

EFFECTIVENESS OF THE STRENGTHENING OF PELVIC FLOOR MUSCLES, ADDUCTORS OF HIP, GLUTEUS MAXIMUS AND GLUTEUS MEDIUS IN THE TREATMENT OF STRESS URINARY INCONTINENCE: BLIND RANDOMIZED CLINICAL TRIAL – PARTIAL RESULTS

Hypothesis / aims of study

The strengthening of pelvic floor muscles (PFM) is recommended as first-line treatment for stress urinary incontinence (SUI), with the level A of scientific evidence. However, the relation between function and biomechanics of the hip muscles and the pelvic floor in the treatment of SUI has not been much discussed. The aim of this study is to assess whether the strengthening of PFM, hip adductor muscles, gluteus maximus and gluteus medius reduces the frequency of urinary losses more effectively than the isolated strengthening of PFM.

Study design, materials and methods

A randomized single-blind clinical trial conducted at a university hospital from June 2012 to February 2014. The sample was composed of women between 30 and 70 years diagnosed with SUI and who performed the urodynamic study. The distribution of the participants followed the permuted block randomization generated by computer at the *randomization.com*. The participants were included and distributed in two groups: the group of exercises for strengthening the muscles of the pelvic floor (PF) and the group of exercises for strengthening the muscles of the pelvic floor, adductors and abductors of hip (PFAH). All participants have signed an informed consent. It was considered as exclusion criteria: women with overactive bladder, sphincter deficiency, mixed urinary incontinence, one or zero rating on modified Oxford scale, diagnosis of neurological or muscular disease that interferes in the function of urinary continence; active or recurrent infection of genitourinary tract; genital prolapse grade two or more; gynecological surgery to correct urinary incontinence in last year; therapy hormone replacement in the last six months; ongoing gestation. Power calculation was based on the variable "number of urinary losses" with a power of 80%, suggesting 20 patients in each group. The protocol of treatment was conducted for 20 individual sessions of physiotherapy twice a week. In the PF group were performed exclusively the strengthening exercises for fast and slow fibres of the PFM. In the first eight sessions, the exercises had the digital aid. Every five sessions the degree of difficulty for execution of the exercises was increased with the inclusion of other postures (lying down, sitting and standing). In the PFAH group the above mentioned exercises also were carried out in all the sessions, however, followed by exercises to strengthen the adductor muscles of hips, gluteus maximus and gluteus medius. One session was devoted to the adductor muscles of the hip and the following one to the gluteus. Every five sessions occurred a change of posture for the realization of the PFM strengthening exercises and an increase of the load imposed on exercises for the muscles of the hip, according to the following phases: Isometric exercise without load; concentric with 1 Kg; concentric with 2 Kg; and concentric with 3 Kg. The evaluation and re-evaluation were performed by an examiner blinded to the type of intervention. The frequency of urinary losses was evaluated from the voiding diary, which the participants were driven to fill for three consecutive days. For the statistical analysis of the sample characterization data the t test, Chi Square and Mann Whitney Test ($p=0.05$) were used. Non-parametric Anova was used in urinary loss frequency (ULF) data ($\alpha=0.10$).

Results

The analysis refers to the partial sample (PF =15 and PFAH = 20). The groups were similar in age, body mass index (BMI), number of pregnancies, childbirth and cesarean section, and use of lining, as per Table 1. The analysis of the frequency of urinary loss showed that there is no statistical evidence that the two treatments differ over time, according to the group/time interaction effect ($p=0.1718$). However, the analysis of the effect of time ($p=0.0037$) indicates that, overall, patients had a significant reduction in the frequency of urinary loss from pre to post-treatment. The analysis of the average profiles of the two groups and the confidence interval demonstrate a greater reduction of losses in the PFAH group. However, the confidence interval of the PF group at post-treatment is wide, which does not allow the rejection of the hypothesis that the averages in the post-treatment are equal (figure 1).

Table 1 - Sample Characterization. Median of quantitative variables, distribution of qualitative variables and *p* value for groups PF and PFAH.

Variable	Category	Group PF	Group PFAH	p value
Age (years)	Median	52	51,5	*0,883
BMI	Median	27,63	28,75	*0,907
Number of pregnancy	Median	3	2,5	**0,525
Number of vaginal delivery	Median	2	1	**0,163
Number of cesarean section	Median	0	1	**0,252
Use of lining	No	6	4	***0,266
	Yes	9	16	
Menopause	No	6	12	***0,407
	Yes	9	8	

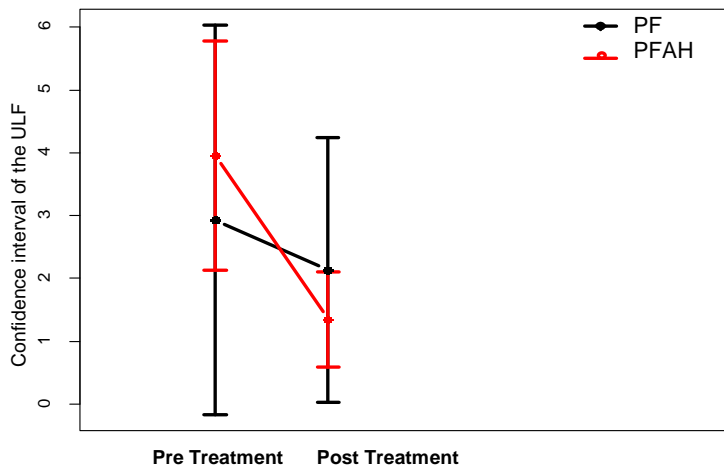


Figure 1- Average profile and confidence interval of the urinary loss frequency data

Interpretation of results

There is no doubt of the effectiveness of the strengthening of pelvic floor muscles in the treatment of stress urinary incontinence (SUI), but there is merit in the use of relevant biomechanical relations that can collaborate to more assertive treatments. The clinical improvement of the two groups is consistent with the efficacy of the strengthening of the pelvic floor muscles, widely shown in literature (1). There was no statistically significant difference between the groups over time, but the average profile and dispersion of the urinary frequency data suggest a tendency that the PFAH group experiences greater reduction of urinary losses. The analysis of the total sample will enable this finding to be supported, in which case the justification would be the anatomical, biomechanical and functional relationship of the muscles in the hip and in the pelvic floor. The PFMs are related to the internal obturator given that the origin of the pubococcygeus muscle is on the fascia that surrounds the internal obturator. The gluteus maximus is connected anatomically to the levator ani muscle by a very strong apparatus of connective tissue that crosses the ischioanal fossa. During the gluteus medius and adductor exercises, movements of adduction and internal rotation of the hip involve the internal obturator elongation and tensioning of the tendinous arch of the pelvic fascia. In this way, the contractile fibers of the pubococcygeus are also mechanically tensioned, improving their performance. In exercises for gluteus maximus, the contraction of this muscle results in cranial displacement of adipose body of the ischioanal fossa associated with a synchronous movement of the levator of the ani muscle, as observed by MRI in another study (2).

Concluding message

The two approaches resulted in significant reduction in the frequency of urinary loss. Partial analysis of the data showed no significant difference between the groups, but there are indications that the PFAH group tends to a greater reduction in symptomatology. Considering the variability of the data, the increase of the sample size will collaborate to elucidate the result.

References

1. Dumoulin C, Glazener C, Jenkinson D. Determining the Optimal Pelvic Floor Muscle Training Regimen for Women with Stress Urinary Incontinence. *Neurourology and Urodynamics*. 2011; 30:746-753.
2. Carrière B, Feldt CM. *The Pelvic Floor*. Nova York: Thieme, 2006.

Disclosures

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