

Effects of Pelvic Floor Muscle Training with Biofeedback in Women with Stress Urinary Incontinence

Nazete dos Santos Araujo^{1,*}, Érica Feio Carneiro Nunes¹,
Ediléa Monteiro de Oliveira¹, Cibele Câmara Rodrigues²
and Lila Teixeira de Araújo Janahú³

¹Amazonia University,

²Federal University of Pará,

³College of Amazonia,
Brazil

1. Introduction

This chapter addresses the effects of training of the pelvic floor muscles using an electromyographic biofeedback equipment as a tool for treatment in women with stress urinary incontinence.

The Stress Urinary Incontinence (SUI) is defined by the International Continence Society (ICS) as involuntary loss of urine during physical effort with sneezing and coughing, and it is considered a consequence of the weakness of the pelvic floor^{1,2}. It is the most common type of urinary incontinence and its prevalence can vary from 12% to 56% depending on the population studied and the diagnostic criterion adopted^{3,4}. In Brazil the prevalence of complaints of stress urinary incontinence is around 35%².

Approximately 1/3 of women of the research presented mixed complaints, i.e., urinary loss during stress associated with irritative symptoms, such as increased urinary frequency, urinary urgency, nocturia, urgency incontinence and/or enuresis³.

Nowadays there are several risk factors for the onset of sui, and we can realize that the literature often relates it to obesity, menopause, smoking, parity, types of delivery and exercise. The white ethnicity is also related to risk factors; In an American study, when the authors compared white to black people, it appears an higher incidence for the first group (white one), varying from 23 to 32% and a lower incidence to the second group, with na average from 16 to 18%^{5,6,7}.

It is known that SUI compromises the quality of life (QOL) of women of different ages^{5,6}. However, many women with UI believe that sporadic involuntary urinary loss is a normal part of the aging process and, also because they find it embarrassing, they do not refer to its impact on their daily activities or report these symptoms to their doctors⁸.

*Corresponding Author

In the literature, there are some questionnaires to assess quality of life of women with SUI, but the King's Health (KHQ) is the most commonly used in Brazil, which is validated in Portuguese and evaluates the presence of UI symptoms AND ITS relative impact, leading to more consistent results⁹.

Many factors are involved in the SUI physiopathology, especially the rotational descent of the urethra, a functionally short urethra, pudendal nerve lesions, fascia laceration, pelvic floor muscle (PFM) ruptures, intrinsic urethral mechanism deficiency and bladder neck hypermobility¹⁰.

PFM functional deterioration, or weakness is an important factor causing SUI¹¹. Physical therapy is considered a first line option for the rehabilitation of the pelvic floor muscles. Regarding to the conservative treatment, Kinesiotherapy is considered as level 1 evidence of its beneficial effects in SUI women (ICI 2009), but when we talk about operative interventions, Slings are the level 1 evidence. The most commonly used treatment modalities are pelvic floor muscle training (PFMT) to strengthen the PFM, vaginal electrostimulation, biofeedback (BF), vaginal cones and behavioral therapy, including information, education, awareness and advice¹².

Electromyographic biofeedback (EMG BF) can be used to measure, assess and treat PFM dysfunctions and is one of the potential treatment modalities used for the rehabilitation of pelvic floor muscles¹⁰, once in its clinical use allows the patient to obtain informations about the physiological process of contraction, which used to be unknown in most of the cases. it facilitates the motor control of the pelvic floor muscles, favoring the re-education through a visual or hearing feedback generated by electromyography¹³.

2. Methodological description

This was a randomized clinical trial research developed in the city of Belém, state of Pará, Brazil. the aim of this research was to study the effects of PFMT with EMG BF on bladder neck mobility, motor activity of PFM with EMG, PFM strength, levator ani muscle thickness and the quality of life of women with SUI, involving 50 women, 25 in each group, complaining of SUI was carried out. The relevant baseline characteristics are shown in Table 1.

The inclusion criteria were women aged from 30 and 55 years, with negative urine test and urodynamic diagnosis of SUI due to bladder neck hypermobility, pressure of stress-induced urine loss (PSIUL) higher than 90 cm of H₂O. Patients with SUI due to intrinsic insufficiency with PSIUL of less than 60 cm, those who have undergone previous SUI surgery and those who presented vaginal prolapse of any degree in the physical examination were excluded. All the patients were referred by urologists or gynecologists, who requested and executed the urinary sediment and quantitative urine culture, urodynamic study and ultrasound test. The sample was randomized using sealed envelopes to choose the patients who would receive EMG BF and the ones who would be part of the control group. The control group was offered the same treatment given to Gbio after the end of the study. The Gbio underwent thirty-minute training sessions twice a week for eight weeks¹⁴.

