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PRELIMINARY RESULTS OF A CLINICAL TRIAL USING A NOVEL DEVICE FOR THE AUTOMATION OF MEASUREMENT OF VOIDED VOLUMES IN THE BLADDER DIARIES OF WOMEN WITH LOWER URINARY TRACT SYMPTOMS

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Introduction:

The care of women with LUTS remains challenging. Bladder diaries represent a first line, gold standard tool in assessing patients with LUTS. However, their accuracy has been challenged, as current estimates suggest errors of 10% [1] against an agreed international standard of physiological measurement of 3% [2]. Aim: The aim of this clinical trial is to compare the accuracy of the existing measurement method of voided volumes versus an automated method of measurement via a novel device.

Methods:

This is a prospective, single centre, cohort study of female adults presenting with LUTS in a tertiary teaching hospital over a 5-month period between September 2022 and January 2023.Eligible participants were asked to complete a consecutive 3-day bladder diary by voiding in the diary pod, whilst at the same time providing their estimates for the volumes voided.The participants were blinded to the automated diary pod measurements.The accuracy of the novel, electronic, cloud based, automatically generated, bladder diaries was then compared to the bladder diaries generated by the conventional eyeballing-estimate method of measuring voided volumes.Statistical analysis was performed using IBM-SPSS-Software-v.29.

Results:

A total of N=151 participants have been registered for the trial. Results from 24 healthy individuals and 26 women with LUTS were available for analysis at the time of writing.Mean age was 38.67 and 55.14 years respectively.There was no statistically significant difference between the diary parameters of the two methods, in any of the two groups as demonstrated in Table 1 & 2 respectively.

Discussion:

The preliminary results of our study are likely skewed, as the diameter of the diary pod used for voided volume estimation is far smaller than the conventional measuring jugs, thus, minimising the margin of error in estimation. Studies with larger sample size are needed to draw safe conclusions regarding the benefit of automated voided volume measurement.

References

1. BS EN ISO 3819:2015 - Laboratory glassware. Beakers [Internet]. [cited 2021 Mar 31]. Available from: https://shop.bsigroup.com/ProductDetail/?pid=000000000030283713

2. Rosier PFWM, Schaefer W, Lose G, Goldman HB, Guralnick M, Eustice S, et al. International Continence Society Good Urodynamic Practices and Terms 2016: Urodynamics, uroflowmetry, cystometry, and pressure-flow study. Neurourology and Urodynamics [Internet]. 2017 Jun 1 [cited 2021 Mar 31];36(5):1243–60. Available from: http://doi.wiley.com/10.1002/nau.23124