

Application of two pelvic floor muscle function tests in men following radical prostatectomy: relationship to urinary incontinence

ABSTRACT

This study examines the impact of posture and measures of urinary incontinence relating to two non-invasive, real-time, ultrasound-based tests. Using real-time ultrasound with transperineal and transabdominal approaches, we previously assessed pelvic floor muscle function in men and found the rapid response and sustained endurance tests possessed strong reliability in both supine and standing postures, and for both ultrasound approaches. However, questions remained pertaining to the relationship of the tests to other outcome variables, including measures of urinary incontinence. Participants (n=95) undergoing radical prostatectomy were assessed to determine the relationship between incontinence and pelvic floor muscle function, as seen on ultrasound. The presence and severity of incontinence was measured via 24-hour pad weight. When related to pad weight, the transabdominal protocol produced weak to moderate correlations between the rapid response test in standing ($r=0.43$) and supine ($r=0.46$), and the sustained endurance test in standing ($r=-0.56$) and supine ($r=-0.56$). Similar results were found using the transperineal approach. All Bland-Altman analyses showed no significant difference ($p>0.05$) between the two postures, for either test or scan approach. While the plots also demonstrate no heteroscedasticity or proportional bias, with the bias being close to 0, the magnitude of variation in difference scores suggests different outcomes for tests performed in standing compared to supine postures. We present two simple tests that provide objective, non-invasive, and reproducible assessment of pelvic floor muscle function in men that relate to the clinical outcome of urinary leakage.

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

INTRODUCTION

Urinary incontinence (UI) is often associated with compromised function of the pelvic floor muscles (PFM) and while most studies regarding this association have involved women, there is a high prevalence of UI in men following radical prostatectomy (RP)^{1,2}. It is estimated that more than one million new cases of prostate cancer (PCa) are diagnosed annually³, and RP is considered the gold standard surgical approach to treatment. Current opinion states that strategies to enhance PFM function may improve continence outcomes in men who undergo RP^{4,5}. However, researchers have been hampered by the lack of a reliable and practical test of PFM function in men.

Post-prostatectomy incontinence (PPI) is one of the most distressing side effects following RP treatment, with up to 91%⁶ of men reporting urinary leakage initially and 30-76%^{7,8} continuing to experience it one year following RP⁷. Incontinence is mostly caused by damage to the internal urethral sphincter affecting autonomic function, coupled with an increased demand on the PFM following complete removal of the

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Competing interest statement: All authors declare they have no relevant relationships or circumstances that present actual or potential conflicts of interest.

prostate^{1,9}. Evidence currently supporting the benefits of PFM training in men^{8,10} is inconclusive and this may be due to most PFM research (both assessment and treatment) being focused on female PFM dysfunction and translating knowledge across the sexes may be difficult, particularly in the implementation of rehabilitation strategies.

Men are typically continent in supine positions following RP. In contrast, upright posture and actions such as sitting and sit-to-stand cause increased intra-abdominal pressure that leads to stress UI^{2,11}, a problem also seen in women¹². For men with PPI the condition can worsen as the amount of time in the upright position increases over a day, particularly in association with physical activities such as walking¹¹. The existing evidence does not address these incontinence issues in recovery following RP and validation of a reliable test to meet clinical presentation may help bridge this gap.

The study reported here is of two objective, real-time ultrasound (RTUS) tests, that are specific to sustained and rapid demands placed on the pelvic floor muscles. The sustained endurance test (SET) and rapid response test (RRT) of PFM function used in the current study are non-invasive and avoid the need for rectal assessment of the pelvic floor¹³. The aim was to determine the extent to which the SET and RRT may be posture-dependent and whether they relate to clinical outcomes such as PPI. To determine the severity of UI, 24-hour pad weight was assessed and compared to performance on the RRT and SET assessments. We chose 24-hour pad weight as our criterion measure of PPI, since pad number can be influenced by the variety of pads used and individual differences in hygiene management. In addition, 24-hour weight has been described as the most reliable non-invasive method of quantifying the severity of urine leakage over longer time frames than the previously utilised 20-minute and 1-hour tests^{14,15}. In 2012, Mungovan and colleagues determined that in men most PPI episodes occur in the upright posture¹¹, and so we performed the dynamic tests of PFM function in supine and standing for comparison.

METHODS

This study was approved by the University of Western Australia HREC (Ref RA/4/1/6265). Participants received written information about the study and provided written consent. Participants were enlisted from a cohort referred sequentially by their urologist for pre-prostatectomy PFM training. Following surgery, participants were reviewed between two weeks and six months post urinary indwelling catheter removal and assessed in random order for the RRT and SET assessments in both supine and standing postures.

