Conservative Management of Stress Urinary Incontinence by Biofeedback-Assisted Pelvic Floor Physiotherapy

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Abstract

Objectives: The aim of this study is to evaluate the rule of biofeedback-assisted pelvic-floor muscle exercise (PFME) in relieving the symptoms of stress urinary incontinence (SUI) in premenopausal women.

Patients and Methods: Sixty-five women with stress urinary incontinence (SUI) attending the outpatient clinics of Al-Azhar University Hospitals were enrolled in this study from March 2011 to March 2012 and were managed by biofeedback-assisted PFME with surface electromyography (sEMG). All participants were of reproductive age and were treated individually for 16 sessions. Results were evaluated with a 7-day voiding diary, a 1-hour pad test, pelvic floor muscle strength measurements, sEMG amplitudes, a leakage index, and a quality of life questionnaire. These variables were compared before and after the intervention.

Results: The frequency of urine loss, the occurrence of nocturia, and the number of pads required decreased significantly after the intervention. Objective cure was found in 61.5% of women. There was a significant improvement in the quality of life, in pelvic-floor muscle strength, and in the sEMG amplitudes of all contractions throughout the intervention.

Conclusion: A relatively short term intervention of biofeedback-assisted pelvic floor muscle exercise (PFME) with sEMG appeared to be helpful in relieving symptoms of SUI in premenopausal women and represents a reasonable conservative management option.

Key Words: Conservative – Urinary stress incontinence – Biofeedback – And pelvic floor physiotherapy.

Introduction

There is a wide range of published prevalences for urinary incontinence (UI), and this is explained by differences in the definition of UI, in epidemiologic methodology, and in demographic characteristics among the studies. However, recent prospective studies have provided data on the incidence of UI and its natural history (progression, regression, and resolution) [1-4].

The annual incidence of UI in women ranges from 2% to 11%, with the highest incidence occurring during pregnancy. Rates of complete remission of UI range from 0% to 13%, with the highest remission rates after pregnancy. The annual incidence of overactive bladder (OAB) ranges from 4% to 6%, with annual remission rates of OAB ranging from 2% to 3% [3].

Urinary Incontinence (UI) is the complaint of any involuntary leakage of urine. The most common form is stress UI, which is leakage of urine on effort or exertion or coughing or sneezing [5]. UI is distressing and socially disruptive. It may be the cause of personal health and hygiene problems. It may restrict employment and educational or leisure opportunities, and lead to embarrassment and exclusion [6]. Due to the highly sensitive nature of this health care issue women may take up to 10 years before seeking help. Many believe UI to be a normal consequence of the ageing process or may not appreciate that effective treatments are available [7].

Surgery has been widely accepted as the treatment of choice for SUI. However, there has recently been an increased interest in the conservative management of this condition [8-11]. Because the initial treatment ideally should be the least invasive with the fewest potential side effects, behavioral methods have been recommended as the first option for the treatment of SUI in many cases [11]. The aim of conservative rehabilitation therapy is to stabilize the urethra by increasing pelvic floor muscle strength (force-generating capacity). Pelvic-floor muscle strength is important for stabilizing
the bladder neck and urethra. Encouraging results obtained with pelvic floor rehabilitation based on the integral theory recently reinforced this approach [10]. This theory postulates that the pelvic floor is a closely integrated system in which 3-directional muscle forces pull against the pelvic ligaments and fascia to open and close the neck of the bladder and urethra. It is a fundamentally biomechanical concept that strengthening a muscle also will strengthen its insertion point [10].

Training and strengthening the pelvic floor muscles (these are the muscles that support the bladder and urethra), is recommended as first-line management for women with stress, urge or mixed urinary incontinence [5]. A recent health technology assessment reviewed the clinical evidence and modelled several non-surgical strategies. The results showed that more intensive pelvic floor muscle training, for example by delivering extra sessions (more than two per month), plus lifestyle changes was the most clinical and cost effective first line strategy [12]. A study evaluated the clinical effectiveness and costs of physiotherapy sessions in a group compared with the same sessions delivered to individuals. The group sessions had comparable health outcomes and notable lower costs [13].

Conservative modalities of treatment include pelvic floor muscle exercise (PFME), vaginal cones, electrical stimulation, and biofeedback. Since Kegel first presented his results, some randomized controlled trials have shown that PFME is more effective than no treatment [8,9,14]. Low cost and lack of side effects are features that make biofeedback and PFME the usually preferred methods of treatment [5,8,9]. Biofeedback is useful in promoting correct contraction control and visualization of muscle activity, because many women are unaware of how to contract their pelvic floor muscles and need some motivation [15-18].

