Pelvic floor muscle assessment in men post prostatectomy: comparing digital rectal examination and real-time ultrasound approaches

ABSTRACT

This paper reports three studies. Study 1 assessed the degree of association between traditionally used digital rectal measures, and real-time ultrasound assessments of pelvic floor muscle function in men who report incontinence following prostatectomy. Study 2 compared transabdominal and transperineal approaches to view the pelvic floor using real-time ultrasound. Study 3 explored inter- and intra-observer reliability of two functional tests using real-time ultrasound: a rapid response test requiring participants to perform 10 rapid pelvic floor muscle contractions with elapsed time recorded, and a sustained endurance test wherein participants performed a single sustained pelvic floor muscle contraction with task failure visually confirmed and elapsed time recorded. A modest correlation was observed between the rectal assessment of squeeze pressure and objective perineometer measures (r=0.51, p<0.05). Rapid response test (r=0.18, p=0.36) and sustained endurance test (r=0.18, p=0.36) assessments were unrelated to pelvic floor muscle squeeze pressure measured by perineometry. Strong agreement was found using Bland-Altman analysis for both the rapid response and sustained endurance tests when they were performed using transabdominal and transperineal approaches, or when determining inter- and intra-observer reliability. The two simple functional tests using real-time ultrasound provide objective, non-invasive and reproducible assessment of pelvic floor muscle function that is more acceptable to men than rectal approaches.

Keywords: Men's health, pelvic floor muscle, prostate cancer, prostatectomy, physiotherapy, real-time ultrasound.

INTRODUCTION

Prostate cancer (PCa) is a global health problem and the second most commonly diagnosed cancer among men[1]. Radical prostatectomy (RP), involving complete removal of the prostate, is a standard surgical treatment performed via retropubic, perineal laparoscopy or robotic-assisted laparoscopic techniques[2,3]. After radical prostatectomy men report a high prevalence of urinary incontinence (UI) and erectile dysfunction (ED)[4-6], and compromised function of the pelvic floor musculature (PFM) is one of several contributing causes. Post-operative rehabilitative therapy includes strategies to improve PFM function, to address issues such as UI[7] and ED[8] that impact on quality of life. The objective of this three-part study was to assess tests of PFM function using real-time ultrasound (RTUS) to further enhance clinical practice.

The standard approach to assessing PFM function in men has involved digital rectal examination (DRE) and scoring of "squeezing" pressure on an ordinal scale (for example, Modified Oxford Scale)[8-11]. However, this approach only provides ordinal data and is described as physically invasive, psychologically challenging[12-17], possessing poor inter-observer reliability and lacking universal standardisation (studies predominantly undertaken in women)[18]. Aversion to this method of assessment is supported by research indicating the procedure induces a sense of shame and men are reluctant to receive DREs due to it being personally invasive[19,20]. In addition, rectal PFM strength assessment in men has been shown to be largely unrelated to male

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urinary function[21,22]. The muscles assessed during a DRE can include those related to anal sphincter function (external and internal anal sphincter and puborectalis).

Using RTUS assessment of PFM, function is observed as elevation at the base of the bladder during a PFM contraction and relaxation cycle[14]. Transabdominal real-time ultrasound (TrA RTUS) is a valid and reliable method for use in both men and women, although specific components of PFM that are associated with continence cannot be assessed individually[21,23,24]. An alternative approach involves transperineal real-time ultrasound (TrP RTUS), which uses the pubic symphysis as a bony landmark and enables simultaneous visualisation of all three striated muscles (the striated urethral sphincter, the bulbocavernosous and the puborectalis) that control male urinary continence via a complex "horseshoe action"[25,26]. No research to date has compared TrA versus TrP RTUS measures in men.

