

Pelvic floor muscle training in female stress urinary incontinence: comparison between group training and individual treatment using PERFECT assessment scheme

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Abstract

Introduction and hypothesis Pelvic floor muscle training (PFMT) is a treatment for stress urinary incontinence (SUI) that can be done individually or in a group. The aim of this study was to compare these two types of treatment.

Methods Sixty women 30 to 75 years old with SUI were randomly assigned to participate in the two groups. They were evaluated before and after the treatment with the Oxford grading system, pad test, voiding diary, and the King's Health Questionnaire.

Results Both groups experienced significant reductions in urinary leakage as measured by the pad test and bladder diary. A negative pad test was observed in about 50% of patients in both groups. There were statistically significant improvements in both muscle strength and quality of life. When the groups were compared, there were no differences in the results between them.

Conclusions Individual treatment and group PFMT appear to be equally effective for improving SUI.

Keywords Pelvic floor muscle training · PERFECT assessment scheme · Stress urinary incontinence

Introduction

Stress urinary incontinence (SUI) is a distressing symptom that can have a major impact on a woman's quality of life, and it is a common condition affecting 20% to 40% of older women [1]. The etiology is multifactorial, and a variety of surgical and conservative solutions have been proposed for this problem. Strengthening the muscles of pelvic floor is one of the first options recommended for the treatment of mild to moderate SUI. Modalities include pelvic floor muscle training (PFMT) alone or in combination with biofeedback or vaginal cones/balls [2, 3]. Pelvic floor muscle training has an important place in the treatment of urinary incontinence. Success rates of 56–75% have been reported [4, 5]. According to a Cochrane review, PFMT should be recommended in first-line conservative management programs for SUI [6].

Pelvic floor muscle training leads to hypertrophy of muscle fibers, enhanced cortical awareness of muscle groups, strengthening of connective tissue in the muscles, and more effective recruitment of active motor neurons. It is suggested that increasing the power and tone of the pelvic floor leads to permanent elevation of the levator plate to a higher resting position inside the pelvis, 'lifting' the pelvic viscera and restoring normal reflex activity and other protective continence mechanisms [7]. PFMT is effective and represents the least invasive option for treating SUI. Also important is the absence of side effects associated with pelvic floor exercises; thus, these exercises are the only method with no restrictions for any patient, and they can be applied individually or in a group setting [8].

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Digital evaluation is an essential part of the examination of the pelvic floor muscles. Evaluation of muscle strength and endurance provides information about the severity of muscle weakness and forms the basis for patient-specific exercise programs. There are several techniques for assessing pelvic floor muscles including digital palpation, pressure manometry, electromyography, ultrasound scanning, and magnetic resonance imaging [9].

PERFECT was originally described as an acronym to remind all health professionals of the need to assess the main components of pelvic floor muscle contractility. This assessment scheme was developed to provide a simple and reliable method of PFM evaluation, increasing the results. The first component P represents power (or pressure). The second component is E and represents endurance. R stands for repetitions, F represents fast contractions, and finally ECT stands for every contraction timed. Evaluating the function of the perineal muscles via PERFECT assessment involves the introduction of the index and middle fingers into the distal 3 cm of the vagina or the assessment can be done per rectum in men and women. This technique evaluates both fast and slow contractions of the patient's muscle fibers to help plan the exercise program [10].

There is an important variability between PFMT training programs. Despite an increasing number of trials comparing various approaches to PFMT for female SUI, to date there are limited data on the efficacy of individual PFMT using the PERFECT assessment scheme and group PFMT. The purpose of this randomized trial was to compare these two regimes with respect to subjective and objective outcome measures of female SUI.

Materials and methods

From August 2007 to September 2008, women with confirmed urodynamic SUI were successively enrolled in this randomized trial in the Urogynecology and Reconstructive Pelvic Surgery, a division of the Gynecology Department at the Federal University of São Paulo.

Subjects were required to have urodynamic SUI and no detrusor overactivity, a positive cough stress test, and less than 3 g of leakage as measured by a pad test with a standardized bladder volume (200 ml) [11]. All subjects had predominant symptoms of SUI with an average of at least three stress incontinence episodes per week. Additional major exclusion criteria included chronic neurological or muscular diseases, abnormal genital bleeding, uterine prolapse, advanced genital prolapse, active genitourinary tract infections, pregnancy, or vaginal atrophy. Also excluded from the study were patients with intrinsic sphincter deficiencies as identified by Valsalva leak point

pressure ≤ 60 cm H₂O measured in the sitting position with a volume of 250 ml in the bladder and/or by urethral closure pressure ≤ 20 cm H₂O in the sitting position at maximum cystometric capacity. Postmenopausal women received topical hormonal therapy for at least 3 months before the beginning of the protocol.