The focus of PF muscle training is to build strength, endurance, speed and the coordination of the PF muscles in different situations. An effective PF muscle training program has been shown to increase contractile strength, as well as increased resting tone of the PF, which then provides improved support of the pelvic organs higher in the pelvis [19,20]. There is evidence for high success rates only from specifically trained health professionals and not from others, without specific training [21]. Once the PF muscles are contracting correctly, the key factor for success is adherence to the training program [22]. Training is individually tailored but may involve as little as 2 minutes of exercises 2-3 times a day. Correct technique, an adequate challenge to the muscles and daily practice are the important ingredients, not hundreds of ineffective contractions a day [22].

Assessment of the PF is an important part of a PF muscle training program. Digital per vaginum assessment, with informed consent, provides most information about the tone, structure and strength of the PF. Once they have overcome initial inhibitions, the majority of women find this a helpful and educational experience. However, for some women it will be a stumbling block that could prevent them from taking up the option of physiotherapy treatment. Many PF physiotherapists now have real time ultrasound that can provide information about a woman’s ability to elevate and relax her PF muscles [22].

Adherence to an exercise program is a basic requirement, but the time and place are individually negotiated to improve self efficacy. One study in which women were contacted 15 years after a physiotherapy program for SUI found that half of the women had stopped exercising their PF muscles [23]. Therefore, women may be offered an annual review by their physiotherapist in order to promote long term continence. Women who have done well initially but lapsed with their home exercises may respond well to further supervised training.

The results reported in the literature concerning the use of biofeedback in addition to PFME are conflicting. In randomized trials with only older and postmenopausal women, Burns et al. [8] and Aksac et al. [14] found that 8 weeks of treatment did not result in any clinical differences between groups treated with PFME alone and groups treated with PFME with biofeedback, although both groups improved more than the control group. Conversely, another randomized study with pad test weight as the outcome measure showed a significant improvement in the group using PFME with biofeedback compared with PFME alone [24].

There are also conflicting results in systematic reviews and meta-analysis. In a systematic review, Berghmans et al [25] did not find any evidence that adding biofeedback to PFME was superior to PFME alone. However, De Kruif and van Wegen [26] conducted a meta-analysis that showed a trend toward PFME with biofeedback being more effective than PFME alone. Similarly, in a meta-analysis of 3 studies, Weatherall [27] found that a pooled odds ratio of 2.1 favored biofeedback with PFME over PFME alone, although the 95% confidence interval (0.99-4.4) for the pooled odds ratio did not reach significance.
The aim of this study is to evaluate the rule of biofeedback-assisted pelvic-floor muscle exercise (PFME) in relieving the symptoms of stress urinary incontinence (SUI) in premenopausal women.

**Patients and Methods**

A total of 65 premenopausal women with symptoms of SUI attending the outpatient clinics of Al-Azhar University Hospitals were enrolled in this study from March 2011 to March 2012. Their premenopausal status was determined by self-report. The symptoms of SUI were mild to moderate. The initial evaluation included clinical history, pelvic floor examination, and urine analysis. Inclusion criteria were: Premenopausal women, mild to moderate symptoms of SUI, no previous surgery for SUI, no pharmacological treatment, physical therapy, or a combination of both for SUI. Exclusion criteria were postmenopausal patients, severe symptoms of SUI, previous surgery for SUI, history of pharmacological treatment, physical therapy, or a combination of both for SUI. Multichannel urodynamic testing was performed to exclude overactive bladder or intrinsic sphincter deficiency. Complete assessment done by the obstetrician and repeated by the physiotherapist.

The mean age of the women enrolled in this study was 39.3 years (range 30-49). The mean body mass index was 29.2 kg/m\(^2\) (range 23.6-37.7). The mean duration of symptoms was 3.6 years (range 2-7). Two women were nulliparous, 35 women had 1 to 3 deliveries, and 28 women had more than 3 deliveries. Seventeen women had cesarean delivery only, whereas 48 had at least 1 vaginal delivery. Pelvic examination revealed cystocele in 45 women; 40 cystoceles were classified as grade I, and 5 were classified as grade II.