The ultrasound was conducted by the Toshiba-Nomio equipment (Tokyo, 2004) to measure urethral mobility (in centimeters) and the thickness of the levator ani muscle (in centimeters). Urethral mobility was measured by the transvaginal technique using a convex

endocavitary probe with a frequency of 6.5 MHz and the thickness of the levator ani muscle was measured by the transabdominal technique using a 3.5 MHz transducer. This test was conducted while the bladder contained a maximum of 50 ml of urine¹⁵ and by the same specialist in diagnostic imaging.

After referral, the patients were assessed by the same specialized physical therapist before and after the study. PFM strength was done by digital vaginal palpation using the Ortiz¹⁶ scale to assess PF muscle strength. PFM EMG motor activity was measured with PHENIX equipment (Vivaltis, Paris, France), model USB-4 through a 5-cm long and 5.5-cm wide vaginal probe, dampened with KY Johnson gel. The probe was introduced 3 cm inside of the vagina's introitus. The PFM electric signal was registered in microvolts (μV) by two 1-cm rings located in the probe, captured and viewed by patients on the computer screen.

The electrical signal of the PFM was registered in microvolts (μV), with the use of an individual intravaginal probe with the patient lying in supine position, flexed legs and feet supported by a stretcher after instruction the patient was asked to perform 3 maximal PFM contractions. The highest registration of the contraction was selected as starting point for the treatment that was registered by and transmitted to the computer through a visual signal. The King's Health Questionnaire (KHQ) was also applied.

The King's Health Questionnaire (KHQ) assesses both the presence of urinary incontinence and its relative impact. It consists of 30 questions distributed across nine domains: general health, impact on life, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy and severity (coping) measures¹⁷. There is also a scale of symptoms: increased urinary frequency, nocturia, urgency, bladder overactivity, SUI, nocturnal enuresis, incontinence during sexual intercourse, urinary infections and bladder pain. Each domain receives a individual score; therefore, there is not an overall score. Scores vary from zero to 100 and the higher the score, the worse the quality of life associated with that domain¹⁷.

Before they started treatment, Gbio patients received information on the function of pelvic floor muscles and were informed of the importance of continuing their exercises and functional training, so, adaptation into daily life activities. In addition to the EMG BF-assisted exercises, patients were advised to do the same exercises at home to strengthen the PFM through slow and rapid contractions, being told to do three series of 10 contractions in the supine, sitting and orthostatic positions three times a day with a duration of 5-10 seconds, the contraction per subject was verified through an initial assessment of each individual¹⁸. They were also encouraged to undergo functional PFM training, i.e. to contract this muscle group during stress activities and increased intra-abdominal pressure.

The same EMG BF that was used to test the electromyographic activity of the PFM was also used to train the Gbio. The EMG BF was connected to a computer, equipped with specific software. Two pre-established programs with alternate contraction and relaxation periods were used: a twenty-minute program (85 rapid contractions and 34 slow contractions including) and a ten-minute program (including 54 rapid contractions and 24 slow contractions)¹⁹. The women watched the contractions on the computer screen receiving visual feedback. Recent literature reviews show there is no a consensus regarding what kind of training program would be the most effective^{20,21}. This study's protocol was based on the review of Hay-Smith et. al, in which the maximum number of daily contractions requested from patients was estimated at between 36 and 200^{21,22}.

Descriptive statistics, with mean and standard deviation, were used to analyze the data. The normality of the sample was evaluated by the Shapiro-Wilk test and the homogeneity variance by the Levene test. The inter-group data were analyzed using Student's t test for independent samples, when there was heterocedasticity we applied the Mann-Whitney U test. Categorical variables were tested by the chi-square test. The significance level $\alpha = 0.05$ were considered to reject the null hypothesis. The data were put into an Excel database and analyzed with SPSS, version 14.0²³.

3. Results

Relevant baseline and KHQ characteristics before the treatment, presented in Table 1, showed that there were no present statistically significant differences between both groups.