Treatment groups

Once enrolled by a physician investigator, subjects were stratified into two distinct groups: pelvic floor exercises in a group or individual pelvic floor exercises based on the PERFECT assessment scheme. Allocation of the groups was undertaken using a computer-generated random number generator to stratify randomization. The main investigator was blinded to the intervention group allocation.

Urogynecology physiotherapists provided subjects with explanations of the anatomy of the pelvic floor muscles and the lower urinary tract, as well as physiology and continence mechanisms. Both groups were taught to contract the pelvic floor muscles correctly, and this was assessed by vaginal palpation. Once proper contractions were confirmed, pelvic floor muscle training began. All treatments consisted of a structured 12-week program as follows.

Group training

The first group did the standard PFMT in group with two weekly sessions of 45 min each. In the orthostatic position, patients received oral instructions to perform ten contractions of 5 s with 5 s of recovery time, 20 contractions of 1 s with 1 s of recovery time, and three contractions of 10 s with 5 s of recovery time followed by five repetitions of strong contractions together with a stimulated cough, with a 1-min interval between sets.

Individual treatment using PERFECT assessment scheme

The second group did the individual exercises based on the PERFECT assessment scheme, i.e., the contractions were done in accordance with the endurance, power, and time that the patients could tolerate. The patients performed ten slow contractions with 10 s of recovery time, ten fast contractions with 10 s of recovery time, ten alternating fast and slow contractions, five fast contractions associated with a cough, and five slow contractions associated with a cough. They performed two weekly sessions of 30 min each.

As the original authors described, power was measured on a modified Oxford scale. Endurance was expressed as

the length of time, up to 10 s, that a maximal vaginal contraction could be sustained before the strength was reduced by 35% or more. Thus, the contraction was timed until the muscle started to fatigue. A further possible indication of muscle fatigue was the simultaneous contraction of hip adductors and glutei, and the stronger co-contraction of transversus abdominis. Breath-holding was discouraged, and the subject was instructed to contract the pelvic floor on expiration. The time and number of repetitions of the specific maximal vaginal contraction were recorded.

Adverse events and adherence to all treatments were registered in a training diary updated by the physical therapist in charge of the sessions during each clinic visit.

Outcome measure

At the initial visit, all subjects underwent a complete medical history and physical examination, including evaluation of the function of the pelvic floor using the Oxford grading system, pad test with a standardized bladder volume of 200 ml [11], and a voiding diary recording the number of incontinence episodes during a 7-day period. All study subjects were also asked to complete the validated King's Health Questionnaire containing 30 questions (in nine domains). A score of 100 represents the worst possible quality of life, and 0 represents the best possible quality of life [12]. Methods, definitions, and units conformed to the standards proposed by the International Continence Society [13].

The primary outcome measure was objective cure of stress incontinence based on a negative one hour pad test (<2 g in weight). Secondary outcome measures included King's Health Questionnaire, voiding diary, and pelvic floor muscle strengthening. A subjective SUI cure was measured by a simple question about how the patient felt about her incontinence problem after treatment. The only two response options available were "satisfied" and "dissatisfied". Answering "satisfied" indicated that the patient did not want a different treatment. Answering "dissatisfied" indicated that the patient wanted a different treatment than the initial one.

The study was approved by the Institutional Review Board Committee and all patients provided written informed consent.

Statistical analysis

The χ^2 test was used for the comparison of categorical data between the groups, with significance accepted at $p < 0.05$. Numerical data were compared using the paired

Wilcoxon test within groups or the non-parametric Mann–Whitney U test between groups. All statistical analyses were performed using SPSS statistical software (Statistical Package for Social Science), version 14.0. The power calculation for the study was based on the power estimation and results of a previous study designed to detect differences between groups of 1 standard deviation (SD) with a significance level of 0.05 and a power of 0.8. In the previous study, significant differences in the same outcomes were shown for groups of 23 and 31 subjects; therefore, 30 participants were recruited for each of the groups in this trial [5, 8, 14, 15, 16, 17]. Post hoc analysis revealed that the final sample size was sufficient to provide a power of at least 90%.