For each measurement, a commercially available point-of-care ultrasound machine (3.5 MHz sector probe, Mindray DP-30 Ultrasound, 6U-42000440, China) was used. To standardise bladder volume for the TrA approach, each participant voided their

bladder and then drank 500 ml of water, 1 hour prior to testing and were instructed not to void. A full bladder is not required routinely for TrP assessments. To assess severity of incontinence, pad weight was calculated by the collection of continence pads across a 24-hour period, on the day testing was completed^{16,17}. All participants wore pads and applied their first pad of the day after their first morning void. All pads were placed in a single plastic bag and stored in a refrigerator to avoid evaporation. The net weight was calculated by deducting dry pad weight, using a single standardised digital scale¹¹. Any positive net weight, recorded in grams (g), was deemed indicative of incontinence, with 'zero' weight assessed as no leakage and full continence. Participants were assessed for PFM function in the crook lying position (supine) with a pillow underneath the head and hips and knees flexed at 60 degrees and with the lumbar spine positioned in neutral. They were also assessed when standing in the anatomical position (standing). Cues to relax abdominal muscles and avoid breath holding were also given. Verbal instruction was provided on correct PFM exercise technique, as per Stafford and colleague's 2016 study¹⁸, 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"^{18,19}. Participants had one 'practice' contraction prior to the test, while in view of the screen, in order to provide feedback for both tester and participant, and to promote good 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, and continue to breathe". The time to task failure was recorded (with a maximum time of 60 seconds), where task failure was defined as being the onset of descent of the bladder base (TrA approach) or bladder neck (TrP approach).

Transperineal RTUS assessments

Prior to the test using the TrP approach, RTUS participants were invited 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, after which the participant removed his hand. To optimise the images, the symphysis pubis was used as the bony reference point, with the urethra, bladder, bladder neck and anorectal angle visible simultaneously¹³. Using screen callipers, a measure of the position of the bladder neck was taken at rest ('x') and the change from this resting position in a vertical direction was observed. Any cranial movement of the bladder neck was interpreted as a correct action; whereas, no cranial

movement or any caudal movement of the bladder neck was noted as an incorrect action, in accord with previous guidelines¹⁹. During SET assessments, an arrow was placed at the bladder neck as a visual marker to determine the elapsed time (seconds) at which task failure, defined as the moment of descent toward the resting position of the bladder neck ('x'), was observed.

Transabdominal RTUS assessments

For tests using the TrA approach, ultrasound assessment was performed by placing the covered 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 to achieve a clear image of the inferior-posterior aspect of the bladder. Standard infection control measures were observed and a layer of gel was placed over the head of the probe. Screen callipers were used to place a mark ('x') on the bladder base at rest where any elevation of the bladder base was interpreted as a correct action and any depression of the bladder base was noted as an incorrect action in accordance with previous guidelines^{20,21}. As per the TrP approach, during SET assessments, an arrow was placed at the bladder base as a visual marker to determine the elapsed time (seconds) at which task failure, defined as the moment of descent towards the resting position of the bladder base ('x'), was observed. Any participant unable to perform the PFM contraction correctly (that is, cranially versus caudally), was given the opportunity to rest and repeat the test.

Statistical analysis

Data for the SET and RRT assessments and pad weight were entered into SPSS (v22.0, SPSS, Chicago, IL) for subsequent analysis and significance was accepted for all analyses at $p < 0.05$. To determine whether two scores were related, we performed correlations. For example, the association between SET and RRT (in both standing and supine postures) versus pad weight scores was determined using Pearson's correlation. For this paper we defined the strength of all correlations as follows²²:

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

To assess agreement, Bland-Altman analysis and plots were performed. For example, the level of agreement between tests performed in supine versus standing postures was assessed with a series of Bland-Altman plots for the SET and RRT assessments created using both TrA and TrP RTUS.

RESULTS

Participants in the study were 95 men, average age 63 years (range 52 to 74 years). All participants were in a healthy weight range (height 172.0 ± 15.2 cm, body weight 72.9 ± 16.9 kg, all Gleason 7).

