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Original Article

Pelvic floor muscle training and electrical stimulation as rehabilitation after radical prostatectomy: a randomized controlled trial

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Abstract. [Purpose] To investigate the effect of electrical stimulation and pelvic floor muscle training on muscle strength, urinary incontinence and erectile function in men with prostate cancer treated by radical prostatectomy. [Subjects and Methods] One hundred twenty-three males were randomized into 3 groups 1 month after RP: (G1, n=40) control; (G2, n=41) guideline: patients were instructed to perform three types of home exercises to strengthen the pelvic floor and (G3, n=42) electrical stimulation: patients in this group were also instructed to perform exercises as group G2, and also received anal electro-stimulation therapy, twice a week for 7 weeks. The primary outcome assessment was based on the measurement of the recovery of pelvic floor muscle strength between groups. Secondary outcomes were: 1 hour Pad Test, ICIQ-SF, IIEF-5 and IPSS. Data were obtained preoperatively and at 1, 3 and 6 months after surgery. [Results] There was no significant difference in the demographic data among groups. Greater urinary leakage and pelvic floor muscle weakness in the first month compared to pre treatment improved after 3 and 6 months postoperative, without difference among groups. [Conclusion] The muscle strength recovery occurs independently of the therapy employed. Pelvic floor exercises or electrical stimulation also did not have an impact on the recovery of urinary continence and erectile function in our study.
Key words: Urinary incontinence, Radical prostatectomy, Electrical stimulation

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INTRODUCTION

Despite technical refinements and better knowledge of pelvic and prostate anatomy, there is still great concern about the functional outcomes after radical prostatectomy (RP) to treat prostate cancer, especially regarding urinary incontinence (UI) and erectile dysfunction (ED) that have great negative impact on quality of life[1–5)].

Pelvic floor muscles can play a crucial role in the mechanism of male urinary continence and their strength is also related to erectile function. The contraction of ischiocavernosus and bulbocavernosus muscles may cause an increase in intracavern-

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ous pressure improving penile rigidity[6–14]. The bulbocavernosus muscle also compresses the deep dorsal vein of the penis to prevent venous leak during the erection process[15]. However, the importance of pelvic floor muscle rehabilitation in the recovery of erectile function is not well elucidated.

Recently, there has been an increasing interest on the action of the pelvic floor muscles as a possible predictor for the recovery of urinary continence and erectile function in patients undergoing RP. Therefore, preoperative evaluation of pelvic floor muscle strength (PFMS) can also be an important factor to detect the risk of UI and ED post prostatectomy, as well as determine the effectiveness of physical therapy resources. In the present randomized, prospective study, the effect of electrical stimulation (ES) and pelvic floor muscle training (PFMT) was investigated after RP on pelvic floor muscle strength, urinary incontinence and erectile function in men with prostate cancer treated by radical prostatectomy.

SUBJECTS AND METHODS

One hundred and twenty-three incontinent males, submitted to RP, by a team of experienced surgeons from a cancer center hospital, were studied in a prospective controlled trial. This study was approved by the Medical Research Ethics Committee of the Barretos Cancer Hospital (Protocol CEP 273/2010) and registered in Clinical Trials (www.clinicaltrials.gov) NCT02226237, moreover, all patients gave their informed consent. The protocol for the research project has been approved by a suitably constituted Ethics Committee of the institution within which the work was undertaken and that it conforms to the provisions of the Declaration of Helsinki.

The eligibility criterion was set to patients who presented higher than 2 g in a 1 h-pad test 1 month after RP. Exclusion criteria were: prior pelvic floor muscle dysfunction (urinary or fecal incontinence), stenosis of the anastomosis or not being able to complete the protocol for any reason. No patient had received preoperative radiotherapy or neoadjuvant hormonal blockade.

A computer-generated random list of group assignments was prepared and was blocked with a random block size, to reduce the possibility of guessing the next assignment. Assignment was placed in numbered opaque envelopes and sealed. Envelopes were opened by an individual not directly involved with the study. Only one researcher physiotherapist (A.CEL) was informed about the randomization of the patients and was the one who performed the interventions. The other evaluators in the study were all blind.

Patients were randomized 1 month after surgery and only one physiotherapist responsible for the interventions was aware of the group to which the patient was assigned. At that very moment patients were evaluated for their urinary continence. Patients with minimal loss (less than 2 grams) were considered continents and were not included in our analysis. On the other hand, 77.5%, 73% and 81% of the cases presented moderate and severe UI and were allocated into groups G1, G2 and G3, respectively.