At the initial visit, the patients individually received verbal information about pelvic floor anatomy, muscle localization, and function. The biofeedback training was performed with an intra-vaginal sEMG sensor consisting of bipolar longitudinal electrode plates connected to the biofeedback equipment and an additional sEMG electrode attached to the inferior abdominal wall. The device was designed only for feedback, not for electrical stimulation. The women were instructed to contract their pelvic floor muscles and relax their abdominal muscles to avoid increasing intra-abdominal pressure. Both the vaginal sEMG output and the abdominal muscle sEMG output were displayed to the patients on a computer screen. The sEMG data were displayed as line graphs, with a green line corresponding to the signal from the vaginal probe and a red line corresponding to the abdominal muscle sEMG signal, thus providing visual feedback to the patients.

Patients were treated individually for 40 minutes twice each week for a total of 16 sessions. All patients performed phasic contractions [fast (3 seconds), followed by 6 seconds of relaxing] and tonic contractions [sustained (10-20 seconds), followed by 20-40 seconds of relaxing]. Patients initially performed 20 phasic contractions and 20 tonic contractions in a supine position and then 10 phasic contractions and 10 tonic contractions each in the sitting and standing positions, for a total of 80 contractions. From sessions 2 to 7, there was a gradual increase in the number of contractions (10 phasic contractions and 10 tonic contractions for each session of the intervention) until the women were able to complete a total of 200 contractions. Therefore, from session 7 until the last session, the women were performing 40 phasic contractions and 40 tonic contractions in the supine position and then 30 phasic contractions and 30 tonic contractions each in the sitting and standing positions. Patients were not encouraged to perform any sort of home program during the 16 intervention sessions.

A 7-day voiding diary was completed twice during the study, before sessions 1 and 16. To quantitatively evaluate the results, a standardized 1-hour pad test was performed before and after the intervention. Objective cure was defined as 1 g or less of leakage after the intervention. Subjective cure was graded by participants' self-evaluation of their condition after the intervention as “cured,” “almost cured,” “improved,” “unchanged,” or “worse”.

Pelvic-floor muscle strength was assessed by vaginal palpation and perineometry (vaginal squeeze pressure). Vaginal palpation was performed by 2-finger palpation, and contractions were graded as 0 (“none”), 1 (“weak” 1 second), 2 (“moderate” 1-5 seconds), or 3 (“strong” >5 seconds). Perineometry was performed by use of an air-filled silicone sensor connected to a portable perineometer with a pressure transducer. All women were encouraged to contract the pelvic floor muscles, and the maximum contraction pressure was recorded.

All patients underwent sEMG evaluation of pelvic-floor muscle activity before the intervention and at sessions 8 and 16 of the intervention. The vaginal sEMG sensor and biofeedback equipment were the same as those used to perform the inter-
Pelvic-Floor Muscle Strength Evaluation Method

### Before Intervention
- **Amplitude of Contraction (RV)**
  - 40
  - 35
  - 30
  - 25
  - 20
  - 15
  - 10
  - 5
  - 10-s Tonic Contractions
  - 20-s Tonic Contractions

**Before** vs after session 16:
- \( p < 0.0001 \)

**Before** vs after session 8:
- \( p < 0.0001 \)

### After Intervention
- **Leakage Index Value**
  - 5
  - 4.5
  - 4
  - 3.5
  - 3
  - 2.5
  - 2
  - 1.5
  - 1
  - 0.5
  - 0

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### Data Analysis:

Because sEMG measurements were obtained at 3 times, initially a repeated-measures analysis of variance on ranks was performed with the Friedman test. Additionally, a Wilcoxon signed rank test was applied to compare the values before the intervention and after the intervention. Absolute frequencies were calculated to describe the percentages of reduction and remission. Statistical significance was defined as \( p < 0.05 \). Data analysis was performed with the SAS software package.

### Results

On the basis of the 7-day diary, there was no change in voiding frequency. However, the frequency of urine loss, the occurrence of nocturia, and the number of pads required significantly decreased by the end of the intervention (Table 1).

**Table (1): Seven-day voiding frequency, frequency of urine loss, occurrence of nocturia, and number of pads used before and after intervention (N=65).**

<table>
<thead>
<tr>
<th>7-d Diary</th>
<th>Before ±SD</th>
<th>After ±SD</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voiding frequency</td>
<td>47.8±18.3</td>
<td>48.9±11.3</td>
<td>0.28780</td>
</tr>
<tr>
<td>Frequency of urine loss</td>
<td>14.8±17.0</td>
<td>3.2±4.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Occurrence of nocturia</td>
<td>11.1±11.1</td>
<td>5.6±3.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No. of pads used</td>
<td>6.0±8.1</td>
<td>1.0±2.1</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

**Table (2): Pelvic-floor muscle strength evaluated by vaginal palpation and perineometry before and after intervention (N=65).**

<table>
<thead>
<tr>
<th>Pelvic-Floor Muscle Strength Evaluation Method</th>
<th>X±SD Before Intervention</th>
<th>X±SD After Intervention</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal palpation (grade)</td>
<td>1.0±0.8</td>
<td>2.4±0.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Perineometry (maximum contraction [cm H(_2)O])</td>
<td>24.5±16.0</td>
<td>40.0±17.0</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Determined by Wilcoxon signed rank test. Statistical significance was set at \( p < 0.05 \).