The PFM comprises two broad types of skeletal muscle fibres, with each responsible for different functions. Slow twitch (type 1) endurance fibres make up approximately 80% of the PFM[27,28] and are capable of long-lasting but relatively weak contractions[29]. These fibres are activated to maintain bladder and bowel continence, assist in upright posture and help maintain PFM tone during rest or activity[29,30]. The remaining ~20% of PFM fibres are fast twitch (type 2)[11,28], which are adapted for strong, rapid contractions, required for both reflex occlusion of the urethra and for voluntary retention of urine[29]. Although they fatigue faster than type 1 fibres, type 2 fibres are primarily responsible for preventing urinary leakage during sudden actions such as coughing and sneezing[31,32]. In these scenarios, reflex reactions are required to compress the urethral wall during periods of increased abdominal pressure[29,33]. To assess the different functional capacities of the pelvic floor in men, we used two tests; the rapid response test (RRT) and sustained endurance test (SET), involving RTUS visualisation of PFM function.

The results of three studies are reported in this paper. Study 1 investigated the relationship between muscle function measured via traditional rectal examination approaches versus RTUS methods. Study 2 compared RTUS TrA and TrP approaches and study 3 assessed intra- and inter-tester reliability for the RRT and SET tests seen on RTUS.

METHODS

This study was approved by the University of Western Australia, Human Research Ethics Committee (Ref RA/4/1/6265) and the participants provided written informed consent.

Description of studies

Participants in study 1 were enlisted from a cohort of patients referred sequentially by their urologist for pre-prostatectomy PFM training to a single physiotherapy clinic. No specific inclusion or exclusion criteria were applied. Each participant underwent rectal perineometry assessment and a rectal squeeze pressure assessment by DRE. The Modified Oxford Scale[9] was used to assess PFM squeeze pressure in the lateral decubitus (side-lying) posture by a clinician experienced in PFM dysfunction. Prior to each examination, instructions were provided on correct PFM exercise technique[34], to ensure a full contraction and relaxation cycle was implemented with the cue given to "stop the flow of urine and shorten the penis while continuing to breathe"[34]. Cues to relax abdominal muscles and avoid breath holding were also given. The DRE was performed with palpation beyond the external anal sphincter (EAS) to assess the pelvic floor musculature approximately 3–4cm within the anal canal, to minimise contamination of EAS contraction. The use of a perineometer (Peritron A PRTN-1-1-1301135, Ontario) was to provide an objective measure of PFM squeeze pressure. The covered probe was inserted beyond the EAS, such that the hilt of the probe was adjacent to the anus, in keeping with the guidelines provided in the Peritron A instruction manual. Whilst we cannot exclude the possibility that anal sphincter pressure affected the probe reading, the pressure-sensitive component of the perineometer lies on the shaft of the device, distal to the hilt, and it is therefore likely that our measurement approximated the PFM assessment described for the manual DRE approach[35]. This test was also performed in the lateral decubitus posture. On a separate day within one week of their initial clinic visit, these participants also underwent SET and RRT testing using the TrA approach. The TrP approach was not used at this stage of the experiment, with subsequent testing used to directly compare these two approaches (study 2).

Participants in study 2 were also enlisted from a cohort of patients sequentially referred by their urologist and were all assessed between two weeks and six months post-surgery. Participants were assessed (in random order) for the RRT and SET tests in the supine posture during two consecutive testing sessions, by the same tester, one week apart to determine intra-tester reliability. For each measurement, participants underwent both TrP and TrA RTUS assessments using a commercially available point-of-care ultrasound machine (3.5 MHz sector probe, Mindray DP-30 Ultrasound, 6U-42000440, China).

In a third study, to determine inter-tester reliability, the RTUS tests were repeated by a second experienced observer within one week of the original test (at the same time of day) on a sub-sample of participants, with instructions between testers and participants standardised. To standardise bladder volume, each participant voided their bladders and then drank 500 ml of water, and were instructed not to void again prior to testing.

Description of pelvic floor muscle function tests

Participants were assessed for PFM function in the crook lying position (the 'supine' posture) with a pillow underneath the head, and hips and knees flexed at 60 degrees and with the lumbar spine positioned in neutral.

Cues to relax abdominal muscles and avoid breath holding were also given. Instruction was provided on correct PFM exercise technique[34], to ensure a full contraction and relaxation cycle was implemented with the cue given to *"stop the flow of urine and shorten the penis while continuing to breathe"*[21,34]. Participants were allowed one 'practice' contraction prior to the test in order to provide feedback for both tester and participant, and to avoid poor technique.

