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 per rectal assessment of squeeze pressure and objective perineometer measures (n=27, 67±7 y, 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 per rectal approaches.

Introduction:

- Prostate Cancer (PCa) global health problem and second most common cancer in men, affecting 1 in 7 globally.
- Radical prostatectomy (RP) most effective and gold standard treatment but has side effects of urinary incontinence & erectile dysfunction which greatly impact on quality of life for men, which can be facilitated by PFM training.
- Currently recommended gold standard for PFM assessment is by per rectal examination in men, but this provides only ordinal data and is seen by men as ‘invasive’ and physically and psychologically challenging. Also lacks poor inter-observer reliability between testers.
- Recent clarification of PFM anatomy involved in male urinary continence mechanism by Stafford et al (2013-16) showed posterior rectal PFMs and external anal sphincter (EAS) to be largely unrelated to urinary function.
- Evolution of transabdominal and transperineal RTUS assessment in women well established by Thompson et al 2005-07, but not as developed in men. Comparisons between the two techniques show support for each in women, not previously assessed in men.
- Transabdominal RTUS PFM imaging assesses elevation and depression of bladder base
- Transperineal RTUS PFM imaging assesses bladder neck elevation in caudal direction with all three skeletal muscles involved in continence- ESU/SUS, bulbocavernosus and puborectalis- able to be assessed simultaneously with pubic symphysis as bony landmark.
- PFM has two types of fibres- fast and slow twitches- both need assessment and training for continence. 70-80% slow twitch fibre – utilised for endurance, 20% fast twitch fibre utilised for reflex closure/ fast strength-based reactions with increases of intra-abdominal pressure
- Two RTUS-based tests, based on these physiological functions were designed:
  1. Rapid Response Test (RRT)- how long does it take to perform 10 ‘rapid/fast twitch maximal contractions and relaxations of the pelvic floor? (Aim for 10 in under 8sec)
  2. Sustained Endurance Test: how long can one maximal PFM contraction be maintained whilst the patient is breathing, before it reaches a point of fatigue? (Up to 1 min)
- Three separate studies in men undergoing RP were investigated:

**Methods:**
- Study 1: Per Rectal DRE and Perineometry vs RTUS tests: Post-prostatectomy men (27)
- Study 2: RTUS tests assessed in supine over two consecutive weeks, to determine intra-tester reliability. Transabdominal and transperineal assessments performed in all participants.
- Study 3: RTUS tests assessed in supine over two consecutive weeks, to determine Inter-tester reliability. Transabdominal (TrA) and transperineal (TrP) assessments performed in all participants.
- PFM function Tests; as described in paper as RRT (elapsed time recorded) and SET (time to task failure recorded with descent of bladder base (TrA) or bladder neck (TrP), marked by ‘x’ on screen and arrow, showing direction of movement, visible to tester and participant
- Correct cues given for urinary incontinence ‘relax abdominals, aim to stop the flow of urine and shorten the penis while continuing to breath’.
- Transperineal application: gel on probe, cover, gel- probe on perineum mid-sagittal between base of penis and the anus
- TransAbdominal application: gel on probe, cover, gel- probe supra-pubically on lower abdomen, transverse image

**Statistical Analysis:** SPSS software
- Strength correlations used Pearson’s correlation and linear regression with:
  - r=0.25-0.5 weak to moderate
  - r= 0.5 -0.75 moderate to good
  - r>0.75 good to excellent
- Limits of agreement used: Bland-Altman plots
Results:

- **Study 1**: Relationship between rectal examination approaches and RTUS tests, n=27
  
  DRE PFM Mod Oxford Scale score vs Perineometry cm2H20 moderately correlated (r=0.5)
  
  RRT and SET scores were unrelated to DRE PFM (r=0.18, p=0.36)
  
  RRT and SET scores were unrelated to Perineometry scores (r= 0.04, p=0.86)

- **Study 2**: Comparison of RTUS TrA and TrP approaches, n=95:
  
  RRT and SET limits of agreement – no significant difference when comparing TransAbdominal vs TransPerineal RTUS RRT and SET PFM tests

- **Study 3**: Intra and inter-tester reliability, n=47, no significant difference in results between operators and there was no significant difference in results when performed by the same operator over two subsequent weeks

Discussion:

- Moderate correlation between per rectal approaches, much stronger correlation between RTUS measures of RRT and SET in both intra-operator and inter-operator assessments
- Our RTUS tests were poorly correlated to per rectal tests, similar to results found in women.(Sherburn 2007).
- Previous studies comparing TrA vs TrP RTUS in women confirmed excellent reliability and we were able to show the same.
- TrP approach more reliable for inter-patient comparisons due to fixed bony landmark, nil need for full bladder, however more complex, higher skill level and longer time to assess required. Still moderately invasive.
- TrA approach – minimally invasive, quick to perform, easy to learn, helpful for reluctant men, pads in the way, sexual abuse victims, the elderly and children. However, bladder volume required and no bony landmark
- Either option appropriate, with clinical evaluation individualized to patient presentation
- Inter and intra-test results of RTUS test results were highly correlated.

- Limitations: Automatic edge detection could have been utilised to better measure fatigue of PFM
  
  Side lying posture for DRE and perineometry versus crook lying position of RTUS based tests may have influenced lack of correlation.

Conclusion:

- Both TrA and TrP approaches are reliable, are easy to utilise and measure function over time, versus squeezing pressure as an ordinal data score, which has poor inter-tester reliability

- Tests of PFM can be offered to patients, used as a simple clinical bedside test and can be repeated, and may provide a baseline for treatment strategies.