



## Pelvic Floor Muscle Training for Female Stress Urinary Incontinence: Five Years Outcomes

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**Aim:** To evaluate the clinical status, lower urinary tract symptoms (LUTS) and quality of life (QOL) 5 years after completion of a pelvic floor muscle training (PFMT) program for female stress urinary incontinence (SUI). **Methods:** Two hundred and eight consecutive women who underwent a guided PFMT program as first-line management of SUI were invited to participate in a questionnaire-based outcome study 5 years after treatment. Primary outcome measures comprised of adherence to PFMT, interim surgery for SUI, and patients' self-assessment of LUTS and QOL. **Results:** One hundred and thirty-two (63%) women completed all questionnaires, 55 of whom (41.7%, mean age  $52.1 \pm 10.8$ ) reported adherence to PFMT, 75 (56.8%, mean age  $49.8 \pm 10.8$ ) discontinued training, and two (1.5%) underwent surgery. Further analysis of the 76 non-responders revealed six more patients who underwent surgery. Thus, overall, eight patients (3.8% of the original cohort) underwent surgery within 5 years after completion of the training program. Except for those who underwent surgery, almost all women reported SUI, however their ICIQ-UI scores for frequency and amount of leakage were low ( $2.2 \pm 0.9$ ,  $1.18 \pm 1.04$ , respectively) and I-QOL score was high ( $96.2 \pm 13.6$ ). All investigated parameters and domains, in each of the three questionnaires and among all women, consistently demonstrated low severity of LUTS and relatively high continence-associated QOL. There were no statistically significant differences in favor of adherence to PFMT. **Conclusions:** Although relatively high rates of 5-year adherence to training were demonstrated among our patients, this adherence was not associated with superior treatment outcomes. Further studies are needed to establish the long-term efficacy of PFMT for SUI. *NeuroUrol. Urodynam.*

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**Key words:** outcome assessment; pelvic floor muscle training; stress urinary incontinence

### INTRODUCTION

Stress urinary incontinence (SUI) may affect women of all ages, however it is more common among young and middle-aged women.<sup>1</sup> These relatively young women are usually physically healthy and socially active individuals and SUI may therefore adversely affect their daily activities and quality of life. Pelvic floor muscle training (PFMT), first introduced by Kegel<sup>2</sup> in 1948 for the treatment of female SUI, is now recommended by leading health organizations as first line therapy to all women with stress, urgency, or mixed urinary incontinence.<sup>3–6</sup> This recommendation is further supported by an up-to-date Cochrane systematic review of 21 randomized or quasi-randomized trials involving 1,281 women.<sup>7</sup> Results of this review show that stress incontinent women who undergo PFMT are 17 times more likely than controls to report short-term cure or improvement (RR 17.33, 95%CI 4.31–69.64). Long-term outcome results, of more than 1 year after completion of treatment, were not reported.

Data regarding long-term outcomes of PFMT for female SUI are scarce and controversial. Further, as with any other life style interventions, long-term outcomes depend on various factors, such as severity of symptoms, self-motivation, response to initial therapy, social support, medical status, etc. Little is known about the association between these factors and the long-term outcomes of PFMT. The aim of our study was to evaluate adherence to therapy, lower urinary tract symptoms (LUTS) and continence-related quality of life (QOL) parameters 5 years after completion of a PFMT program for female SUI.

### METHODS

Two hundred and eight consecutive stress incontinent women who completed a guided PFMT program 5 years earlier were invited to participate in a questionnaire-based cross-sectional follow-up study to evaluate adherence to therapy, current LUTS, incontinence-associated QOL issues, and also to determine how many had undergone interval surgery. The study was undertaken using the computerized database of Maccabi Healthcare Services (MHS), the second largest Health Maintenance Organization in Israel. The study was approved by the Institutional Review Board at MHS and the ethics committee of Tel Aviv University.

All eligible women complained of SUI for at least 3 months prior to therapy. Initial clinical evaluation, comprised of history and general assessment, physical and pelvic examination, and urinalysis, was performed according to the recommendations of the 3rd International Consultation on Incontinence.<sup>8</sup> Further studies, as well as urodynamic evaluation, were performed

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according to medical judgment. The diagnosis of SUI was based on a demonstration of urinary leakage on straining or coughing with a comfortably full bladder. In women presenting with mixed incontinence, SUI was classified as predominant according to the patient's self-report. Women included in this study had not received either PFMT or incontinence surgery prior to the index intervention. Additional exclusion criteria included: urgency urinary incontinence (UUI), mixed urinary incontinence with predominant UUI, concomitant significant pelvic organ prolapse (stage 2 or more by POP-Q classification), patients who discontinued the PFMT program, and those who underwent additional guided PFMT sessions during the 5-year follow-up interval.

