$  (95% CI  $-0.074, 0.028$ ). Bland-Altman plots showed tight clustering of bladder volume measurements between BLAI and human measurements indicating strong overall agreement with individual human measurements. The ICC showed strong agreement between all reviewers, and between BLAI and reviewer mean (Table 1). Dice and Jaccard coefficients showed strong agreement between the BLAI model compared to each reviewer and between each reviewer pair (Table 2).



**Table 1. Comparison Pair Intraclass Correlation Coefficient**  
There was a high degree of agreement between reviewer (human) bladder volume measurement and between mean human reviewer volume assessment and BLAI.



**Table 2. DICE Index and Jaccard Similarity scores**  
Both indices were used to determine the similarity of human vs AI bladder volume assessment. A value of 1 indicates data sets are identical

### INTERPRETATION OF RESULTS

Overall, results confirm high levels of agreement and consistency across all bladder volume measurements (BLAI and human). The study's secondary objective to determine whether BLAI can correctly identify transverse and sagittal bladder views was also successfully met.

### CONCLUDING MESSAGE

- Accurately assessing bladder volume is crucial in determining a host of LUT conditions.
- Including BLAI can reduce measurement errors and improve efficiency, diagnostic accuracy, and the treatment of bladder-related conditions.
- BLAI provides real-time bladder volume measurements in seconds, which can benefit patients who require frequent bladder volume monitoring, allowing for more cost-effective care.
- Timely and accurate volume measurements can positively impact patient care and enable clinicians make informed decisions about patient management across multiple settings

### REFERENCES

1. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U., et al. Standardization Subcommittee of the International Continence Society. The standardization of terminology of lower urinary tract function: report from the standardization subcommittee of the International Continence Society. *Neurourol Urodyn* 2002;21:167–178.
2. Dicuio M, Pomara G, Menchini Fabris F, Ales V, Dahlstrand C, Morelli G. Measurements of urinary bladder volume: comparison of five ultrasound calculation methods in volunteers. *Arch Ital Urol Androl*. 2005 Mar;77(1):60-2. PMID: 15906795.
3. Matsumoto M, Tsutaoka T, Yabunaka K, Handa M, Yoshida M, Nakagami G, Sanada H. Development and evaluation of automated ultrasonographic detection of bladder diameter for estimation of bladder urine volume. *PLoS One*. 2019 Sep 5;14(9):e0219916. doi: 10.1371/journal.pone.0219916. PMID: 31487299; PMCID: PMC6728037.