

The effect of pelvic floor muscle training on urodynamic parameters in women with stress urinary incontinence

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Introduction Pelvic floor muscle training (PFMT) is suggested for women with stress urinary incontinence (SUI). The aim of our study is to examine the effectiveness of PFMT on urodynamic (UDS) parameters.

Material and methods This is a prospective observational study enrolling women with SUI. Pelvic surgery, prolapse, body mass index >30, and cognitive disability were exclusion criteria. Patients had baseline UDS, then PFMT only (Group A) or PFMT plus biofeedback (BFD) (Group B) for 6 months and UDS 3 months after treatment. The primary investigated parameters were the number of pads used per day and Valsalva leak point pressure (VLPP).

Results Forty-six women completed the study, 22 in Group A and 24 in Group B. At baseline, all patients documented SUI with 3 median pads used per day. Urodynamic SUI was documented with a median Valsalva leak point pressure (mVLPP) of 45 cmH₂O. At the re-evaluation, 12 women (26.1%) had SUI in BDs with median number pads per day of 1, which was statistically different to baseline ($p = 0.02$). Urodynamic SUI was reported in 8 (17.4%) women with a mVLPP of 88 cmH₂O.

Six patients were from Group A and 6 from Group B. In Group A, the median number of pads per day was 1, and urodynamic SUI was found in 3 women. In Group B, the median number of pads per day was 1, and urodynamic SUI was found in 5 women. Thirty-four women (73.9%) were dry – 16 (47.1%) from Group A and 18 (52.9%) from Group B.

Conclusions PFMT improves urodynamic parameters among women with SUI.

Key Words: stress urinary incontinence <> pelvic floor muscle training <> biofeedback <> urodynamics <> Valsalva leak point pressure

INTRODUCTION

Stress urinary incontinence (SUI) is the complaint of involuntary loss of urine during effort or physical exertion, including sporting activities, or when sneezing or coughing, as defined by the International Continence Society (ICS) [1]. This is a common condition affecting women of any age; however, it is more prevalent in middle-aged and elderly groups [2]. The National Health and Nutrition Examination Survey (NHANES), retrieving data from the

U.S. registry, confirmed that 49.6% of women suffered from UI, with 49.8% reporting pure SUI and 34.4% claiming mixed urinary incontinence (MUI) [3]. The peak of SUI prevalence seems to be between the ages of 45 and 59 years [4].

SUI is further classified as complicated or not, depending on the co-existence of further lower urinary tract dysfunction (LUTD), neurological disorders, prior pelvic surgeries, or radiotherapy and prolapse [5]. The 2 proposed mechanisms of SUI are urethral hypermobility and intrinsic sphincter deficiency [1].

The degree of severity varies from completely asymptomatic cases detected only during clinical examination to complete abstinence from social life due to symptoms. For SUI quantification, the ICS suggests the use of a pad test for 1 or 24 hours. [6]. Although this test is not always reliable, it is quite useful for the evaluation of SUI, when it is applicable in a formula of 24–72-hour testing [6].

The diagnosis of SUI is clinical; however, in cases of unclear aetiology such as urgency or urge incontinence, urodynamic study (UDS) is indicated [7]. The typical urodynamic finding is involuntary leakage during filling cystometry, accompanied by increased intra-abdominal pressure, without a concomitant detrusor contraction [7]. Based on strong evidence, the EAU guidelines panel of female LUTS now recommends against the use of urodynamics in uncomplicated female SUI cases, unless it is expected that UDS might change the treatment plan [8, 9, 10].

The management of SUI should be personalized according to the patient's needs and health care status. It should involve lifestyle and behavioural changes, loss of weight, and pelvic floor muscle training (PFMT) or a complete surgical approach. PFMT improves pelvic floor function, increases muscle strength and endurance, and enhances sphincteric function in the long term. Treatment with PFMT can reduce or eliminate urine leakage episodes, especially in cases of mild to moderate SUI [11, 12]. EAU guidelines recommend offering PFMT to women with mild to moderate SUI or in cases not eligible for a surgical approach [8].

Although there are data to support the clinical effect of PFMT in women with SUI, there is insufficient evidence on its effect on urodynamic parameters. The aim of our study is to investigate the effectiveness of PFMT on the parameters of urodynamic study.