	Gc	Gbio	Value-p
General characteristics			
Age (years)	445.5 ±5.6	45.8 ±5.2	0.3957
Number of children	2 ±1	2 ±1	0.8757
Time of incontinence (years)	3.9 ±3.8	3.5 ±2.1	0.0776
EMG-test (µV)	9.36 ±5.66	7.76 ±5.06	0.2977
Muscular strength (me, min, max)	3 (1 - 4)	3 (1 - 4)	0.1519
Thickness (mm)	11.55 ±1.77	11.01 ±1.97	0.3139
Urethral mobility (mm)	16.97 ±4.40	16.10 ±7.04	0.3467
Kings Health Questionnaire			
General health	25 (0 - 75)	25 (25 - 75)	0.1282
Impact on life	50 (0 - 100)	33.3 (0 - 66.6)	0.3781
Role limitations	33.3 (0 - 100)	0 (0 - 77)	0.3987
Physical limitations	0 (0 - 100)	33.3 (0 - 100)	0.2959
Social limitations	16.6 (0 - 83.3)	26.6 (0 - 80)	0.4231
Personal relationships	33.3 (0 - 100)	0 (0 - 66.6)	0.6208
Emotions	16.6 (0 - 66.6)	0 (0 - 66.6)	0.6766
Sleep and energy	0 (0 - 100)	22.2 (0 - 100)	0.6139
Severity (coping)	16.6 (0 - 100)	26.6 (0 - 100)	0.4492

Student's t test and Mann-Whitney's test
me: mean; min: minimum value; max: maximum value; EMG: Electromyographic.

Table 1. Relevant baseline characteristics and KHQ domains - data obtained before intervention, Gc (n=25) and Gbio (n=25).

Based on statistically significant differences in all the characteristics assessed (Table 2), comparison of anatomic and functional characteristics between the groups after intervention showed that treatment was associated with changes in the configuration of anatomic and functional structures of the PF.

	Gc	Gbio	Value-p
Anatomo-functional characteristics			
EMG-test (μV)	9.40 ±5.99	15.28 ±8.52	0.0068*
Muscular strength (me, min, max)	3 (1 - 4)	4 (2 - 4)	0.0009**
Thickness (mm)	11.66 ±1.65	13.27 ±2.12	0.0044*
Urethral mobility (mm)	17.67 ±4.53	9.26 ±3.01	<0.0001*
Kings Health Questionnaire			
General health	25 (0 - 75)	25 (0 - 50)	0.3933
Impact on life	50 (0 - 100)	33.3 (0 - 66.6)	0.0305**
Role limitations	33.3 (0 - 66.6)	0.0 (0 - 33.3)	0.0099**
Physical limitations	33.3 (0 - 100)	0.0 (0 - 33.3)	0.0010**
Social limitations	0.0 (0 - 77)	0.0 (0 - 66.6)	0.3084
Personal relationships	0.0 (0 - 100)	0.0 (0 - 50)	0.0426**
Emotions	33.3 (0 - 100)	11.1 (0 - 44.4)	0.2444
Sleep and energy	16.6 (0 - 83.3)	(16.6 (0 -66.6)	0.8311
Severity (coping)	26.7 (0 - 80)	6.6 (0 - 73)	0.0021**

* Student's t test

** Mann-Whitney

me: mean; min: minimum value; max: maximum value; EMG: Electromyographic.

Table 2. Gc (n=25) and Gbio (n=25) after the treatment.

4. To show the bladder neck mobility

Figures below show transvaginal ultrasound from bladder neck during rest and effort phases, before and after treatment with EMG BF. Figures 1 and 2 : ultrasound before treatment. Figures 3 and 4: ultrasuond post- treatment.

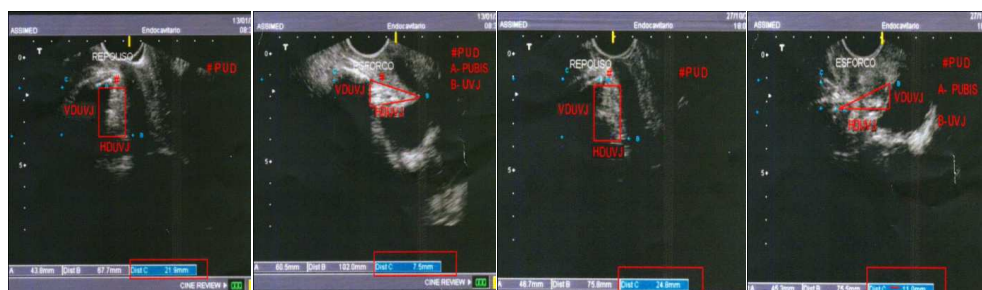


Fig. 1. Rest

Fig. 2. Effort

Fig. 3. Rest

Fig. 4. Effort

HDUVJ: Horizontal Distance from Urethrovesical Junction; PUD: Pubo-Urethral Distance; UVJ: Urethrovesical Junction; VDUVJ: Vertical Distance from Urethrovesical Junction.