Patients were randomly distributed into 3 groups 1 month after radical prostatectomy:

Group 1 (Control n=40): Patients assigned to this group received only the routine instructions about the postoperative period at the time of hospital discharge, given by the Urology and Nursing staff. No type of treatment or orientation of home exercises was performed in this group.

Group 2 (Guideline n=41): Patients randomized to this group were instructed to perform three types of home exercises to strengthen the pelvic floor, which are described below: In dorsal decubitus, with flexed lower limbs, perform contraction of the pelvic floor, followed by relaxation. The targeted movements were:

1) Elevation of the hip (bridge), then relaxing muscles while lowering the hip;

2) Contraction of the thigh adductors, “pressing” a ball, then relaxing;

3) Pelvic floor contraction and relaxation during inspiration and expiration, respectively.

Patients in this group were instructed and encouraged to perform these three exercises at home two to three times a day until they completed 6 months of postoperative period.

Group 3 (Electrical stimulation n=42): Patients in this group were also instructed to perform the same home exercises as group G2 group, and also received anal electro-stimulation therapy, always with the same physiotherapist twice a week for 7 weeks, totalling 14 sessions. Anal electrical stimulation was performed using the equipment Dualpex Uro 961, Quark® (Registration at Anvisa number 80079190018) using the following parameters: frequency: 35 Hz; pulse width: 1 milliseconds; rise time: 2 seconds stimulus duration: 6 seconds; fall time: 2 seconds; standing time: 12 seconds. Intensity was modulated to promote visible pelvic floor muscle contraction with no discomfort to the patient.

All patients were evaluated preoperatively and at 1, 3, and 6 months after RP using the following objective methods and validated questionnaires in Portuguese: 1-hour Pad Test as recommended by the International Continence Society[16], evaluation of pelvic floor muscle strength, using a perineometer by one physiotherapist (blind to randomization), quality of life (QoL) using ICIQ-SF[17], erectile function using IIEF-5[18] and urinary symptoms using IPSS. All measurements were applied by a blind researcher.

One hour Pad Test results were classified according to Laycock & Green classification: 0 to 2 grams: dry; 3–10 grams: light urinary loss; 11 to 50 grams: moderate urinary loss; >50 grams: severe urinary loss[19].

To evaluate the pelvic floor muscular strength (PFMS) a digital perineometer (DM01 model, Dynamed®) was used with a rectal balloon, with an unlubrificated condom and filled with air using a Plastipack syringue (Becton Dickinson®, São Paulo,

Brazil), which allowed contact with the anal wall. For such measure, patients were kept in a supine position with bent legs. After the introduction of the balloon, the equipment was immediately zeroed, and the patient was asked to hold three PFM contractions for as long as possible, with approximately 30-second rest intervals between them. Three measurements were made and an average was considered. The measurement was registered in cmH_2O.

The brand and model of the perineometer used in this study is a reference in our study group[20, 21].

The sample size of a minimum of 40 individuals per group was set considering 10% estimation error (90% sample power) for the primary and secondary endpoint[22]. Allowing for dropouts and withdrawals, 237 subjects were recruited.

Participants who dropped out or withdrew for reasons unrelated to treatment protocol (ie, moving to another location) were classified as dropouts. Patients who completed the follow up period were analyzed in the groups that they were initially allocated.

Parametric analysis of variance complemented by Tukey test and nonparametric techniques complemented by Dunn's test were used. All tests were discussed at the 5% level of significance.

The primary outcome assessment was based on the measurement of the recovery of pelvic floor muscle strength obtained by perineometry between groups. Perineometry is an objective measure of pressure, which can be obtained in cmH_2O or mmHg. In this study, the maximal peak of each contraction was registered in cmH_2O. Perineometry is considered an objective form of muscle strength measurement, frequently used in studies involving the strength of the female pelvic floor. In men undergoing prostatectomy, there is still no evidence of the relationship between recovery from urinary continence or erectile function with recovery of muscle strength from the male pelvic floor.

Secondary outcomes were: 1 hour Pad Test (urine loss), ICIQ-SF score (quality of life), IIEF-5 score (erectile function), and IPSS score (urinary symptoms).

The 1 hour Pad Test is recommended by the International Continence Society (ICS)[16] and is an objective measurement of urine loss. It is a practical test and of easy reproducibility.