Results

Sixty-nine women were screened; of these, eight declined to participate in the study. The 61 remaining women were randomly assigned to the two study groups. Of these, only one woman was unable to comply with the treatment or return visits, and was subsequently excluded. Subject compliance was acceptable, with a mean compliance of 90% for individual PFMT using the PERFECT assessment scheme and 95% for group PFMT after 3 months of treatment.

At baseline, there were no significant differences between the groups in terms of demographics, clinical characteristics, or outcome measurements such as age, race, BMI, pregnancy, parity, hormonal status, duration of symptoms, vaginal deliveries, number of C-sections, hysterectomy, previous surgery for SUI, pad test, King's Health Questionnaire, voiding diary, or muscle strength (Tables 1, 2, and 3).

Primary outcome measurement

A negative pad test with a standardized bladder volume was observed in 14 (46%) subjects in the PFMT in group and in 16 (53%) patients of the individual treatment group. There was a significant decrease in the pad weight in both groups. There was no significant difference in these measures between groups.

Secondary outcome measurements

Results of the King's Health Questionnaire are shown in Table 3. After 12 weeks, the quality of life increased significantly in both groups. No significant difference was identified between groups.

Voiding diaries revealed that the physical therapy techniques significantly decreased the stress incontinence

Table 1 Distribution of the patients according to demographic and clinical characteristics before the beginning of the treatment

	Group therapy (N=30)	Individual assessment (N=30)	p value
White	23 (76.6)	26 (86.7)	0.317 ^b
Non-white	7 (23.4)	4 (13.3)	
Age in years	51.6±9.6	50.3±8.7	0.580 ^a
Duration of symptoms	4.9±3.0	5.0±3.9	0.236 ^a
Number of deliveries	4.1±2.4	4.1±2.1	0.822 ^a
Vaginal delivery	2.7±2.4	2.6±2.1	0.525 ^a
Cesarean section	0.9±1.1	0.6±0.9	0.341 ^a
BMI	26.8±4.5	25.5±4.7	0.276 ^a
Menopausal status	18 (55.6)	15 (50%)	0.436 ^b
Hysterectomy	3 (10)	6 (20)	0.251 ^b
Previous incontinence surgery	5 (16.6)	6 (20)	0.411 ^b

Data presented as mean±standard deviation data in parentheses are percentages

BMI body mass index

^a p value obtained by the chi-square test

^b p value obtained by the Mann-Whitney test

episodes. In the 7-day voiding diaries, 66% of participants in both groups reported no leakage. After 3 months, there was no significant difference between the treatment groups ($p=0.2$; Table 2).

Subjectively, 18 (60%) and 20 (66%) of the women in the group therapy and individual treatment groups, respectively, claimed to be satisfied and did not desire a different treatment after the 12-week study treatment period (Table 2).

Muscle strength

There was significant improvement in muscle strength as measured by the Oxford scale in both groups before and after treatment. The improvement in PFM strength was significantly greater in participants undergoing individual PFMT using the PERFECT assessment scheme as compared to participants undergoing group therapy ($p=0.0003$; Table 2).

Table 2 Outcome measures and muscle strength at baseline and at 12 weeks, divided by treatment groups

	Measures	Groups of treatment		p value
		Group therapy (N=30)	Individual treatment (N=30)	
Baseline pad test	Min–max	2.2–41	2.5–69	0.7977 ^b
	Median	2.5	3	
	Average ± SD	7.3±10.3	9.2±15.5	
Final pad test	Min–max	0–14	0–4	0.0709 ^b
	Median	0	0	
	Average ± SD	1.9±3.5	0.6±1.4	
	p value ^a	0.0001 ^a	<0.0001 ^a	
Baseline leakage episodes (voiding diary)	Min–max	3–6	3–9	0.2121 ^b
	Median	3	3	
	Average ± SD	3.2±1.4	3.1±1.5	
Final leakage episodes (voiding diary)	Min–max	0–3	0–2	0.2429 ^b
	Median	0	0	
	Average ± SD	0.2±0.6	0.1±0.4	
	p value ^a	<0.0001 ^a	<0.0001 ^a	
Baseline muscle strength	Min–max	0–4	1–4	0.0592 ^b
	Median	3	2	
	Average ± SD	2.6±0.8	2.2±0.9	
Final muscle strength	Min–max	2–5	2–5	0.0003 ^b
	Median	4	4	
	Average ± SD	3.6±0.8	4.3±0.7	
	p value ^a	<0.0001 ^a	<0.0001 ^a	

