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Full length article

Reproducibility of the transvaginal sonographic assessment of bladder wall thickness

Suneetha Rachaneni[a,*], Lee Middleton[b], Anuradha Sajja[c], Moji Balogun[c], Jane Daniels[d], Pallavi Latthe[c], Jonathan Deeks[b]

[a] Department of Urogynaecology, Derriford Hospital, Derriford Hospital, Plymouth, UK
[b] Birmingham Clinical Trials Unit, University of Birmingham, Birmingham, UK
[c] Birmingham Women's Hospital Foundation Trust, Birmingham, UK
[d] Nottingham Clinical Trials Unit, University of Nottingham, UK

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ABSTRACT

Objective: To assess whether transvaginal sonographic measurements of bladder wall thickness (BWT) have adequate reproducibility to detect differences in BWT potentially indicative of detrusor overactivity in women with overactive bladder.

Study design: Three reproducibility studies were undertaken to assess (A) total measurement error, (B) intra-observer variability and (C) inter-observer measurement in the interpretation of scans. Women recruited to the Bladder Ultrasound Study underwent a transvaginal ultrasound scan to obtain a measurement of BWT. When a second observer was available, women who agreed to have two transvaginal scans by different operators were recruited into study A. For study B the first observer reassessed a sample of the recorded images at a later date whilst for study C, a random selection of BWT images were read by a second assessor. Analytical variability, percentage of variability attributable to measurement error, within-person variation and the smallest real difference detectable were estimated.

Results: One hundred and twenty-one women took part: 27 had repeat scans, 37 had scans re-read by the same observer, and 57 had scans read by two observers. In study A, 39% of the total variability in measurements was explained by measurement error (the remainder to within person change); the standard deviation (SD) of measurement error was 0.76 mm and the smallest detectable clinical difference was 2.1 mm. The SD of measurement error from scan interpretation was 0.42 mm within observers (study B) and 0.35 mm between observers (study C).

Conclusion: The high levels of measurement error for a small measurement of BWT means it is unlikely Transvaginal ultrasound measurements have insufficient reliability and reproducibility to be an accurate diagnostic test.

Introduction

Overactive bladder (OAB) is defined as urinary urgency with or without incontinence, increased frequency, or nocturia, in the absence of infection or other proven pathology [1]. Women who do not respond to initial conservative management are investigated by performing urodynamics(UDS). Patients find the test embarrassing, invasive and it is associated with a 5% risk of urinary infection [2]. Detrusor overactivity (DO) is diagnosed by urodynamics and is characterized by involuntary detrusor contractions during the filling phase that may be spontaneous or provoked [1]. Studies of transvaginal ultrasound measurement of BWT have indicated that women with DO may have thicker bladder walls [3] but it is uncertain whether the BWT can accurately replace urodynamics in the diagnosis of DO.

A minimum standard of reproducibility needs to be met for a diagnostic test to achieve adequate accuracy to have potential as a bedside test. Inter-observer reproducibility of BWT can be evaluated by studying the difference between blinded observers independently repeating the measurement in the same patient at different points of time. Reproducibility of BWT is of particular concern given the fact that bladder is distensible organ and its thickness is known to change with the amount of urine present in the bladder. Assessing the reproducibility of repeated interpretations of the same image, both between and within observers allows

* Corresponding author.
E-mail address: sunilalam@yahoo.com (S. Rachaneni).

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assessment of the degree to which image interpretation introduces measurement error.

The aim of this study was to assess whether measurements of BWT using transvaginal ultrasound have adequate reproducibility to be able to detect differences in BWT potentially indicative of DO, and to investigate the proportion of the measurement error which arises from interpretation of the image.

Objectives

The three key objectives were:

(a) To estimate the total variability due to measurement error in the complete scanning and interpretation process (Prospective interobserver variation).
(b) To estimate the intra-observer measurement error in interpreting images(Retrospective).
(c) To estimate the inter-observer measurement error in interpreting images(Retrospective).

Materials and methods

This reproducibility study was carried out as a part of a large multicentre study evaluating the accuracy of bladder wall thickness ultrasound in the diagnosis of detrusor overactivity (the BUS study) which was approved by Nottingham Research Ethics Committee (ethics no10/H0408/57) and funded by the National Institute of Health Research/Health Technology Assessment Board [4]. 'The BUS study was conducted from 2011 until 2013 and aimed to evaluate whether BWT measurement could replace urodynamics in women with OAB.'

