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

Netta Beyar,1 and Asnat Groutz2*

1Physical Therapy Department, School of Health Professions, Sackler Faculty of Medicine, Tel-Aviv University, Tel Aviv, Israel
2Urogynecology and Pelvic Floor Unit, Lis Maternity Hospital, Tel Aviv Sourasky Medical Center, Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

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 ± 10.8) reported adherence to PFMT, 75 (56.8%, mean age 49.8 ± 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 ICQ-UI scores for frequency and amount of leakage were low (2.2 ± 0.9, 1.18 ± 1.04, respectively) and I-QOL score was high (96.2 ± 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.

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. 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 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. This recommendation is further supported by an up-to-date Cochrane systematic review of 21 randomized or quasi-randomized trials involving 1,281 women. 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, resilience, 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. Further studies, as well as urodynamic evaluation, were performed.

© 2015 Wiley Periodicals, Inc.
Neurourology and Urodynamics DOI 10.1002/nau

Table I. Demographic Characteristics (Five Years After Therapy)

<table>
<thead>
<tr>
<th>Table Parameter</th>
<th>No adherence to PFMT (N = 75)</th>
<th>Adherence to PFMT (N = 55)</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interval after therapy (years)</td>
<td>5.64 ± 0.84</td>
<td>5.58 ± 0.64</td>
<td>0.679</td>
</tr>
<tr>
<td>Age (years)</td>
<td>49.81 ± 10.82</td>
<td>52.05 ± 10.81</td>
<td>0.254</td>
</tr>
<tr>
<td>Body mass index (Kg/m²)</td>
<td>25.25 ± 4.35</td>
<td>24.9 ± 3.63</td>
<td>0.589</td>
</tr>
<tr>
<td>Parity</td>
<td>2.69 ± 1.47</td>
<td>2.54 ± 1.05</td>
<td>0.526</td>
</tr>
<tr>
<td>Vaginal deliveries during interval</td>
<td>17 (22.7%)</td>
<td>8 (14.5%)</td>
<td>0.270</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elementary school</td>
<td>3 (4%)</td>
<td>1 (1.8%)</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>14 (18.7%)</td>
<td>13 (23.6%)</td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>58 (77.3%)</td>
<td>41 (74.5%)</td>
<td></td>
</tr>
</tbody>
</table>

The recommended self-training protocol comprised of three 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 (BFLUTS8, ICQI-UI12, I-QOL13), 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. Analysis of these, 55 women (41.7%, mean age 52.1 ± 10.8 years, range: 34–79) who underwent guided PFMT as first-line management for SUI 5 years earlier were available for outcome analysis. Of these, 55 women (41.7%, mean age 52.1 ± 10.8) reported adherence to therapy, 75 (56.8%, mean age 49.8 ± 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. Although, most women (76%) had received tertiary education, a significantly higher percentage than the official reported rate (45.6%) in the general population12. The mean number of guided PFMT sessions per woman was 4.7 ± 2. The mean Oxford grade at the beginning of treatment was 2.8 ± 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 UII. The two women who underwent surgery were cured. Further analysis of the 76 women (mean age: 50.9 ± 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, ICQI-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 ICQI-UI scores for frequency and amount of leakage were low (2.2 ± 0.9, 1.18 ± 1.04, respectively) and I-QOL score was high (96.2 ± 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
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. 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. 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 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. 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.
REFERENCES