For the RRT, participants were instructed to *"perform 10 maximal PFM contractions and relaxations as fast as possible"*, with the elapsed time recorded as the outcome measure. In the SET participants were instructed to *"hold a maximal contraction for as long as possible, whilst continuing to breathe"*. The time to task failure was recorded (with a maximum time of 60 seconds), where task failure was defined as the descent of the bladder base (TrA) or bladder neck (TrP).

Transperineal RTUS assessments

Prior to the TrP RTUS, each participant was asked to disrobe in private and to drape a towel around their waist, before reaching under and gently moving their genitals to one side with their hand. Standard infection control measures were observed. After applying a layer of transmission gel, TrP RTUS was performed by placing the covered probe on the perineum in the mid-sagittal location, midway between the base of the penis and the anus, with the transducer orientated to obtain sagittal images, and then the participant removed his hand. To optimise the images, the pubic symphysis (SYMP) was used as the bony reference point, with the urethra (U), bladder (BL), bladder neck (BN) and anorectal angle (ARA) visible simultaneously (Figure 1). Using screen calipers, a measure of the position of the bladder neck was taken at rest 'x' and the change from the resting position in a vertical direction was observed. In this study any cranial movement of the bladder neck was noted as a correct action, whereas no cranial movement or any caudal movement of the bladder neck was noted as incorrect action, as with previous guidelines[21]. During SET assessments, an arrow was placed at the bladder neck as a visual marker to determine whether changes in amplitude were indicative of task failure.

Any participant unable to perform the PFM contraction correctly (that is, cranially versus caudally), was given the opportunity to rest to allow for PFM recovery. Cues to contract and relax the pelvic floor were repeated and, with the benefit of visual feedback, all participants were able to correct their technique. This approach was also adopted during the transabdominal procedure if initial contractions were incorrect.

Transabdominal RTUS assessments

Assessment via the TrA RTUS approach was performed by placing the probe suprapubically on the lower abdomen at a mid-sagittal location with the transducer probe orientated to obtain transverse images and angled in a caudal/posterior direction such that a clear image of the inferior-posterior aspect of the bladder was obtained (Figure 1). Standard infection control measures were observed and a layer of gel was placed over the head of the probe. Screen calipers were used to place a mark 'x' on the bladder base (BB) at rest where any elevation of the BB was noted as a correct action and any depression of the BB was noted as incorrect action in accordance with previous guidelines[14,24]. As per TrP RTUS assessments, during SET measures, an arrow was placed at the bladder neck as a visual marker to determine whether changes in amplitude were indicative of task failure.

Statistical analysis

Data for the DRE, perineometer, SET and RRT tests were entered into SPSS (v22.0, SPSS, Chicago, IL) for subsequent analysis and significance was accepted for all analyses at $p<0.05$. The association between scores from DRE and perineometer measurements was analysed using a Pearson's correlation with linear regression performed to characterise association