Concerning pelvic-floor muscle strength, 50 women (76.9%) had contractions classified as grade 0 (“absent”) or 1 (“weak”) before the intervention. After the intervention, almost all women (92.3%) had contractions classified as grade 2 (“moderate”) or 3 (“strong”), demonstrating an upgrade of at least 1 grade after biofeedback-assisted PFME with sEMG (Fig. 1).

**Fig. (1): Surface electromyography amplitudes (in microvolts) for phasic contractions and for 10-and 20-second tonic contractions before the intervention, after session 8, and after session 16 (N=65). Values are reported as mean ± standard error. *\( p\)-values were determined by Wilcoxon signed rank test. Statistical significance was set at \( p < 0.05 \).**

**Fig. (2): Leakage index values before and after the intervention (N=65). Values are reported as mean ± standard error. *\( p\)-value was determined by Wilcoxon signed rank test. Statistical significance was set at \( p < 0.05 \).**
Fig. (2) shows the leakage index values before and after the intervention. The corresponding means (SD) were 3.52 (0.83) and 1.66 (0.63), respectively. This difference was statistically significant (p<0.001).

Quality of life, as evaluated by the King Health Questionnaire, showed a significant improvement in all score domains, with the exception of personal relationships. The results for the score domains are shown in (Table 3).

Regarding subjective cure, 57 women (87.6%) reported an improvement: 15 (23.0%) considered themselves “cured” and 42 (64.6%) considered themselves “almost cured.” No woman considered her condition to be “unchanged” or “worse” after the intervention.

Table (3): Comparison of scores on domains of the king health questionnaire before and after intervention (N=65).

<table>
<thead>
<tr>
<th>Quality-of Life Domain</th>
<th>Before Intervention</th>
<th>After Intervention</th>
<th>P a</th>
</tr>
</thead>
<tbody>
<tr>
<td>General health perception</td>
<td>49.4±23.9</td>
<td>26.9±15.6</td>
<td>.00150</td>
</tr>
<tr>
<td>Incontinence impact</td>
<td>78.2±28.1</td>
<td>32.5±30.5</td>
<td>0.0001</td>
</tr>
<tr>
<td>Role limitation</td>
<td>75.0±27.1</td>
<td>13.4±22.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Physical limitation</td>
<td>72.4±29.4</td>
<td>15.3±24.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Social Limitation</td>
<td>38.2±28.5</td>
<td>6.4±14.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Personal relationships</td>
<td>60.5±33.8</td>
<td>14.6±16.6</td>
<td>0.0679</td>
</tr>
<tr>
<td>Emotions</td>
<td>58.9±33.8</td>
<td>14.1±24.6</td>
<td>0.0001</td>
</tr>
<tr>
<td>Sleep/energy</td>
<td>33.9±23.66.98</td>
<td>6.4±16.3</td>
<td>0.0001</td>
</tr>
<tr>
<td>Severity measures</td>
<td>66.9±19.6</td>
<td>22.3±24.2</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Determined by Wilcoxon signed rank test.
Statistical significance was set at p<0.05.

Discussion

The use of this structured programme of pelvic floor exercise has previously been reported to be more effective than exercise carried out just at home [28]. Our results confirm that such a programme is more effective than no treatment for stress urinary incontinence, as have other well designed randomized controlled studies [29,30].

The finding that pelvic floor exercises are more effective than electrical stimulation confirms the results of Henalla et al., who found pelvic floor exercise, was more effective than electrical stimulation or oestrogen therapy in the treatment of stress urinary incontinence [30], but contrasts with other studies that did not find any differences in outcome between the two interventions [31].

That regular exercise seem to be more effective than electrical stimulation is not surprising from a physiological perspective. Several consensus statements have concluded that electrically stimulated muscle contractions in humans are less effective than voluntary contractions for strengthening [32-34]. In addition, Bø and Talseth showed that voluntary contraction of pelvic floor muscle was twice as effective as an electrically stimulated contraction at increasing urethral pressure [35].