Women with OAB were offered conservative measures like fluid management and bladder retraining as the initial management. Women who did not respond and required further management and who gave written informed consent were recruited into the study.

Inclusion criteria

Women with

1. Frequency of nine or more voids in 24 h as reported in a 3 day bladder diary (on at least on one of the days).
2. Urgency (cannot defer the urge to void) recorded on at least two occasions in the 3 day bladder diary.
3. PVR volume $\leq$ 100 ml on the screening bladder scan.
4. No stress incontinence surgery and/or BTX-A in the past 6 months.
5. Provided written informed consent.

Exclusion criteria

1. Current pregnancy or up to 6 weeks postpartum.
2. Pure symptoms of stress incontinence or stress-predominant mixed incontinence.
3. Evidence of cystitis (dipstick positive for leucocytes/nitrites).
4. Voiding difficulties (e.g. PVR of $>$ 100 ml).
5. Prolapse $>$ grade II (any compartment, as defined by the Pelvic Organ Prolapse (POP) Quantification system).93_
6. Previous UDS assessment in the past 6 months.
7. Use of antimuscarinics for more than 6 months continuously.
8. Current use of antimuscarinics (e.g. tolterodine, solifenacin, oxybutynin). If the woman was taking antimuscarinics at the point of consent, she was eligible if the medication was ceased immediately and there was a delay of at least 2 weeks before the index and reference tests were carried out.

Consecutive women fulfilling these criteria were approached to undergo both transvaginal ultrasound measurement of BWT and urodynamic investigations; these were done independently by investigators blinded to the results of the other test. The tests were performed according to standardised procedures for which the assessors underwent training and were certified by the investigators to have achieved competence. The study is based on measurements of BWT images and the details of the characteristics of included participants are described in the HTA monograph of BUS study (Table 3 https://dx.doi.org/10.3310/hta20070).

Though there were several ultrasound machines used in the study, the settings for all the scans were uniform. The probe frequency was 7–9 MHz and a gynaecological setting was used. The optimum urine volume in the bladder to measure transvaginal BWT is still a matter of debate. At bladder volumes between 0 and 50 ml, BWT was shown to be fairly constant [5]. In the current study, we measured BWT at a bladder volume $<$30 ml and if it was more, patient was advised to double void.

Measurements of BWT at the trigone, dome midline and anterior wall midline were made as per a standard operating procedure using 2-D transvaginal end firing probe, as shown in Fig. 1. The tip of the probe transducer was placed at the vaginal introitus to avoid pressing on the bladder wall to reduce the measurement error from distortion of the image. The reported BWT measurement was defined as the mean of the measurements made at the three locations ([trigone+ dome midline+ anterior wall midline]/3). The process of measurement required placing a calliper reference point on the image, using a mouse operated cursor on the electronic image, at the interface between the bladder wall and the adjacent tissue or lumen (Fig. 1). Images were saved with and without the calliper placement. For the prospective interobserver study, majority of the BWT measurements were carried out on the same day with the maximum time interval between two observer measurements being 4 weeks. The observers were blinded to each other's BWT measurement in the prospective study. For the purpose of the retrospective intraobserver and interobserver studies, the images without calliper placement were used where the observer was blinded to the initial measurement.

Three cohort studies were undertaken to address the three objectives:

In study A, to prospectively assess the inter-observer variability, 27 women underwent two separate ultrasound scans on the same day undertaken by different observers. The second scan and measurement of BWT was made blind to the measurement from the first observer. Three observers were used in total, all women received scans from observer one, followed by either observer two or observer three (Table 1). The sample was opportunistic and determined by the availability of observers.

In study B to retrospectively assess intra-observer measurement error, BWT was measured on 37 ultrasound images from individual participants by observer one. Repeat measurements were all made by observer one on the same Images 6–12 months later. All second measurements were made blind to the original measurement, using images without calliper marks. All images were obtained from women recruited at the Birmingham Women's Hospital, to enable them to be measured on the same scan machine.

In study C to retrospective assess inter-observer measurement error, BWT was measured on ultrasound images from 57 individual participants by a single observer, who was the clinician who recruited the most participants. Repeated measurement were made by one of 6 different observers on the same images, such that