MATERIAL AND METHODS

Patient selection

This is a prospective observational study enrolling patients from the Urodynamics Clinic of our hospital between October 2021 to January 2023. The study was approved by the Local Ethics Committee. All patients signed a consent form after they had been thoroughly informed, and all principles of the Helsinki Declaration regarding patients' rights were followed. The inclusion criteria were women with uncomplicated SUI already certified with a stress test, naïve of any other treatment. Women with previous pelvic intervention, co-existing prolapse, body mass index (BMI) over 30, and those with cognitive disability were excluded.

BMI over 30 corresponds to obesity and consecutive disturbances, such as heart failure, diabetes mellitus, and high blood pressure. These clinical conditions can affect lower urinary tract function with a direct action, e.g. peripheral neuropathy in diabetic patients, or indirectly, e.g. pharmaceutical treatment with diuretics for heart failure or hypertension. Hence, the results of our investigation could be misleading. Also, obese women sometimes cannot be adequately cooperative for a urodynamic study, with significant artifacts for this examination, and finally a false conclusion.

Cognitive ability was evaluated with use of the Global Deterioration Scale, and patients with a score over 2 were excluded [13].

At baseline all patients had a urodynamic study according to the Good Urodynamic Practice standards of ICS [14, 15, 16]. UDS included the non-invasive part with bladder diaries (BD), pad-test, uroflow, and bladder scan and the invasive part with cystomanometry and pressure-flow study.

Then, they were advised regarding treatment with a supervised PFMT with or without biofeedback (BFD) for 6 months, and they all had a repeat UDS 3 months after the end of the physiotherapy program. The muscle assessment of the pelvic floor was based on the PERFECT protocol (P: power, E: endurance, R: repetitions, F: fast, E: ability to elevate the posterior vaginal wall during contraction, C: appropriate co-contraction of transverse abdominus, T: co-ordination of contraction prior to coughing) [17]. Women under PFMT only were randomized into Group A, while those with biofeedback (BFD) as an add-on method were allocated into Group B (Figure 1). Patients' randomization was performed with the use of an electronic randomizer (<https://www.randomizer.org>).

Following the findings of non-invasive and invasive urodynamic tests, the investigated parameters at baseline and 3 months after treatment were the number of pads used per day, the maximum voided volume (MVV), the post-void residual volume (PVR), and Valsalva Leak Point Pressure (VLPP) for patients of each group (Figure 1).

The VLPP was checked with a cough stress-test, deep sitting abdominal strain, and Valsalva manoeuvre with a forced expiration against a closed glottis, which is associated with an increase in the intrathoracic and intra-abdominal pressure.

The PFMT and biofeedback protocol

At their first visit to the physiotherapy centre, the women were evaluated for the functionality and strength of their pelvic floor. They were interviewed

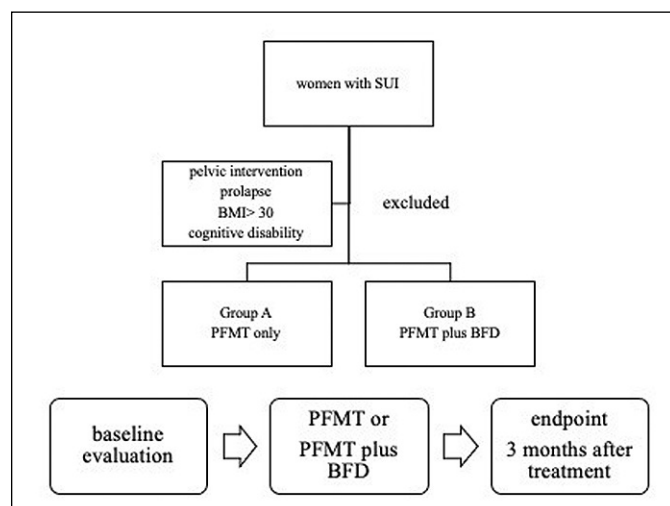


Figure 1. Study design flowchart.

for their medical history, and then they were given information about the anatomical structures and physiology of their pelvis and pelvic floor specifically. The PFMT protocol was explained in detail and the program of upcoming sessions was delivered, including supervised exercise and home practice for 6 months. Patients were evaluated with a stress-test (cough, deep sitting, Valsalva manoeuvre) for their severity of SUI, and then they were asked to empty their bladder. In a supine position, they were prepared for a vaginal examination, and with a finger inside their vagina they were asked to describe the sensation and then to contract and relax their pelvic muscles, so that the functionality and strength of the pelvic floor could be configured. The muscle assessment was based on the PERFECT protocol. Additionally, a separate evaluation of the whole pelvis was performed, including whole pelvic area, activity of hip joints, lumbar muscles, and lower extremities.