The EMG test presented a statistically significant difference (p= 0.0068) between the groups; Gbio (15.28 ±8.52 μV) presented higher levels of PF motor activity than Gc (9.40 ±5.99 μV).

The assessment of pelvic floor muscular strength showed a statistically significant difference ($p = 0.0009$): Gbio (mean = 4) was higher than Gc (mean = 3).

In Gbio the levator ani muscle thickness (13.27 ± 2.12 mm) was statistically significant bigger compared to Gc (11.66 ± 1.65 mm) ($p = 0.0044$).

Bladder neck mobility was statistically significant less in the Gbio group (9.26 ± 3.01 mm) than in Gc (17.67 ± 4.53 mm) ($p = 0.0044^*$).

The intergroup KHQ analysis showed significant differences in 5 domains. In the impact on life domain ($p = 0.0305$), Gbio (mean = 33.3%) presented lower levels compared to Gc (mean = 50%); in the role limitations domain, there was a significant improvement ($p = 0.0099$) in Gbio (mean = 0.0%), but not in Gc (mean = 33.3%); in the physical limitations domain, the result was statistically significant ($p = 0.0010$), since Gbio (mean = 0.0%) showed fewer limitations than Gc (mean 33.33%); in the personal relationships domain ($p = 0.0426$), the mean for both groups was the same (0.0%), but no Gbio individual had scores higher than 50%; and in the severity (coping) measures, there was also a significant difference ($p = 0.0021$), with a mean of 6.6% in Gbio, versus a mean of 26.7% in Gc.

On the other hand, general health, social limitations, emotions and sleep/energy did not show a statistically significant difference between groups after treatment.

Comparison between groups of KHQ urinary scale symptoms (Table 3) shows that urinary frequency, nocturia and SUI were statistically significantly different after intervention

Symptoms	Gc				Gbio				Value-p
	slight (%)	Moderate (%)	Severe (%)	NRA (%)	Slight (%)	Moderate (%)	Severe (%)	NRA (%)	
Frequency	56	36	0	8	32	24	8	36	0.0337*
Nocturia	52	32	0	16	40	8	8	44	0.0261*
Urgency	36	40	0	24	36	12	4	48	0.0796
Urge incontinence	60	12	0	28	40	12	0	48	0.3141
Stress urinary incontinence	28	56	16	0	52	4	0	44	<0.0001*
Nocturnal enuresis	8	4	0	88	4	0	0	96	0.4916
Sexual intercourse incontinence	20	12	0	68	12	0	0	88	0.1261
Frequent infections	12	0	0	88	16	0	0	84	0.9999
Bladder pain	4	0	0	96	8	4	0	88	0.4916

*Chi-square

NRA: omitted response

Table 3. Urinary symptoms in Gc (n=25) and Gbio (n=25) after intervention.

Regarding urinary frequency ($p = 0.0337^*$), Gbio presented lower percentages in the “low” (32%) and “moderate” (24%) categories, versus 56% “low” and 36% “moderate” for Gc. However, the “severe” category presented an inversion, with Gbio (8%) exceeding Gc (0%).

Nocturia was statistically significantly different ($p = 0.0261$) between the groups, Gbio presented lower percentages in the “low” (40%) and “moderate” (8%) categories, versus 52% “low” and 32% “moderate” for Gc. However, the “severe” category presented an inversion, with Gbio (8%) exceeding Gc (0%).

When we analyze SUI results, we observe a statistically significant improvement ($p < 0.0001$) in the “low” (52%) and “moderate” (4%) and “severe” (0%) intensities in Gbio, versus “low” (28%), “moderate” (56%) and “severe” (16%) intensities for Gc.

The other symptoms did not present any statistically significant difference between the groups.

5. Discussion

The results of this study indicate that the training of pelvic floor muscles through EMG BF can lead to changes in the anatomic and functional structures of PF, since there were statistically significant differences in all the assessed characteristics of the incontinent women treated.

When compared to healthy women, decrease of surface electromyographic activity in women with SUI, urgency incontinence and mixed incontinence has been found, which suggests a deterioration of the neuromuscular function in these women²⁴. In this study, we observed that the quantification of muscular activity carried out through the EMG test showed statistically significant increase ($p = 0.0068$) after treatment in Gbio, which suggests that BF can restore PF neuromuscular function.

