# 17

McLean L<sup>1</sup>, Varette K<sup>2</sup>, Baker K<sup>3</sup>, Harvey M<sup>2</sup>, Brison R<sup>4</sup>, Day A<sup>2</sup> **1.** University of Ottawa, **2.** Queen's University, **3.** The Ottawa Hospital, **4.** Kingston General Hospital

# WOMEN WITH LESS SEVERE STRESS URINARY INCONTINENCE SYMPTOMS ARE MOST LIKELY TO SHOW A COMPLETE CURE ON A STANDARDIZED PAD TEST AFTER PERFORMING A 12 WEEK EXERCISE PROGRAM.

## Hypothesis / aims of study

The purpose of this study was to determine what clinical features best predict which women with stress urinary incontinence (SUI) benefit from pelvic floor muscle (PFM) exercises. A preliminary analysis of 64 women with SUI is presented.

## Study design, materials and methods

Data were recorded as part of an ongoing clinical trial aimed at (1) determining potential predictors of women with SUI who are most likely to benefit from PFM training and (2) determining whether physiotherapist-directed PFM exercise therapy before and following transvaginal tape (TVT) surgery improves outcomes in women with SUI. Preliminary data from all women who were randomized to either a physiotherapist-directed PFM exercise group or a control group who received a hand-out describing PFM exercises to perform at home, and who have to date returned for follow-up evaluation are included. The study received ethical approval from the local research ethics board and all women provided written informed consent prior to participating.

To be eligible, women had to (1) be over the age of 18, (2) have received a diagnosis of SUI from a urogynaecologist, (3) have no evidence of pelvic organ prolapse and (4) be on the surgical wait list for transvaginal tape (TVT) surgery. If they were taking medications known to impact urinary continence and/or using a pessary at the time of recruitment, they were required to discontinue these for the duration of their participation. Participants were also required to have no history of previous surgery for urinary incontinence or pelvic organ prolapse and be free from confounding health conditions such as cancer, connective tissue or neuromuscular diseases. They were not to have attended physiotherapy for the management of incontinence or prolapse symptoms over the previous year.

At the initial laboratory evaluation, the women's height and weight were recorded as well as their history of parity, hysterectomy and menopause. They completed the short form ICIQ [1], a 30 minute standardized pad test [2] and underwent a pre-intervention digital examination of their PFM strength (Modified Oxford Scale) and muscle tone using a 5 point scale [3]. Transperineal ultrasound imaging of their urethral morphology, levator hiatus morphology and bladder neck and urethral excursion during a series of standardized tasks was performed however the imaging results are beyond the scope of the current abstract.

Following their initial assessment, women were randomized to either a treatment or control group. The women in the treatment group received a semi-standardized physiotherapist-directed PFM exercise program of twelve weeks duration. The treatment protocol involved using digital palpation and electromyography biofeedback in weeks 1 and 2 in order to assist learning of PFM contraction and improve motor control of their PFMs, and manual digital palpation assessment and instruction on exercise progression in weeks 4,6,8 and 10. They were also instructed to perform a PFM pre-contraction prior to activities known to increase intra-abdominal pressure, such as coughing. Between physiotherapy visits, they were asked to perform three sets of ten maximal voluntary PFM contraction efforts daily, as well as other strength and motor control exercises depending on specific deficits identified by their physiotherapist. Women in the control group were given the same exercise sheet as the women in the treatment group, however they were not given any specific instruction on which exercises to perform. The sheet did advise women to perform three sets of ten maximal effort PFM contractions daily as well as instructions for other exercises and progression. Exercise compliance in both groups was monitored through biweekly telephone calls by a research assistant and was recorded as the average number of repetitions per week performed of any PFM exercise listed on the exercise handout. All women returned for a reassessment in the laboratory within one week of completing the 12 week intervention period and prior to their TVT surgery; the same assessment procedures were repeated.

The standardized pad test data were used to determine which women were effectively cured, whereby women were defined as "cured" if, at the post-intervention evaluation, they had a pad weight increase of 2g or less over the course of the 20 minute test. The cure-rate of the physiotherapist directed PFM exercise program was compared to the cure-rate of the control group (handout) using a Chi-Square analysis, as was the cure rate of those who reported to have done some exercise at home compared to those who did none. One-way analyses of variance (ANOVAs) investigated differences between the "cured" and "uncured" groups on demographic variables, initial pad test and ICIQ scores and change in pad test and ICIQ scores as well as compliance data reported as average number of repetitions of a PFM contraction performed per week. Due to the small sample size, binary logistic regression, which is planned for the larger study, was not performed at this time.