SD standard deviation

^a p value obtained by the Wilcoxon test

^b p value obtained by the Mann-Whitney test

Table 3 Association between the variations in the quality of life questionnaire at baseline and at 12 weeks, divided by treatment group

	Measures	Groups of treatment		<i>p</i> value
		Group therapy (<i>N</i> =30)	Individual treatment (<i>N</i> =30)	
Baseline general health	Min–max	0–75	25–100	0.2092 ^b
	Median	75	75	
	Average ± SD	58.3±23.1	66.7±20.1	
Final general health	Min–max	0–75	0–75	0.7582 ^b
	Median	50	37.5	
	Average ± SD	39.2±21.5	37.5±20.5	
	<i>p</i> value ^a	<0.0001 ^a	<0.0001 ^a	
Baseline incontinence impact	Min–max	0–100	0–100	0.2733 ^b
	Median	66.7	66.7	
	Average ± SD	56.7±27.9	64.5±28.9	
Final incontinence impact	Min–max	0–100	0–100	0.2030 ^b
	Median	0	0	
	Average ± SD	20±25.7	13.3±24.1	
	<i>p</i> value ^a	<0.0001 ^a	<0.0001 ^a	
Baseline physical activities limitations	Min–max	0–100	0–100	0.1405 ^b
	Median	33.3	33.3	
	Average ± SD	36.1±27	49.9±33.3	
Final physical activities limitations	Min–max	0–33.3	0–66.7	0.0668 ^b
	Median	0	0	
	Average ± SD	3.3±8.1	10.6±17.8	
	<i>p</i> value ^a	<0.0001 ^a	<0.0001 ^a	
Baseline physical limitations	Min–max	0–100	0–100	0.0111 ^b
	Median	16.7	50	
	Average ± SD	28.9±29.3	52.2±36.8	
Final physical limitations	Min–max	0–50	0–83.3	0.4210 ^b
	Median	0	0	
	Average ± SD	4.4±11.5	10.6±11.5	
	<i>p</i> value ^a	<0.0001 ^a	<0.0001 ^a	
Baseline social limitations	Min–max	0–88.9	0–100	0.2429 ^b
	Median	11.1	11.1	
	Average ± SD	12.6±18.4	19.3±24.2	
Final social limitations	Min–max	0–11.1	0–44.4	0.2122 ^b
	Median	0	0	
	Average ± SD	0.7±2.8	3.7±10.2	
	<i>p</i> value ^a	0.0001 ^a	0.0001 ^a	
Baseline personal relationships	<i>N</i>	21	22	0.0555 ^b
	Min–max	0–50	0–100	
	Median	0	0	
Final personal relationships	Average ± SD	5.6±13.3	25±34.4	0.1723 ^b
	<i>N</i>	20	22	
	Min–max	0–0	0–33.3	
	Median	0	0	
Baseline emotions	Average ± SD	0±0	2.3±7.8	0.7334 ^b
	<i>p</i> value ^a	0.0459 ^a	0.0030 ^a	
	Min–max	0–100	0–100	
Final emotions	Median	11.1	5.6	0.2142 ^b
	Average ± SD	21.9±27.6	25.6±35.4	
	Min–max	0–77.9	0–55.6	
	Median	0	0	
	Average ± SD	5.6±19.3	4.8±11.6	

Table 3 (continued)

	Measures	Groups of treatment		<i>p</i> value
		Group therapy (<i>N</i> =30)	Individual treatment (<i>N</i> =30)	
Baseline sleep/disposition	<i>p</i> value ^a	<0.0001 ^a	0.0004 ^a	0.2896 ^b
	Min–max	0–100	0–100	
	Median	16,7	25	
	Average ± SD	25.6±35.2	31.7±31.4	
Final sleep/disposition	Min–max	0–83.3	0–50	0.7107 ^b
	Median	0	0	
	Average ± SD	7.2±17.9	4.4±10.7	
	<i>p</i> value ^a	0.0002 ^a	0.0001 ^a	
Baseline gravity	Min–max	0–100	0–100	0.5319 ^b
	Median	50	50	
	Average ± SD	47.2±26.2	50.6±24.4	
	<i>p</i> value ^a	<0.0001 ^a	<0.0001 ^a	
Final gravity	Min–max	0–83.3	0–75	0.8047 ^b
	Median	8.3	8.3	
	Average ± SD	15.3±20.3	14.4±20.3	
	<i>p</i> value ^a	<0.0001 ^a	<0.0001 ^a	