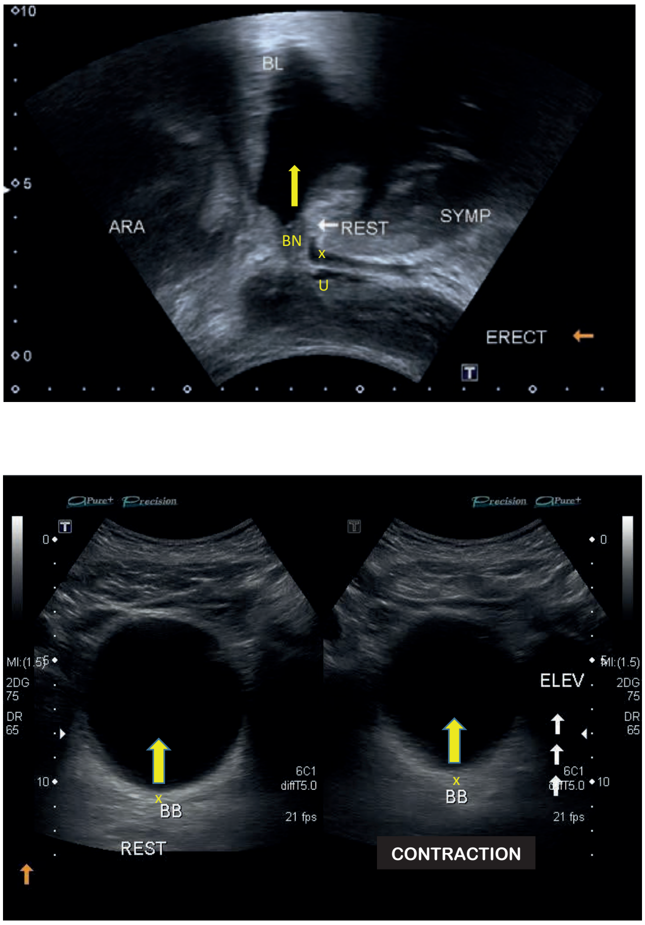

Figure 1: Upper panel: Transperineal real time ultrasound image (RTUS) image used to assess pelvic floor muscular (PFM) function utilising screen calipers to determine correct PFM action during the rapid response test (RRT) and sustained endurance test (SET). Movement should be in a cranial direction as indicated by the arrow. BL = bladder, BN = bladder neck seen in relation to SYMP = symphysis pubis, U = urethra, ARA = anorectal angle and bladder. Lower panel: Transabdominal (TrA) RTUS images used to assess PFM action during the RRT and SET (left image = at rest; right image = whilst contracting). BB= base of bladder and arrows indicate direction of pelvic floor muscles.

between these variables. For this paper we defined the strength of correlation as follows:[36]

- r= 0.25–0.50 weak to moderate
- r=0.5–0.75 moderate to good
- r> 0.75 good to excellent

Bland-Altman analyses and plots were used to determine the limits of agreement for:

- the relationship between RRT and SET outcome scores using TrP versus TrA approaches with patients in the supine posture
- inter-observer reliability for SET and RRT tests conducted using TrA RTUS with patients in the supine posture
- intra-observer reliability for SET and RRT tests conducted using TrA RTUS with patients in the supine posture.

RESULTS

Study 1: Relationship between rectal examination approaches and RTUS tests

Test scores for 27 post-prostatectomy patients (63±7y, 170.0±18.3cm, 76.2±16.3kg, all Gleason 7) averaged 3.0 ± 0.8 on the Modified Oxford Scale and 44.3±22.2 cmH_2O by perineometry. DRE results were only moderately correlated with the more objective perineometry measurements (r=0.5, p<0.05).

RRT (r=0.18, p=0.36) and SET (r=0.18, p=0.36) assessments were unrelated to perineometry-based PFM squeezing pressure. Correlations between the digital rectal squeeze pressure and the SET (r=0.02, p=0.94) and RRT (r=0.04, p=0.86) were also not correlated.

Study 2: Comparison of RTUS TRA and TrP approaches

Of the 100 patients recruited to Study 2, five were excluded from analysis due to post-surgery complications involving the bladder neck, which required further surgical intervention (n=95, 63±11y, 172.0±15.2cm, 72.9±16.9kg, all Gleason 7), with ± referring to the mean ± standard deviation.

The limits of agreement for each of the RRT and SET assessments, performed using TrP and TrA methods, are presented as Bland-Altman plots in Figure 2. These data show no significant difference (p>0.05) between the assessment methods. The plots also demonstrate no heteroscedasticity or proportional bias, with the mean difference in scores between both methods being close to 0 and the standard deviation for difference scores low (0.9 seconds for RRT and 4.1 seconds for SET).

Study 3: Intra- and inter-tester reliability for the RRT and SET tests seen on RTUS

This sub-sample of participants were recruited from the cohort of men in study 2, who were able to attend two consecutive appointments within one week (n=47, 63±12y, 171.0±14.9cm, 76.1±17.2kg). The limits of agreement for each of the RRT and SET assessments, performed on the same participants by two operators, are presented as Bland-Altman plots in Figure 3. These data show no significant difference (p>0.05) between operators. The plots also demonstrate no heteroscedasticity or proportional bias, with the mean difference in scores between operators being close to 0 and the standard deviation for difference scores low (2.0 seconds for RRT and 2.7 seconds for SET).