All PFMT sessions were conducted individually by certified pelvic physiotherapists in MHS clinics. Each woman attended once a week for at least three consecutive private PFMT sessions until she acquired adequate skills to perform self-training. The final number of sessions was determined by the physiotherapist. Vaginal palpation was used to evaluate pelvic floor muscle function and strength and to assess whether contractions were performed correctly. The muscle power was graded from zero to five according to the Oxford grading system. Biofeedback or electrostimulation were used as necessary as an adjunct to training. All women were advised to integrate PFMT into their daily activities and to perform exercises at home twice a week. The recommended self-training protocol comprised of three sets of 8–12 slow velocity, close-to-maximum contractions.

Baseline demographic and clinical data, as well as training parameters and clinical follow up were documented in a detailed computerized database. Using this database we detected 208 consecutive stress incontinent women who completed a PFMT program 5 years earlier and met our inclusion and exclusion criteria. All participants were contacted and invited to complete up-to-date postal questionnaires regarding their adherence to therapy, interval surgery, LUTS, and continence-related QOL. Of the 208 women, 194 (93%) agreed to participate in the study, 12 (6%) were lost to follow-up or refused, and two patients had passed away. Validated LUTS and QOL questionnaires (BFLUTS<sup>9</sup>, ICIQ-UI<sup>10</sup>, I-QOL<sup>11</sup>), as well as a clinical questionnaire devised by the authors, were sent (with a stamped return envelope) to the 194 eligible women, 132 (68%) of whom completed and returned the requested questionnaires (63% of the original cohort). Comparing the 132 responders versus the 76 non responders, there were no statistically significant differences in terms of their mean age, parity, body mass index (BMI), presenting LUTS, or number of PFMT sessions. The 132 responders were further divided into two subgroups according to 5-year adherence to therapy. Primary outcome measures comprised of patients' self-assessment of LUTS, incontinence associated QOL parameters, and interval surgery for SUI. Secondary outcome measures were risk factors associated with severity of incontinence and impaired QOL. Primary and secondary outcome measures were analysed and compared between the two subgroups.

Statistical analysis was performed using Student's *t*-test for continuous data or Fisher exact test for categorical data. Data are summarized as mean  $\pm$  standard deviation (SD), or percentage according to the variables.  $P < 0.05$  was considered statistically significant. Statistical Package for Social Sciences (SPSS), version 15.0, was used for the analysis.

## RESULTS

One hundred and thirty two women (mean age:  $50.5 \pm 10.8$  years, range: 34–79) who underwent guided PFMT as first-line management for SUI 5 years earlier were available for outcome

TABLE I. Demographic Characteristics (Five Years After Therapy)

Mean $\pm$ SD or N (%)	No adherence to PFMT (N = 75)	Adherence to PFMT (N = 55)	P*
Interval after therapy (years)	5.64 $\pm$ 0.84	5.58 $\pm$ 0.64	0.679
Age (years)	49.81 $\pm$ 10.82	52.05 $\pm$ 10.81	0.254
Body mass index (Kg/m <sup>2</sup> )	25.25 $\pm$ 4.15	24.9 $\pm$ 3.63	0.589
Parity	2.69 $\pm$ 1.47	2.54 $\pm$ 1.05	0.526
Vaginal deliveries during interval	17 (22.7%)	8 (14.5%)	0.270
Education level			
Elementary school	3 (4%)	1 (1.8%)	
High school	14 (18.7%)	13 (23.6%)	
Tertiary	58 (77.3%)	41 (74.5%)	

PFMT, pelvic floor muscle training.

\*Statistical analysis was performed using Student's *t*-test for continuous data or Fisher exact test for categorical data.

analysis. Of these, 55 women (41.7%, mean age  $52.1 \pm 10.8$ ) reported adherence to training, 75 (56.8%, mean age  $49.8 \pm 10.8$ ) reported no adherence, and two others (1.5%) had undergone SUI surgery. Demographic and clinical characteristics of the women, divided by adherence to training, are presented in Table I. There were no statistically significant differences between the groups. However, most women (76%) had received tertiary education, a significantly higher percentage than the official reported rate (45.6%) in the general population.<sup>12</sup> The mean number of guided PFMT sessions per woman was  $4.7 \pm 2$ . The mean Oxford grade at the beginning of treatment was  $2.8 \pm 1.2$  and most women received either biofeedback (52%), or electrostimulation (8%), as an adjunct to training.