ICIQ-SF is a simple and brief instrument that assesses the impact of urinary incontinence on the patient's quality of life and qualifies urinary loss in patients of both genders. It was validated for the use in Portuguese by Tamanini et al. in 2004[17]. Its score ranges from 0 to 21, with 0 being the absence of an impact of urinary incontinence on quality of life.

IIEF-5 is a summary version of the International Index of Erectile Function (IIEF) and was developed to diagnose the presence and severity of erectile dysfunction (ED). It is a specific instrument that evaluates the results of a treatment based on the individual's own perception about their sexual life. Its score ranges from 1 (Severe Erectile Dysfunction) to 25 (Absence of Erectile Dysfunction)[18].

IPSS is the most widely used and internationally accepted method for evaluating urinary symptoms. It is a good indicator of the degree of discomfort and effect on quality of life in patients with lower urinary tract symptoms. Their score ranges from 0 (mild symptoms) to 35 (severe symptoms).

RESULTS

From October 2011 to September 2014, 237 patients were prospectively screened. Of these, 82 refused to participate and 23 patients did not satisfy the inclusion criterion. One hundred and thirty-two patients were randomized and after an exclusion criteria-based step, one hundred and twenty-three post-prostatectomy incontinent men were studied (Fig. 1). There was no significant difference on clinical and pathological variables among the studied groups and 77.5%, 73% and 81% presented moderate and severe RPUI and were assigned to groups G1, G2 and G3, respectively. Therefore, groups were considered homogeneous.

The average age was 57.3 (± 6.5), 58.0 (± 5.7) and 58.5 (± 5.4), respectively. The body mass index between groups was, respectively, 26.4 (± 4.1), 27.1 (± 4.0) and 26.9 (± 4.2). In the three study groups, most patients had pathological staging classified into pT2c (67.5%, 61% and 64.3%). During the follow-up period of the study (6 months), no patient had lymph node or distant recurrence. Table 1 shows an overview of the clinical conditions of the patients.

There was a significant worsening of PFMS in all groups in the first month after surgery compared to preoperatively, demonstrating the impact of surgery on this muscle group. At the end of the follow-up, no statistical difference was observed in muscle strength measurement between different groups ($p>0.05$) (Table 2).

In the 1 hour-Pad Test, there was a significant worsening of incontinence, in all groups in the first postoperative month in comparison to different moments, demonstrating objective worsening of urinary loss in the first month after surgery. On the other hand, we also observed a spontaneus recovery of urinary leak in all groups in the third and sixth months. However, there was no statistical difference among groups in different moments ($p>0.05$) (Table 3).

The measure of quality of life (ICIQ-SF score) showed a significant worsening in all groups in the first month after surgery compared to preoperatively ($p<0.05$). This worsening was maintained until the sixth month of evaluation with no significant difference between groups G1, G2 and G3 at the end of follow-up ($p>0.05$) (Table 4).

In the assessment of erectile function (IIEF-5 score), there was a significant worsening in all groups in the first postoperative month compared to initial evaluation. We also noted a significant, though partial, improvement in the score of each group in the sixth post-operative month compared to the first post-operative month. There was no difference among different groups at any time (Table 5).

