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INVESTIGATION OF 2D REAL-TIME ULTRASOUND AS A MEASUREMENT TOOL IN A RANDOMISED CONTROLLED TRIAL OF PELVIC FLOOR MUSCLE TRAINING IN OLDER WOMEN

Hypothesis / aims of study

Of the tools available to measure pelvic floor muscle (PFM) activation, ultrasound alone measures the 'lift' component of PFM action. There is a paucity of published work reporting real-time ultrasound (RTUS) as a measurement tool in a clinical trial. The aims of this study were to establish the concurrent and predictive validity and responsiveness of transabdominal RTUS imaging of the PFM in an elderly female sample.

Study design, materials and methods

The analyses for this study were performed using data generated in a previously reported RCT [1]. Outcomes assessment was performed by an investigator blinded to group allocation. Participants were assessed in supine lying using midline supra-pubic placement of a variable 2-5MHz ultrasound transducer (Logiq Book, GE Medical, Milwaukee, USA), after they had undertaken a bladder filling protocol. RTUS outcomes evaluated were four types of PFM contraction; maximum voluntary contraction (MVC) or 'lift' (mm displacement), supra-maximal voluntary contraction (achieved/not achieved), repeated fast contractions (rate; seconds per contraction), and sustained/endurance contraction (seconds held). Continence outcomes used as reference measures for this study were the ICIQ-UI SF (International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form), and leakage episodes recorded in a seven-day Accident Diary, as these were shown to be the most valid and responsive measures in this older female sample. **Concurrent validity** was evaluated by correlating the ICIQ-UI SF and Accident Diary with mean change from baseline to the primary end-point of the study for each type of PFM contraction using Pearson's product moment correlation coefficient. In addition the primary end-point scores were correlated with baseline scores of the four types of PFM contraction, to ascertain the **predictive validity** of RTUS. Correlations were defined a priori, *r*=0.25-0.5 as fair to moderate correlation, *r*=0.5-0.75, moderate to good correlation and *r*=>0.75, good to excellent correlation [2]. **Responsiveness** was determined by comparing RTUS mean change scores of the two intervention groups using the ICIQ-UI SF and Accident Diary as the reference measures. The mean change RTUS scores of participants with lowest symptom scores on the ICIQ-UI SF and Accident Diary were compared to determine differences between the intervention groups (Table 3).

Results

Seventy-six participants (mean age 72) enrolled in the RCT [1], (41 pelvic floor muscle training and 35 bladder/behavioural training) completed the primary end-point assessment at the end of the 20 week intervention. Data from these participants was used in the analyses. **Validity:** Concurrent validity correlations are presented in Table 1. Overall the correlations were very weak with values of *r* < .3. However, RTUS baseline scores predicted change on each measure with moderate to good correlations (Table 2).
Responsiveness: Comparing those who scored lowest on the ICIQ-UI SF, i.e. less severe incontinence symptoms, three of the RTUS PFM measures (not endurance hold), were significantly higher in the group of participants in the pelvic floor muscle training group (Table 3).

Table 1. Concurrent validity: incontinence outcomes correlated with change in PFM outcomes

PFM outcome scores Δtime 1-4	**ICIQ – UI SF Pearson *r***	**Accident diary Pearson *r***
MVC (mm)	-.11	-.23
Sustained hold (sec)	- .09	-.06
Rate of contraction (sec)	-.01	.-.10
Supra-maximal contraction	-.24	-.19

Δtime 1-4 = change scores from baseline to primary end-point

Table 2. Predictive validity: bivariate correlation between baseline ultrasound outcomes and change in ultrasound outcomes

	Baseline scores			
RTUS outcome scores Δtime 1-4	**MVC (mm) Pearson *r***	**Supra-maximal contraction Pearson *r***	**Sustained hold (sec) Pearson *r***	**Contraction rate (sec) Pearson *r***
MVC	-.63*****	-.19	-.22	-.15
Sustained hold	.02	-.23	.54*****	-.17
Rate of contraction	-.18	.01	-.08	-.57*
Supra-max contractn	**.**40*	.50*	.37*	-.03

Δtime 1-4 = change scores from baseline to primary end-point
* p<0.001

Table 3. Responsiveness of RTUS scores for the two intervention gruops

Outcome measures scores at end-point (scale)	**Best Responders on ICIQ-UI SF**	
	PFMT Mean (95%CI or Median (IQR)	**BT** Mean (95%CI or Median (IQR)
MVC (mm)	**0.35 (0.16,0.55)#**	-0.1
Supra-maximal elevation (no.)	**11 (58.0%)^**	1 (8.3%)
Rate (sec)	**2.7 (2.5,2.9)#**	3.3 (2.8,3.9)
Endurance (sec)	6.2 (16.1)	0.8 (6.1)

ICIQ-UI SF (score 0-21)	3.2 (2.5,3.8)	2.6 (1.1,4.1)
Accident diary (no. leaks)	1.0 (3)	2.0 (3)

*Mann Whitney U Z= -2.577, p=0.01 ^ Chi square χ^2=3.175, df=1, p=0.039
# t-test MVC t score= -2.564, p=0.016 # t-test Rate t score= 2.737, p=0.011
PFMT = pelvic floor muscle training BT = bladder/behavioural training

Interpretation of results

There were either no or weak correlations between change scores at the primary end-point for urinary symptom and RTUS scores indicating little or no concurrent validity. As each of these outcomes evaluates a different domain of incontinence, this is to be expected. Moderate to strong correlations were demonstrated between baseline scores and change scores for each of the four muscle activities. There was a strong negative correlation between baseline displacement and change in displacement, and between baseline rate of contraction and change in rate, indicating a small displacement or slower rate of contraction at baseline predicted a greater change in displacement and rate after intervention. Better baseline ability to perform a MVC and a longer sustained hold predicted the ability to improve supra-maximal contractions after intervention, indicative of a larger strength change.
When comparing participants with least symptom severity at the primary end-point of the study, mean RTUS measures differentiated between the two intervention groups. Those who undertook PFMT were more likely to lift/displace the PFM more, contract faster, and perform a supra-maximal contraction significantly better than the behavioural training group.

Concluding message

The advantage of RTUS is that it is able to non-invasively image and measure both displacement/'lift' and temporal measures which result from PFM activation. The transabdominal approach used in this study showed moderate to strong responsiveness of the tool. Further investigation of transabdominal RTUS as a measuring tool for PFM function is warranted.

References

[1] Neurourol Urodyn (2007) 26; 665-666.
[2] Foundations of Clinical Research; Norwalk, Appleton and Lange,1993 (442)

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Is this study registered in a public clinical trials registry?	**Yes**
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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**