Five years after completion of the guided program, 126 (97%) of the 130 women who did not undergo surgery still had urinary incontinence, 47 (36%) of whom experienced frequent episodes (two or more per week) of incontinence regardless of adherence to training. The main type of incontinence was SUI (97%), however, 21% of the women also had UUI. The two women who underwent surgery were cured. Further analysis of the 76 women (mean age:  $50.95 \pm 12.4$  years, range: 26–84) who did not complete the questionnaires revealed six additional women who underwent SUI surgery within 5 years after therapy. Thus, overall, eight women (3.8% of the original cohort) required surgical intervention for SUI within 5 years after completion of the PFMT program.

Results of the BFLUTS, ICIQ-UI, and I-QOL questionnaires at 5 years after therapy, divided by adherence to training, are presented in Table II. Although almost all women reported SUI, their ICIQ-UI scores for frequency and amount of leakage were low ( $2.2 \pm 0.9$ ,  $1.18 \pm 1.04$ , respectively) and I-QOL score was high ( $96.2 \pm 13.6$ ). All investigated parameters and domains, in each of the three questionnaires and among all women, consistently demonstrated low severity of LUTS and relatively high continence-associated QOL. Further, there were no statistically significant differences in favor of adherence to PFMT. Most women (91% of exercising and 87% of non-exercising individuals) reported that they would recommend PFMT to a friend with a similar problem.

## DISCUSSION

Pelvic floor muscle training is recommended as first-line management of female SUI. Short-term effectiveness, as well as lack of adverse effects, of this treatment modality are well documented, however data regarding long-term outcomes are

**TABLE II. Lower Urinary Tract Symptoms and Quality of Life Questionnaires Five Years After PFMT for Female Stress Urinary Incontinence**

Mean ± SD	No adherence to PFMT (N = 75)	Adherence to PFMT (N = 55)	P*
ICIQ UI TOTAL	7.12 ± 4.33	7.07 ± 4.44	0.777
ICIQ UI FREQUENCY	1.62 ± 1.07	1.56 ± 1.01	0.736
ICIQ UI AMOUNT	2.18 ± 0.88	2.25 ± 1.02	0.686
ICIQ QOL	3.6 ± 3.2	3.2 ± 3.11	0.498
BFLUTS-FS	3.44 ± 2.4	3.18 ± 1.85	0.507
BFLUTS-VS	1.86 ± 2	2.2 ± 2	0.351
BFLUTS-IS	4.73 ± 2.84	4.89 ± 2.84	0.756
BFLUTS-SEX	0.3 ± 0.77	0.49 ± 1.12	0.269
BFLUTS-QOL	3.1 ± 3.11	3.01 ± 2.75	0.867
I-QOL-TOTAL	96.65 ± 13.82	95.96 ± 13.59	0.778
I-QOL- AVOIDANCE	34.29 ± 5.32	34.05 ± 4.85	0.794
I-QOL-PSYCHO	41.57 ± 5.39	41.14 ± 5.35	0.655
I-QOL- EMBARRAS	20.78 ± 4.4	20.76 ± 4.49	0.977

PFMT, pelvic floor muscle training.

BFLUTS<sup>9</sup>, Bristol female lower urinary tract symptoms questionnaire.

FS, filling symptoms; VS, voiding symptoms; IS, incontinence symptoms, Sex, sexual function; QOL, quality of life.

ICIQ-UI<sup>10</sup>, International Consultation on Incontinence Questionnaire.

I-QOL<sup>11</sup>, Incontinence Quality Of Life instrument.

\*Student's t-test.

scarce and controversial.<sup>7</sup> Long-term adherence to PFMT was previously reported to be associated with better outcomes, however the adherence rate is known to be poor in most lifestyle interventions.<sup>13,14</sup> Results of the present study demonstrate up to 42.7% adherence 5 years after completion of a guided PFMT program for female SUI, yet adherence per se was not found to be associated with superior outcomes. Surprisingly, only a few of our patients underwent SUI surgery within 5 years after treatment. This rate is much lower than previously reported.