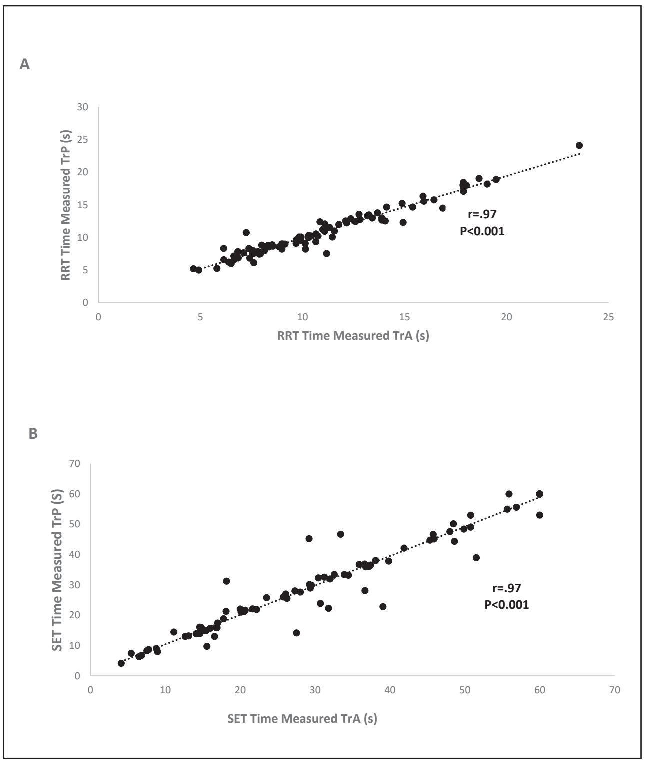

Figure 2: Bland-Altman plots presenting the limits of agreement for PFM function assessed by transabdominal (TrA) and transperineal (TrP) ultrasound for the rapid response test (RRT) in the upper panel, and the sustained endurance test (SET) in the lower panel — all tests were conducted in the supine posture.

Similarly, limits of agreement for each of the RRT and SET assessments, performed by the same operator on two occasions, one week apart, are presented as Bland-Altman plots in Figure 4. These data show no significant difference (p>0.05) between test sessions. The plots also demonstrate no heteroscedasticity or proportional bias, with the mean difference in scores between both test sessions being close to 0 and the standard deviation for difference scores very low (0.4 seconds for RRT and 0.5 seconds for SET).

DISCUSSION

In the present study we observed a moderate correlation between the traditional DRE approach to PFM assessment, compared to more objective perineometry. Conversely, strong agreement was found for both RRT and SET when tests were performed