Relationship between RTUS tests and pad weight

The range of pad weights, for the pads collected from all 95 subjects, was 0 to 98 g. Pad weight averaged 46.0 g (± 52.2 g). Weak to moderate, though statistically significant, correlations were evident between 24-hour pad weight and both the SET and the RRT scores in all combinations of posture and probe position. The relationships between pad weight and RRT via TrA RTUS performed in standing ($r = 0.43$, $p < 0.001$) and supine ($r = 0.46$, $p < 0.001$) were moderate, and moderate to good for the SET in standing TrA ($r = -0.56$, $p < 0.001$) and supine ($r = -0.56$, $p < 0.001$). The relationships between pad weight and pelvic floor function was assessed via TrP RTUS, RRT in standing ($r = 0.52$, $p < 0.001$) and supine ($r = 0.51$, $p < 0.001$) were moderate with similar results for SET via TrP in standing ($r = -0.58$, $p < 0.001$) and supine ($r = -0.54$, $p < 0.001$).

Supine versus standing measurements

The limits of agreement for each of the RRT and SET assessments, performed using TrP and TrA approaches in both standing and supine postures, are presented as Bland-Altman plots in Figure 1. The results for all analyses show no significant difference ($p > 0.05$) between the two postures for RRT and SET assessments using each RTUS scan approach. The plots also demonstrate no heteroscedasticity or proportional bias, with the mean difference (bias) in scores between postures being close to 0 (RRT: TrA = -0.15 s, TrP = -0.16 s; SET: TrA = 1.59 s, TrP = 1.26 s). However, the magnitude of variation in difference scores (an average 1.8 s for RRT and an average 9.5 s for SET) suggests different outcomes for tests performed in standing compared to supine postures, especially for the SET.

DISCUSSION

In this study, we compared PFM function measured by SET and RRT scores with the severity of incontinence assessed using 24-hour pad weight. Moderate correlations were observed between RTUS assessments and this widely accepted clinical measure of continence²³. Lower RRT times related to good PFM function and, therefore, mild incontinence. For example, a patient performing the RRT in 15 seconds, has more PPI (that is, a higher pad weight) than one who performed the test in 7 seconds, with speed of contraction being the significant functional difference. An inverse relationship was noted for the SET, with lower scores relating to higher levels of incontinence. For example, a patient maintaining a contraction for 15 seconds had more PPI (higher pad weight) than one contracting for 45 seconds, with most who achieved a contraction for 60 seconds having full continence. Similar results were obtained between supine and standing postures for both the RRT and SET outcomes. In the same way, TrA and TrP approaches to assessment were very similar for both tests. These findings provide evidence that the non-invasive measures we have introduced are clinically valid and reliable for assessing PFM function, as it may relate to urinary leakage in PPI. Traditionally,