Long-term outcomes of PFMT have been studied in several small series of stress incontinent women. Cammu et al. used postal questionnaires to evaluate 45 women who underwent PFMT 10 years earlier.<sup>15</sup> When PFMT had initially been successful, favorable results were maintained in two-thirds of the patients and only 8% had undergone surgery. When PFMT had initially failed, then as much as 62% had undergone surgery. Bo et al. invited 52 women, who were originally randomized 15 years earlier to home versus intensive PFMT, to participate in a questionnaire-based follow-up assessment.<sup>16</sup> As much as 50% of both groups had undergone surgery during the 15-year follow-up period and 28% performed PFMT at least weekly. The investigators concluded that long-term adherence to training is low and that the short-term effectiveness of PFMT is not maintained 15 years later. Interestingly, 5-year outcome results of the same original cohort were much more favorable: of 23 women who had participated in the intensive PFMT arm, 16 (70%) were exercising the pelvic floor muscles at least once a week, and only three (13%) underwent surgery.<sup>17</sup> These 5 year outcome results were published in 1996, just before the introduction of the mid-urethral sling technique. It is therefore possible that with the increased use of minimally invasive surgical procedures more patients decided to undergo surgery. Schiotz et al. investigated 33 women 10 years after they had

participated in a study on conservative treatment of SUI.<sup>18</sup> During the interim, 15 (47%) women had undergone surgery and only five (15%) were still doing PFMT at least twice per week. Most recently, Bo and Hilde performed a systematic review to evaluate the long-term outcomes of PFMT for female SUI.<sup>13</sup> Nineteen studies were included (1,141 women, followed between one and 15 years). Meta-analysis of the results was not possible due to the high heterogeneity of both original and long-term studies. Long-term adherence to PFMT varied between 10% and 70%. Long-term success based on responders to the original trial varied between 41% and 85%. Five studies reported that the initial success rate was maintained in the long-term. Surgery rates in the long-term varied between 4.9% and 58%. The authors emphasized the need for high quality RCTs comparing different training dosages and follow-up strategies.

The results of our study demonstrate a relatively high adherence rate (42.7%) and a very low rate (3.8% of the original cohort) of surgical intervention within 5 years after completion of a guided PFMT program. However, most women who did not undergo surgery were still stress incontinent, regardless of adherence to training. Despite the lack of cure, results suggest an overall mild degree of existing incontinence and a relatively high QOL. There is no consensus regarding PFMT protocols. The number of contractions recommended across studies range from 8–12 contractions three times a day, to 20 contractions four times a day, to as many as 200 contractions per day. The duration of each contraction varies in published studies from 4 sec to 30–40 sec.<sup>19</sup> The recommended self-training protocol used in the present study comprised of three sets of 8–12 slow velocity, close-to-maximum contractions at least twice a week. Since all investigated outcome parameters were similar among our patients regardless of adherence to training, it is less likely that exercising per se yields these results. It is quite possible that PFMT programs provide additional rehabilitation tools to control leakage other than exercising. For example, conscious pre-contraction of the pelvic floor just ahead and throughout physical stress is known to stabilize the bladder neck and reduce urinary leakage.<sup>20</sup> It is also possible that the results of the present study reflect some selection bias at enrolment since most patients were highly educated, highly motivated, and relatively young women. Further, we speculate that contrary to the international recommendations, significantly affected stress incontinent women were directed to, or preferred surgical intervention as first-line management 5 years earlier, while only those with a mild degree of incontinence were referred to PFMT. This management approach is supported by a recent well designed RCT that verified the superiority of mid-urethral sling surgery over PFMT as first-line management of SUI.<sup>21</sup> The main limitations of the present study include missing data of non-responders, lack of matched questionnaires at baseline, and lack of objective evaluation at end point. Nevertheless, the study strengths comprise of a relatively high response rate, relatively large and homogeneous series, the use of various validated questionnaires, high quality data and high quality medical services.

In conclusion, the results of the present study demonstrate an up to 42.7% adherence rate 5 years after completion of a guided PFMT program for female SUI, yet adherence per se was not found to be associated with superior outcomes. This observation likely reflects the incorporation of additional rehabilitation tools into daily activities, as well as possible selection bias at initial referral for treatment. Further studies are needed to establish appropriate referral criteria, as well as optimal training protocols and long-term effectiveness of PFMT as first-line management of female SUI.

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