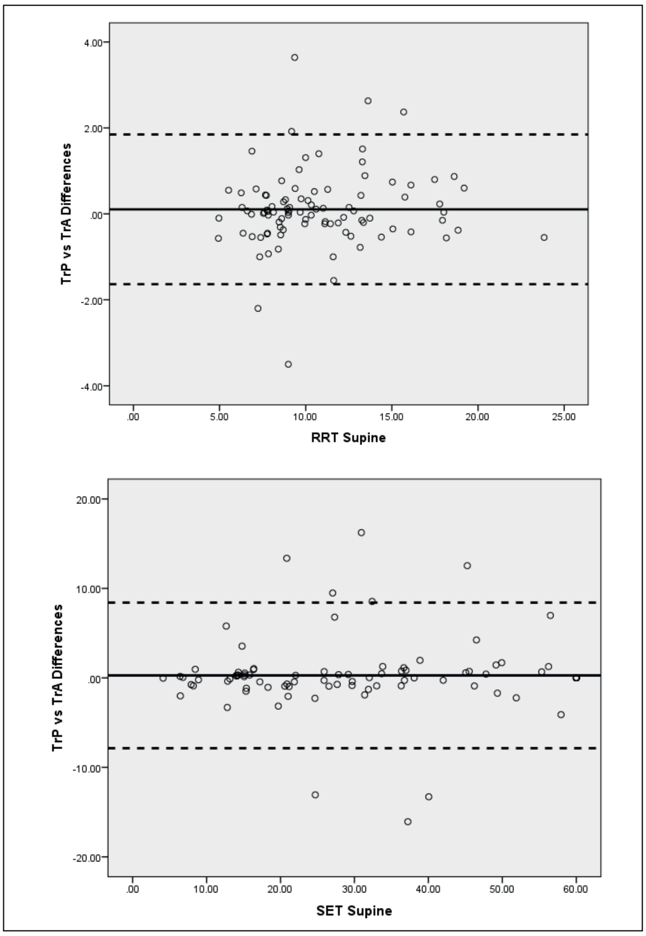

Figure 3: Bland-Altman plots presenting the limits of agreement for two assessors measuring the same patients on the rapid response test (RRT) in the upper panel, and the sustained endurance test (SET) in the lower panel — all tests were conducted using transabdominal real-time ultrasound images with patients in the supine posture.

Figure 4

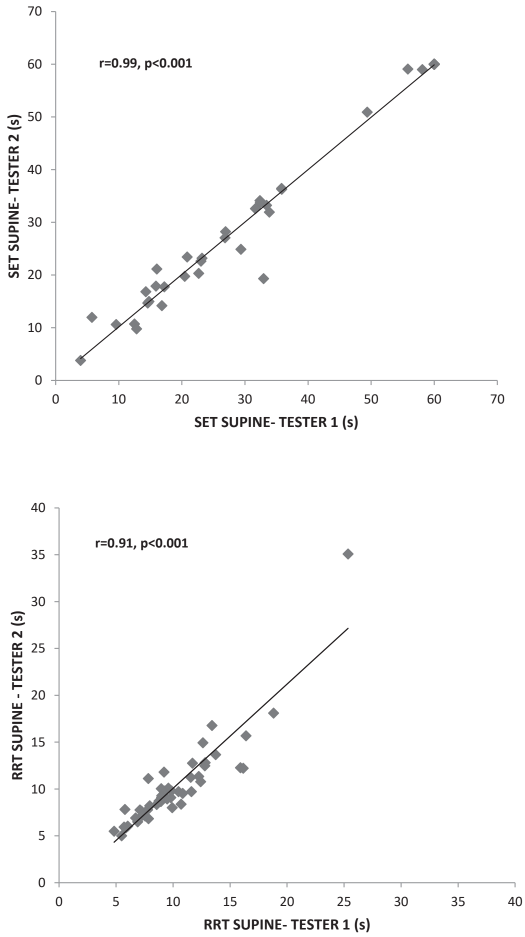

Figure 4: Bland-Altman plots presenting the limits of agreement for a single assessor measuring patients on two occasions, one week apart, on the rapid response test (RRT) in the upper panel, and the sustained endurance test (SET) in the lower panel — all tests were conducted using transabdominal real time ultrasound images with patients in the supine posture.

using TrA and TrP protocols, and when determining inter- and intra-observer reliability.

Study 1: Traditional versus RTUS assessment of pelvic floor muscle function

Our findings indicate that digital rectal squeeze pressure scores correlated only moderately with an objective pressure measurement technique. In addition, PFM strength grading was poorly correlated with our RTUS tests of function (both RRT and SET). This finding is broadly consistent with previous studies in women[12,19,37] which report poor correlations between digital strength grading and ultrasound measures. Sherburn and colleagues[16], in particular, found no significant relationship between ultrasound measures and digital palpation[12]. In contrast, recent investigations by Arab and colleagues[38] comparing TrA RTUS versus digital palpation in females[39] reported a positive correlation if RTUS assessments were performed simultaneously with PFM contraction. These differences in study outcomes are likely due to earlier studies performing the assessments separately and the variability in per rectal methodologies. Hence, our findings concur with previous studies, mostly performed in women, and we conclude that different aspects of PFM function were assessed using the per rectal and RTUS tests. The latter are simple to administer, clinically relevant[14], non-invasive, well-tolerated and provide direct visualisation of PFM contraction[24,40].