After the muscle assessment, the women were eligible for supervised training. In a lying position, they performed 3–5 sets of exercise per session, consisting of a 6–8-second contraction followed by a 3-second rest. The same sets were also performed in sitting and standing positions. Over time, women were asked to lengthen contractions, increase repetitions, and reduce rest periods.

After this first visit, the women were advised to perform every 2 weeks a supervised, one-hour PFMT program for 6 months, accompanied by home practice. The weekly visits included re-education of the diaphragmatic breath, courses for the ideal posture, bladder training, and manual practice for the reinforcement of pelvic floor and neuromuscular stimulation. SUI was evaluated with repeated stress tests,

as in the first visit. The PERFECT protocol was used to determine the effectiveness during the progress of PFMT.

Patients eligible for additional treatment, according to the study protocol, underwent a session with biofeedback, followed by the same evaluation methods as in the PFMT-only group. The biofeedback protocol for each patient was based on the results of the PERFECT assessment in addition to the evaluation according to the Modified Oxford Grading System (MOGS) for pelvic floor muscles [18, 19]. Depending on the MOGS grading (0: no discernible pelvic floor muscle contraction, 5: strong pelvic floor muscle contraction), the relative power was arranged from 5 mV for a 0 MOGS to over 50 mV for a 5 MOGS patient. Also, repetitions were 5–10 per session, and the total time of exercise was from 5 to 20 minutes, according to the above MOGS grading.

The home practice included exercises for the reinforcement of the pelvic floor, restoration of diaphragmatic breath, and correct posture, each of them with 3 sets of 10 repetitions per day.

Statistical Analysis

Continuous variables are given as medians and ranges, while categorical outcomes are shown as proportions. Statistical analysis was performed with the Mann-Whitney test for non-parametric samples. Comparison for categorical outcomes was performed using chi-square or Fisher's exact test. A cut-off value for statistical significance was set at 0.05 with SPSS v26 (IBM Corp. 2017. IBM SPSS Statistics for Windows. Armonk, NY: IBM Corp.)

RESULTS

Forty-six women completed the study – 22 in Group A and 24 in Group B, with a median age of 63 years (range: 32–71 years) and median BMI of 25 kg/m² (range: 22–29 kg/m²).

At baseline, all patients reported SUI in BDs. In the whole sample, the median maximum voided volume (mMVV) was 280 ml (range: 220–410 ml), and the median number of pads used per day was 3 (range 2–5). Urodynamic SUI was documented in all patients. The median Valsalva leak point pressure (mVLPP) was 45 cmH₂O (range: 33–52 cmH₂O), the median peak flow rate (mQmax) was 30 ml/sec (range: 23–35 ml/sec), and the median post-void residual volume (mPVR) was 60 ml (range: 0–80 ml).

In Group A the mMVV was 275 ml (range: 220–400 ml) and the median number of pads used per day was 3 (range: 2–5), while in Group B they were 280 ml (range: 240–410 ml) and 3 pads per day (range: 2–5),

respectively. Patients in Group A had a mVLPP of 45 cmH₂O (range: 35–52 cmH₂O), and those in Group B documented it at 48 cmH₂O (range: 33–50 cmH₂O). The mQmax and mPVR were 31.5 ml/sec (range: 23–35 cmH₂O) and 50 ml (range: 0–60 cmH₂O) for Group A and 29 ml/sec (range: 23–33 ml/sec) and 65 ml (range: 20–80 ml) for Group B. All the baseline characteristics showed no statistical difference between the 2 groups ($p > 0.05$) (Table 1).

On re-examination, 12 women (26.1%) reported SUI in BDs. For the whole sample, the mMVV was 320 ml (range: 230–430 ml) and the median number of pads per day was 1 (range: 0–2), which is statistically different compared to baseline ($p = 0.02$). Urodynamic SUI was reported in 8 (17.4%) women with a mVLPP at 88 cmH₂O (range: 65–94 cmH₂O), which is statistically different compared to baseline ($p = 0.02$), mQmax was 30 ml/sec (range: 22–35 ml/sec), and mPVR was 45 ml (range: 0–60 ml), with no statistical difference compared to initial values ($p > 0.05$) (Table 2).