#### **Results**

Among the data sets recorded from 64 women, 22 were deemed to be cured after the intervention based on their post-intervention pad test results, 8 of 29 in the control group and 14 of 35 in the treatment group. There was a significantly higher cure rate in the treatment as compared to the control group ( $X^2$ =6.02, p=0.014). Similarly, there was a significantly higher number of cured women who did any home exercise (14 of 22) as compared to those who did not (6 of 44).,  $X^2$ =19.34; p=0.000).

The "cured" and "uncured" groups were not statistically different in terms of age, parity, weight of their heaviest baby, hysterectomy status, menopausal status, or average number of PFM exercise repetitions performed per week, but the "cured" group had significantly lower BMI and higher PFM tone at the original assessment (Table 1). They also had lower pre-intervention pad test results (25.6±22.0 vs 36.9±30.0g for the "cured: and "uncured" groups, respectively) and a much larger percent change in pad

test results after the intervention (90.8 $\pm$ 10.3 vs 3.1 $\pm$ 144.0% for "cured" and "uncured" groups, respectively). Both the "cured" and "uncured" women reported reductions ICIQ scores after the intervention (F=93.43, p=0.000); the "cured" group had lower ICIQ scores than the "uncured" group both before (mean=14.3 $\pm$ 3,6 vs 11.5 $\pm$ 5.2) and after (mean = 9.3  $\pm$ 4.8 vs 12.6 $\pm$ 4.0) the intervention, but there was no significant difference in the amount of change recorded on the ICIQ-SF after the intervention based on whether women were "cured" or not.

Table 1

	Age (yrs)	BMI (kg/m <sup>2</sup> )	Parity (n)	Heaviest baby (kg)	Meno- pause (n)	PFM strength	PFM tone	Ex freq (reps/wk)
"uncured"	53.9	28.6*	2.2 (1.2)	3.8	n=19	0.6	-0.1*	111.6
(n=53)	(9.9)	(6.6)		(0.7)		(0.5)	(0.6)	(112.2)
"cured"	50.1	27.9	2.3	3.6	n=10	0.5	0.3	120.1
(n=22)	(9.5)	(6.5)	(1.0)	(0.6)		(0.5)	(0.9)	(111.2)

Data are presented as mean(SD) or counts (n). Statistically significant differences( $\alpha$ =0.05) are indicated by \*. BMI= body mass index, yrs=years, Ex freq =average self-reported number of PFM contractions performed at home over the 12 weeks of the intervention.

#### Interpretation of results

These preliminary results suggest that women with SUI are more likely to be cured through PFM exercise if the exercise is delivered through a physiotherapist directed program as opposed to simply receiving a handout, and if they perform at least some PFM exercises at home. Women who are "cured" by PFM exercise have lower BMIs, higher PFM tone and less severe signs (pad test) and symptoms (ICIQ-SF) of SUI. Women who are "cured" according to the standardized pad test continue to report symptoms of incontinence on the ICIQ-SF.

#### Concluding message

This preliminary analysis suggests that physiotherapy-directed PFM exercise is superior to an exercise handout in terms of curing SUI in women, and that women may be more likely to have their SUI cured with exercise if they have lower body mass index, higher PFM tone on palpation, and less severe signs and symptoms. The larger study will include further assessment of morphological and biomechanical factors that may predict success with physiotherapy treatment. References

- 1. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P.(2004) ICIQ: A brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn 23(4): 322-330
- 2. Turbaro A, Artibani W et al., Imaging and other investigations (2005) In: Incontinence: 3rd Consultation on Incontinence, 2004. Eds. Abrams P, Cardozo L, Khoury S, Wein, A, Health Publications Ltd. West Caldwell.
- 3. Bø, K. and M. Sherburn (2005). Evaluation of female pelvic-floor muscle function and strength. Physical Therapy . 85(3): 269-282

#### **Disclosures**

**Funding:** Canadian Institutes of Health Research **Clinical Trial:** Yes **Registration Number:** NCT01602107 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Queen's University and Affiliated Hospitals Research Ethics Board The Ottawa Hospital Research Ethics Board **Helsinki:** Yes **Informed Consent:** Yes