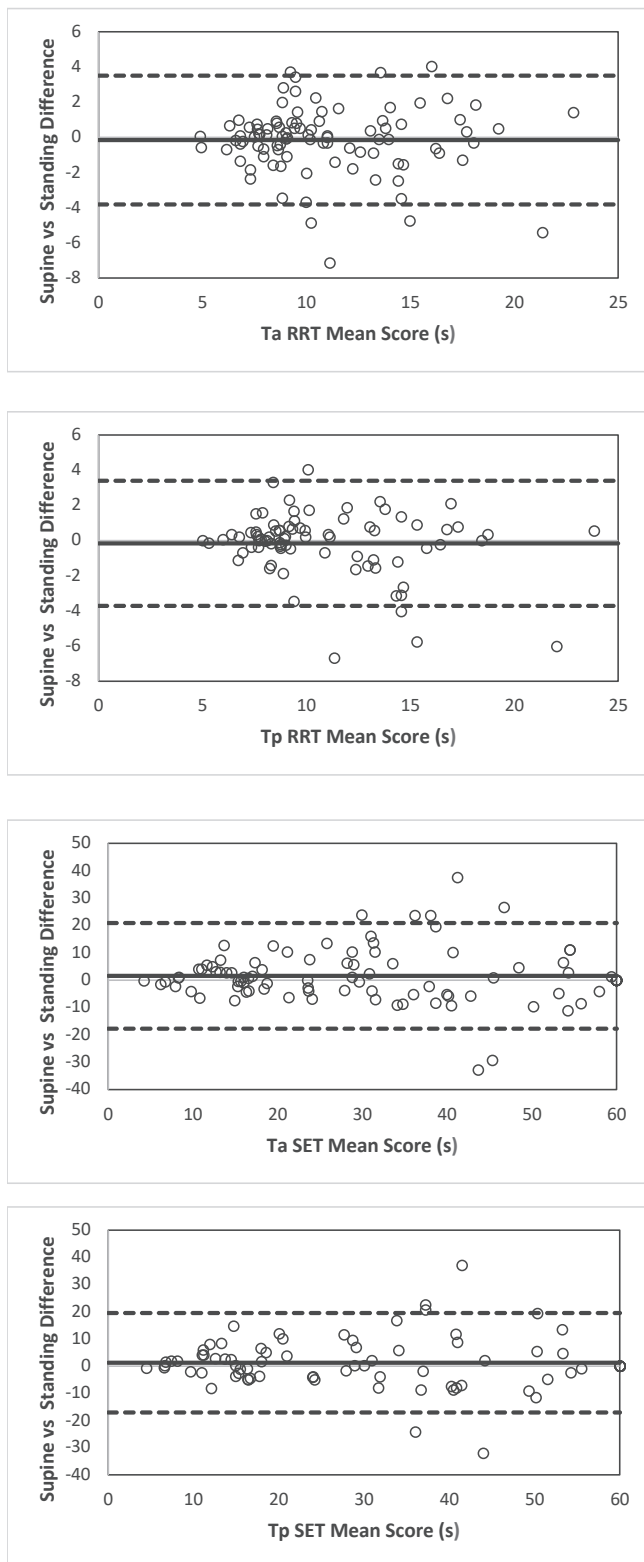


Figure 1: Bland-Altman plots presenting the limits of agreement for PFM function with tests conducted in the standing versus supine postures. The rapid response test (RRT) results are shown for transabdominal assessment in Panel A, and for transperineal assessment in Panel B. The sustained endurance test (SET) results are shown for transabdominal assessment in Panel C, and for transperineal assessment in Panel D. Solid line = mean difference Dotted line = limits of agreement

assessments of PFM function are performed in the supine or lateral decubitus positions¹². The purpose of performing tests in the standing posture in this study was to account for the clinical presentation of PPI, which is often gravity-dependent¹¹. Our results suggest that posture does have an impact on PFM function, with some variation in scores noted for SET measured in supine versus standing. These findings suggest that increased skeletal muscle activation in upright postures may be associated with incontinence. RTUS testing can be performed using whichever posture is specific to individual patient symptomatology; however, we would suggest default assessment in the standing position as this corresponds with the posture and loading conditions under which PPI typically occurs^{1,8,26}. In addition, an individual's RRT and SET results can be used in a clinical setting to provide guidance to both the clinician and patient, for baseline assessment and training purposes.

While outcomes regarding the prediction of pad weight, based on RTUS tests, were moderate, they were not excellent (that is, correlations of 0.75 or greater). This is perhaps not surprising, given that many factors other than PFM function can contribute to PPI. These may include surgical experience, operative approach, associated damage to the internal urethral sphincter and the degree of nerve sparing^{9,24,25}. We did not limit our recruitment according to these factors and it is conceivable that a study stratified by surgical outcome may have produced stronger associations. It may also be possible to further improve these correlations by refining the technical approaches we used. For example, our SET and RRT measures, while reproducible¹³, may be more sensitive if edge detection algorithms had been used to better detect movement of the bladder base. In an attempt to obtain ecological validity, we did not control for factors such as measurement time of day or 24-hour fluid intake; however, such controls may have enhanced the relationships we observed. Equally, while pad weight is an accepted and simple assessment of incontinence, it may be possible in future to correlate our functional outcomes with more recently adopted and sophisticated assessments, such as MRI-derived measures of membranous urethral length². In addition, although we did not use it in this study, the three-day, 24-hour pad weight method introduced by Malik in 2016 may have provided more variability in pad weight scores, given ranges that may occur with physical activity levels in individuals over subsequent days¹⁶.

CONCLUSIONS

In post-radical prostatectomy patients the outcomes of our RRT and SET assessments were associated with the severity of UI. These tests can be used to design personalised treatment plans. Correlations performed between PFM tests and pad weight varied according to whether the SET and RRT assessments were performed in standing versus supine, but not with respect to the TrP versus TrA approach. This indicates that factors specific to the individual patient,

such as the presentation of gravity-dependent PPI, or sensitivity regarding perineal assessment, can be taken into account when selecting the preferred test. Based on our experience, we suggest performing tests in the standing position. One advantage of the TrP approach for the very incontinent patient is the removal of the requirement to have a full bladder, compared with the TrA approach which requires bladder volume for optimal imaging. This further enhances our findings that either TrA or TrP are appropriate options, depending on patient presentation. In conclusion, our studies indicate that the RRT and SET assessments are minimally-invasive, objective, and may be of use in a clinical setting. Further research is needed to ascertain whether spontaneous recovery is impaired following surgery, or to introduce a treat-to-target approach to rehabilitation.

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