These patients with remaining SUI were equally distributed in the 2 groups, i.e. 6 in each group. For Group A, mMVV was 325 ml (range: 230–400 ml), median number of pads per day was 1 (range: 0–2), urodynamic SUI was found in 3 women, mVLPP was 90 cmH₂O (range: 68–94 cmH₂O), mQmax was 29 ml/sec (range: 22–33 ml/sec), and mPVR was 50 ml (range: 20–60 ml). For Group B, mMVV was 315 ml (range: 230–430 ml), median number of pads per day was 1 (range: 0–2), urodynamic SUI was found in 5 women, mVLPP was 86 cmH₂O (range: 65–90 cmH₂O), mQmax was 31.5 ml/sec (range: 23–35 cmH₂O), and mPVR was 40 ml (range: 0–60 ml). No statistically significant difference was found between groups for MVV, number of pads per day, VLPP, Qmax, and PVR (Table 3).

The parameters for 34 (73.9%) dry women after intervention were measured as mMVV 310 ml (range: 230–400 ml), mQmax 31 ml/sec (range: 23–33 ml/sec), and mPVR 55 ml (range: 30–60 ml), without any statistical difference compared to the baseline sample ($p > 0.05$). They were no longer using pads and had no urodynamic SUI at follow-up examination. Sixteen (47.1%) of them had been allocated to Group A and the remaining 18 (52.9%) to Group B, and they were almost equally affected by their treatment.

DISCUSSION

Presently, PFMT is widely accepted as the gold standard for conservative treatment of SUI. To this day, there are numerous randomized control trials aiming to assess the effectiveness of PFMT for female

Table 1. Baseline characteristics

Parameter	Group A 22 women median (range)	Group B 24 women median (range)	p value
MVV (ml)	275 (220–400)	280 (240–410)	0.911
Pads/day	3 (2–5)	3 (2–5)	equal
VLPP (cmH ₂ O)	45 (35–52)	48 (33–50)	0.891
Qmax (ml/sec)	31.5 (23–35)	29 (23–33)	0.811
PVR (ml)	50 (0–60)	65 (20–80)	0.765
Age (years)	61 (34–71)	64 (32–70)	0.752
BMI (kg/m ²)	25 (22–27)	26 (23–29)	0.882

MVV – maximum voided volume; VLPP – Valsalva leak point pressure; Qmax – peak flow rate; PVR – post-void residual volume; BMI – body mass index

Table 2. Treatment efficacy in the whole sample 3 months after treatment

Parameter	Baseline median (range)	3 months after treatment median (range)	p value
MVV (ml)	280 (220–410)	320 (230–430)	0.512
Pads/day	3 (2–5)	1 (0–2)	0.02
VLPP (cmH ₂ O)	45 (33–52)	88 (65–94)	0.02
Qmax (ml/sec)	30 (23–35)	30 (22–35)	equal
PVR (ml)	60 (0–80)	45 (0–60)	0.457

MVV – maximum voided volume; VLPP – Valsalva leak point pressure; Qmax – peak flow rate; PVR – post-void residual volume

Table 3. Comparing parameters for patients with remaining SUI 3 months after treatment

Parameter	Group A 6 women median (range)	Group B 6 women median (range)	p value
MVV (ml)	325 (230–400)	315 (230–430)	0.814
Pads/day	1 (0–2)	1 (0–2)	0.65
VLPP (cmH ₂ O)	90 (68–94)	86 (65–90)	0.742
Qmax (ml/sec)	29 (22–33)	31.5 (23–35)	0.861
PVR (ml)	50 (20–60)	40 (0–60)	0.546

SUI – stress urinary incontinence; MVV – maximum voided volume; VLPP – Valsalva leak point pressure; Qmax – peak flow rate; PVR – post-void residual volume

patients with SUI, but this evaluation is usually grounded on either urine leakage measured on pad tests or questionnaires about QoL (e.g. ICIQ-UI SF) [8, 11, 12]. Interestingly, the literature is scant regarding the effect of PFMT in urodynamic parameters in women with SUI. In our study, we assessed the impact of PFMT on additional urodynamic parameters (Qmax, PVR, VLPP, MVV) utilizing both invasive and non-invasive urodynamic studies.

A literature search was performed (Scopus, PubMed/MEDLINE), and to the best of our knowledge this is the first study to include those parameters

In the current literature, there are some studies attempting to elucidate the positive effect of PFMT on SUI. Balmforth et al. in their prospective observational study reported a correlation between bladder neck mobility changes and SUI symptom improvement after PFMT [20]. More specifically, they depicted significant elevation of the bladder neck position after intensive PFMT and behavioural treatment. In our study we did not seek to interpret additional mechanisms behind PFMT results for SUI, but this could be a subject for future research.