In this study, compared to Gc, PFM strength presented a statistically significant change ($p = 0.0009$) after BF treatment. However, we did not objectively quantify the SUI reduction. In a study of 52 women, aged from 24 to 64 (mean 45.4 years) suffering from SUI, a positive correlation between the increase in PFM maximum strength and the reduction in urine loss during stress was demonstrated²⁵, and in another study by Rett et al²⁶, who included a sample of 26 women with SUI a significant improvement in pelvic floor muscular strength, from 0 (zero) or 1 (one) to 2 (two) or 3 (three) was seen. Yet, the profile of the patients in both studies was different.

Regarding the thickness of the levator ani muscle, Bernstein²⁷ demonstrated through transabdominal ultrasonography a significant reduction in the thickness of the levator ani muscle in women over 60 compared to that of younger women. According to this author, the levator ani muscle was significantly thicker in healthier women than in those with urinary incontinence and this problem can be eliminated through physical therapy, as corroborated by this study, which showed a statistically significant increase in the thickness of the levator ani muscle in Gbio ($p = 0.0044$), but not in Gc, which did not have any statistically relevant improvement.

The investigation of the effectiveness of ultrasound in assessing bladder neck descent in the SUI diagnosis still presents contradictory results and unclear responses. Urethral

hypermobility can occur in patients without UI and the reason to extent urethral hypermobility has been related to (the severity) of UI remains unclear^{28,29}. However, regardless the cause of SUI, nowadays, there is some consensus also to measure urethral hypermobility³⁰. Recently, ultrasound seems to play an important role in the study of the urethral vesical junction(UVJ) and the proximal urethra (PU), also because it is a simple, low-cost, innocent and easily repeatable technique^{30,31,32}.

In this study, there was a statistically relevant reduction in urethral mobility ($p < 0.0001$) in Gbio after the treatment compared to Gc. These results contradict that of a study with transvaginal electrostimulation in a group of 23 women suffering from SUI who did not show a significant difference in bladder neck mobility before and after treatment ($p = 0.30$)³³. However, our data are in line with the studies of Balmforth et al³⁴, which comprised 97 women (49.5 ± 10.6 years) and demonstrated a positive and significant association of the improved position of the bladder neck and the anatomical and functional improvement of the pelvic floor, accompanied by an improvement in the quality of life as measured by the KHQ.

Regarding the impact on the quality of life of the SUI patients in this study, in the intergroup comparison considering the KHQ domains there was a positive response in the following ones: incontinence impact on life ($p = 0.0305$), activity of daily life limitations ($p = 0.0099$), physical limitations ($p = 0.0010$), personal relationships ($p = 0.0426$) and severity (coping) measures ($p = 0.0021$) in Gbio. Similar results were obtained by other studies^{9,30}. It is worth to notice that the impact of these symptoms on the life of each patient is closely related to the individual perception these women have of the severity, type and amount of loss, in addition to each individual's cultural context³⁵.

This study showed that the most prevalent symptoms were SUI, urinary frequency and nocturia, and that, after treatment, the Gbio presented a reduction or elimination of these symptoms compared to the Gc, in line with the findings of the Rett study²⁶, in which a sample of 26 women of reproductive age with SUI showed a significant response to the use of EMG BF, with a decrease of urinary symptoms, especially urinary frequency, nocturia, urinary urgency and urine loss during stress.

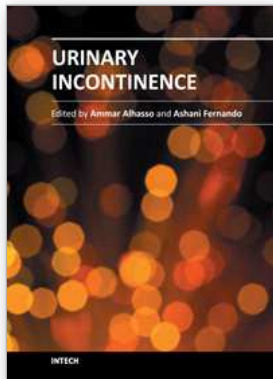
We concluded that the EMG BF for the PFM can lead to changes in anatomo-functional changes in the PF assessed in this study, with a positive influence on the quality of life of these women, although we cannot prove there was a reduction in SUI since we did not use a quantitative instrument to measure the decrease of urinary loss. Considering the results, this study was of huge importance regarding the use of ultrasound as an objective instrument on the evaluation of the efficacy of EMG BF on the reduction of urethral mobility, which is one of the important factors that is directly related to SUI.

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Management strategies are framed within a multidisciplinary team structure and as such a range of specialists ranging from psychologists, specialist nurses, gynaecologists and urologists author the chapters. There are some novel methods outlined by the authors with their clinical application and utility described in detail, along with exhaustive research on epidemiology, which is particularly relevant in planning for the future.

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Phone: +385 (51) 770 447
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Unit 405, Office Block, Hotel Equatorial Shanghai
No.65, Yan An Road (West), Shanghai, 200040, China
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Phone: +86-21-62489820
Fax: +86-21-62489821

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