SD standard deviation

^a*p* value obtained by the Wilcoxon test

^b*p* value obtained by the Mann–Whitney test

Discussion

More than 50 years after the introduction of pelvic floor exercises by Kegel [2], there is a renewed interest in their use to treat mild to moderate SUI in women. There are important reasons for this, including the following: the well-known efficacy, the safety, the low cost, and the need for an effective treatment which can be used on a large scale outside of the hospital and which can be undertaken by the woman herself in the privacy of her home [6, 18]. One of the largest advantages of this approach is that many women's symptoms are cured or improved to the point where they no longer require surgery. In addition, the success rate of future procedures is not adversely affected as it is with failed surgical treatment [19]. Some authors have suggested that pre-operative pelvic floor exercises may improve the outcome of surgery, reducing residual urinary symptoms [18].

The number of pelvic floor muscle exercise regimens reported in the literature indicates a lack of standardization. It is possible that a uniform, standard regimen is not appropriate given the wide range of muscular strength and endurance across any female population. Thus, an individual exercise program has been proposed to specifically target the weakness of each patient. Rehabilitation is implemented at the level appropriate to the patient and progresses sequentially as power and endurance increase, with progression guided by contin-

uous re-assessment. The PERFECT assessment, although subjective, has been shown to be both reliable and reproducible. It gives the examiner more flexibility and is less ambiguous [10]. One of the criticisms of Oxford grading, which is part of PERFECT, is that it is not able to correctly classify a woman with weak muscle, flicker, and so on when compared with pressure measurement [20]. Individual therapy has the advantage that the patient can easily adapt the treatment to personal circumstances, and the total duration of each session is shorter. On the other hand, group therapy is presumed to have additional benefits, as group members can support each other and strengthen their motivation to exercise [16].

We analyzed and compared the effectiveness of individual PFMT using the PERFECT assessment scheme and group PFMT in the treatment of women with stress urinary incontinence. It was not possible to include an untreated control group because our patients found this option unsatisfactory. However, such a group would be especially important for controlling the effects of clinic visits, therapist contact, and self-monitoring (bladder diary).

In our study, the initial expectation that individual treatment would have added benefits and be more effective was not supported. There were statistically significant improvements in all parameters studied in both groups, but when we compared these parameters between groups, there were no differences. Our results

suggest that individual treatments using PERFECT assessment and group PFMT are equally effective for improving SUI in women. Janssen et al. compared 126 women who received individual treatment with 404 patients who underwent group therapy. It was concluded that both therapies are equally successful for treatment of SUI and that the improvement remained at the same level after 9 months [16]. Konstantinidou et al. compared 60 subjects who received group PFMT under intensive supervision to those who received individual home therapy for SUI. PFMT under intensive supervision produced significantly better improvements in primary (Patient Global Impression of Improvement) and secondary outcomes (24-h pad test, 7-day voiding diary, and pelvic floor muscles as measured by the five-grade Oxford and QOL index scale) in the short term as compared to individual, unsupervised home application of PFMT [14].

The most appropriate outcome measure for lower urinary tract symptoms is still undetermined. We attempted to use both objective and subjective outcome parameters in this study. A pad test with a standardized bladder volume was chosen as the primary outcome measure because it has been used in most clinical trials. In the subjective analysis, we tried to reach what we understand to be the “cure” for this condition. The satisfaction of our patients meant that no other treatment, including a surgical procedure, was required. The significant improvements in quality of life that were demonstrated in this trial are important because they help to understand the clinical relevance of the objective observations in the pad test and voiding diary.

Muscle strength was the only parameter that differed after treatment between the two groups. The increase in the muscle strength when using the PERFECT system was significantly greater than when using group therapy. This difference might be explained by the borderline difference between the two groups before treatment. However, this difference did not change the final results, and both therapies were equally effective.

One of the limitations of our study is the analysis of pelvic floor muscle function and strength. A valid and reproducible measurement is very difficult to obtain, although objective evaluation such as vaginal balloon connected to a microtip transducer, perineometry, and transperineal ultrasound should help us understand the correlation between pelvic floor muscle strength and urine loss [20, 21].

Given that these two therapies are equivalent, patients and physiotherapists can choose the option that best fits their lifestyle, never forgetting that success will depend on the patient’s motivation and the quality of her instruction [17]. A longer term follow-up of the present patients might provide more information regarding the decline of effectiveness with time.

Conflicts of interest None.

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