It should be highlighted that all patients in our study underwent PFMT under supervision, because current data demonstrate superiority of outpatient supervised PFMT over non-supervised for female patients with SUI. Remarkably, the effect of our treatment protocol proved to be long-lasting, even after active supervising, because all the women were highly educated and trained to perform home practice. More specifically, Zanetti et al. reported a 48% SUI cure rate in women after supervised PFMT in comparison with 38% for unsupervised PFMT [21]. Konstantinidou et al. reported a significant beneficial effect in favour of supervised training versus home exercises [22]. Furthermore, a RCT conducted by Fitz et al. showed a 75% SUI cure rate for female patients with SUI who underwent outpatient PFMT, but only 35% for women who under home training alone [23]. Chen et al, in their study reported that antenatal unsupervised and self-reported PFMT showed a minimal effect on postpartum SUI [24].

There is controversy over the potential beneficial effect of PFMT or PFMT with biofeedback (BFD) compared to PFMT alone. Hwang et al. in their retrospective cohort study claim that PFMT with BFD is only beneficial for patients with mild SUI. [25]. A meta-analysis by Nunez et al., including only 2 RCTs, aimed to determine if add-on BFD for PFMT offers any difference in terms of urine leakage, episodes of urinary loss, quality of life, and muscle strength. The authors concluded that PFMT with BFD offers no significant therapeutic benefits over other interventions (no training, PFMT alone, and vaginal electrical stimulation) for women with SUI [26]. Data from a multicentre RCT by Hagen et al. pointed towards the same direction, i.e. the authors found no significant difference in terms of SUI improvement between patients on PFMT with BFD and PFMT alone [27]. An interesting endpoint of this study was that both methods had similar monetary costs. Conversely, a systematic review by Herderschee et al., which included 24 RCTs, showed that

women who received add-on BFD were less likely to report no SUI improvement compared to conventional SUI, but no statistically significant difference was found for SUI cure [28]. Another systematic review and meta-analysis conducted by Moroni et al. included 37 studies and set all conservative treatment options for SUI in comparison. The authors concluded that PFMT combined with BFD shows better results on the pad test but has an uncertain effect on QoL [29]. In addition to this, a systematic review and meta-analysis by Wu et al. showed results concordant with the previous analysis, i.e. the authors reached the conclusion that PFMT with adjuvant EMG-BFD achieves better results compared to PFMT alone. [30] An interesting study conducted by Kannan et al. compared the benefits of a novel biofeedback device (PelviSense), conventional biofeedback PFMT, and regular PFMT [31]. The results of this RCT indicated superiority of the biofeedback device over the other 2 methods in regard to SUI symptoms. Evaluating the results of our study, we concluded that PFMT with adjuvant BFD offered no substantial benefit in terms of statistical significance regarding SUI cure and urodynamic parameters like MVV, number of pads per day, VLPP, Qmax, and PVR.

The primary limitation of our results is the limited sample size and the single-centre nature of this study. Despite the small recruitment, to our knowledge, this study is the first to present data on the effect of PFMT on UDS parameters in women with SUI. We could also notice that it is not always feasible to perform a repetitive and objectively equal stress exercise, not only in different patients but even in the same patient. However, the multiple ways of evaluation of VLPP could overcome this possible handicap. Moreover, in our study, instead of relying just on QoL questionnaires, we conducted a second urodynamic study at the end of the training program to evaluate objective changes. Another limitation could be the lack of a separate analysis for post-menopause women, while we assumed that BMI could not have been changed significantly for 3 months, so as to affect our results. Also, the number of pads used per day is not always an accurate measure for incontinence because women sometimes wear them even for safety reasons or change them with very limited leakage. However, we based our results on the ICS suggestion for the estimation of incontinence severity, according to wet pads used per day [32].

CONCLUSIONS

PFMT is a first-line conservative treatment option for women with SUI. In our study, we used invasive

and non-invasive urodynamic methods to assess the effect of a 6-month PFMT program on female patients with SUI, who were naïve of previous treatment for SUI and confirmed the beneficial effect of PFMT for SUI treatment PFMT with biofeedback. Our results

showed no statistical difference between the 2 methods in terms of SUI cure and urodynamic parameters.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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