Study 2: Transabdominal versus transperineal approaches

While TrA and TrP RTUS approaches for PFM assessment in men are validated, there is no previous direct analysis to compare these approaches[14,25]. Similar investigations in women[23,24,41] confirmed the reliability of TrA RTUS as 'excellent' and comparable to TrP for measuring pelvic floor movement during PFM contraction. The TrP approach was found to be more reliable for inter-patient comparisons as it measured from a fixed bony landmark, although the increased complexity of evaluation and increased time of assessment in a clinical setting has been noted[24]. In comparison, the TrA RTUS approach is minimally invasive, quick to perform, does not require the person to undress and is relatively easy to learn[24]. This approach can be particularly helpful for the clinician who is working with men who wear continence pads, those unwilling to undergo perineal assessment due to culture or ethnicity, survivors of sexual abuse, those who are anxious, or children and the elderly who need PFM evaluation.

We were able to demonstrate that during PFM contraction, a strong association exists for scores derived using both the TrP and TrA approaches. This confirms that either option may be used and that clinical evaluations designed for patients can be individualised, particularly when PFM digital palpation may not be appropriate.

Of course, studies in which the assessment of individual muscle groups within the pelvic floor is an imperative should favour the TrP approach. Although not encountered in our investigations, should there be clinical presentations such as complete incontinence, whereby any holding of bladder volume is limited, the TrP RTUS option may be more appropriate, since a full bladder is not required. Obesity, scar tissue and previous abdominal surgery may also impact on the quality of imaging in TrA RTUS. Therefore, having two approaches available is helpful clinically for optimal assessment and rehabilitation.

Study 3: Inter- and intra-tester reliability of RTUS tests

The inter- and intra-tester reliability of the SET and RRT tests were high, with strong associations observed between the sets of scores. By contrast, coefficients of variation reported for repeated assessment of the Modified Oxford Scale squeeze pressure test[9], as previously assessed in women, are >20% and the correlation for repeated assessment is substantially lower than that observed for the SET and RRT in our study[19]. In the analysis of Bland-Altman plots, the relatively small range of the 95% confidence intervals indicates that both the RRT and SET tests have good intra- and inter-tester reliability. However, the limits of agreement for the inter-tester SET test results were slightly higher than expected, which possibly relates to a difference in skill and level of experience between testers. This emphasises the importance of training for clinicians so that a narrower confidence interval may be achieved. Across all Bland-Altman plots, the difference between tests seems consistent across a large baseline of values. These data suggest that the measures we present in this paper are reliable and mostly immune to the effects of different observers.

There are several limitations of the current study. There is no universally accepted “gold-standard” measure of PFM function in men. The DRE derived measures used in study 1 were not intended as a basis for comparing to a gold standard. Such DRE measures remain, however, widely used and considered by some to be the best currently available. The criteria used for task failure could be more objective if, for example, automatic edge detection and wall tracking software were developed. The posture used to perform the DRE-based tests (lateral decubitus) was selected as instructed for use in the Peritron A manual, and because it was the preference of the physician who undertook these tests. It is a posture commonly used in routine clinical DRE examination in men. It differed from the posture used to undertake the SET and RRT tests (crook lying) and the lack of correlation between DRE and RTUS tests we observed in study 1 may be partly explained by this postural difference. The results of the RRT and SET tests can be affected by the technical difficulty of the selected approach. It is relevant in this regard that, whilst the TrP technique is more technically demanding, the TrA and TrP tests are highly correlated. While the SET and RRT data are specific to this study, the objective and timed nature of these tests should make the collation of normative data sets possible in larger cohorts in future. Prospective outcomes, related to performance that is scaled by normative comparison, should also be possible.

CONCLUSIONS

Both TrP and TrA approaches to RTUS of the pelvic floor had high inter- and intra-tester reliability and appear to have advantages over the DRE and/or perineometry, which are only moderately correlated and have poor inter-tester reliability. Similar scores were observed if measurements were performed by either TrA or TrP approaches, with TrA assessment potentially less problematic for those uncomfortable with the TrP approach. Future studies are needed to investigate whether the RRT and SET RTUS tests are posture-dependent or relate to clinical outcomes such as post prostatectomy incontinence (pad weight).

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