The present study showed that a relatively short-term intervention of biofeedback-assisted PFME with sEMG appeared to be helpful in relieving the symptoms of SUI in premenopausal women. These results are in agreement with data published in the literature on the effect of PFME with biofeedback [15,18,24,36-38].

The present study included only women who were of reproductive age and who had adopted conservative therapies as the initial treatment for SUI. Most gynecologists and urologists do not consider reproductive age and potential future in childbearing as a contraindication to anti-incontinence surgery [39]. However, reports regarding the negative effects of surgical procedures on subsequent pregnancies have been published. Casper et al. [40] reported on 4 women who had pregnancies after Burch or Marshall-Marchetti-Krantz procedure and Lynch et al. [41] reported a pregnancy after a sling procedure, resulting in urethral obstruction, pyelonephritis, and a recurrence of incontinence. Determining which surgical procedure offers the greatest benefit to a woman who expresses her desire for future childbearing is difficult.

The present study revealed a significant improvement in the weekly frequency of urine loss: 84.6% of women showed an improvement, although only 10 women (38.4%) reported a complete remission of symptoms. Our results are in agreement with previously published data for rates of cure and improvement that ranged from 69% to 85% [18,39]. The protocols of these studies included longer treatment times or treatment associated with sEMG controlled biofeedback home training. Instead of long term treatment, we applied a protocol of 16 sessions without additional home training. Our results suggest that success can be achieved with relatively fewer physical therapy sessions.

A significant decrease in the amount of urine leakage in the pad test was found in the present study, showing that 61.5% of women were dry.
These results are in agreement with the findings of other trials, which reported rates ranging from 58\% to 80\% [15,24,38]. The objective cure rate was higher than the subjective cure rate (61.5\% versus 23.1\%, respectively). This finding may indicate that an individual’s impression does not always reflect the objective cure and may not be in agreement with the results of the pad test. On the other hand, the pad test may have been subject to bias caused by the participant’s knowledge of the procedure after the first test.

The evaluation of pelvic floor muscle strength by vaginal palpation and perineometry is a very simple method of measuring the success of therapy. In the present study, both techniques revealed a significant increase in pelvic muscle strength. At the initial vaginal palpation, 50 women (76.9\%) were unable to satisfactorily contract their pelvic floor muscles. This figure is similar to data reported in the literature [42]. However, after the intervention, almost all of the women (92.3\%) were able to satisfactorily contract these muscles, and the contraction pressures, as measured by perineometry, were 2 times higher. These findings suggest that one of the probable benefits of sEMG biofeedback is the acquisition of appropriate pelvic floor muscle contractions. An advantage of biofeedback is that it may facilitate this specific physiologic response, which would otherwise be difficult to detect, and it permits the visualization of low amplitude and low strength contractions.

In addition, the greatest increase in sEMG amplitudes was found between intervention sessions 1 and 8, whereas the mean increase from sessions 8 to 16 was not significant. On the basis of these results, we can hypothesize that biofeedback may be useful for achieving faster improvement at the beginning of the intervention. The latter may be a desirable feature, particularly when access to physical therapy is difficult and expensive. Similar results were described by Berghmans et al. [17].

One criticism of PFME has been that the lengthy duration of treatment for SUI may affect adherence to this therapy. Some women may find it difficult to perform the exercises on a regular basis [43]. However, we had no dropouts, perhaps because of the relatively small number of sessions in our study protocol. However, Glavind et al. [36] concluded that the long-term effect of therapy with biofeedback was better than that of PFME alone because the patient’s motivation for training was higher. We believe that this motivation is related not only to the frequency of sessions but also to the treatment credibility and to the interest and ability of both the instructor and the patient.

Quality of life has become an important outcome measure in clinical trials of treatment for incontinence. All participants in the present study were of reproductive age, and some authors have reported that younger women with this condition report a greater loss of quality of life than older women [44]. Younger women tend to be more socially, economically, and sexually active, a situation that probably contributes to a greater negative effect of SUI on their quality of life. We observed a significant improvement in the quality of life for women after the intervention, particularly with regard to factors related to limitations (in physical and social activities) and to severity measures.

**Conclusion:**

A relatively short term intervention of biofeedback-assisted PFME with sEMG appeared to be helpful in relieving the symptoms of SUI in premenopausal women. This approach represents a reasonable conservative option for the management of SUI in women of reproductive age.

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