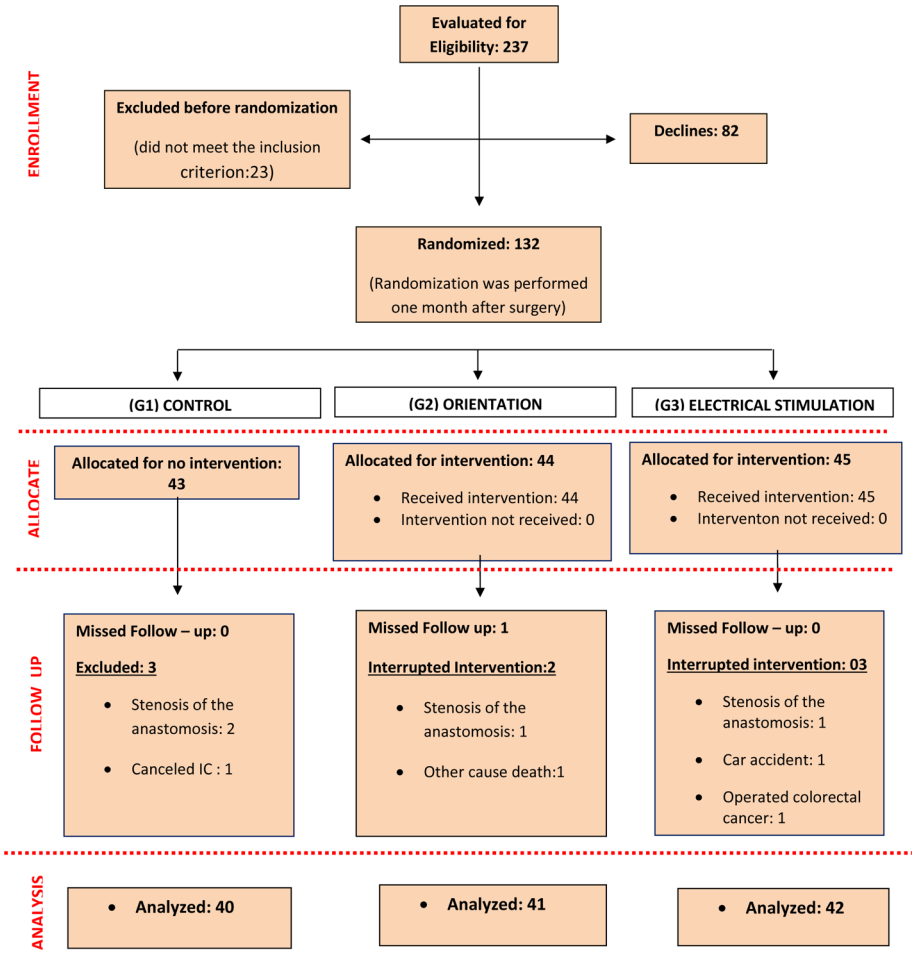

Fig. 1. The CONSORT flowchart of patients.

Table 1. Clinical and pathological characteristics of the patients enrolled

Variable	G1 (n:40)	G2 (n:41)	G3 (n:42)	p value
Age (yrs)	57.3 ± 6.5	58.0 ± 5.7	58.5 ± 5.4	p>0.05
Abdominal circunference (cm)	95.0 ± 10.9	94.9 ± 12.5	94.4 ± 11.5	p>0.05
BMI (m^2/ kg)	26.4 ± 4.1	27.1 ± 4.0	26.9 ± 4.2	p>0.05
Prostate size (g)	43.0 ± 16.1	41.9 ± 15.7	44.7 ± 27.4	p>0.05
Pathological staging of tumor				
pT2a	2 (5%)	2 (4.9%)	4 (9.5%)	p>0.05
pT2b	5 (12.5%)	6 (14.6%)	3 (7.1%)	
pT2c	27 (67.5%)	25 (61%)	27 (64.3%)	
pT3a	5 (12.5%)	7 (17.1%)	8 (19%)	
pT3b	1 (2.5%)	1 (2.4%)	0 (0%)	
Margins				
Positive	11 (27.5%)	13 (31.7%)	16 (38.1%)	p>0.05
Negative	29 (72.5%)	28 (68.3%)	26 (61.9%)	

Table 2. Perineometry (PFMS) measurements between groups during follow-up

Group	Pre Op	1st month po	3rd month po	6th month po	p value
G1	49.5 (6.0–106.0) aB	35.7 (9.3–105.0) aA	56.2 (14.7–135.0) aB	57.5 (18.3–103.7) aB	p<0.05
G2	45.3 (8.0–114.0) aB	38.7 (17.3–100.0) aA	49.0 (20.7–135.0) aB	45.7 (18.7–118.0) aB	p<0.05
G3	63.5 (23.0–107.0) bB	49.0 (5.0–106.7) bA	67.2 (7.3–131.0) aB	63.0 (13.7–128.0) aB	p<0.05
p value	p<0.05	p<0.05	p>0.05	p>0.05	

Different lower case letters indicate significant difference among the groups at the same time point. Different capital letters indicate significant difference among different time point in the same group.

Table 3. 1h-Pad Test Results among different groups during follow-up

Group	Pre Op	1st month po	3rd month po	6 month po	p value
G1	1.0 (0–22.0) aA	5.0 (3.0–351.0) aB	1.0 (0–279.0) aA	1.0 (0–231.0) aA	p<0.05
G2	1.0 (0–3.0) aA	7.0 (3.0–431.0) aB	2.0 (0–74.0) aA	1.0 (0–78.0) aA	p<0.05
G3	0.5 (0–36.0) aA	9.0 (3.0–241.0) aB	1.0 (0–183.0) aA	1.0 (0–18.0) aA	p<0.05
p value	p>0.05	p>0.05	p>0.05	p>0.05	

Different lower case letters indicate significant difference among the groups at the same time point. Different capital letters indicate significant difference among different time points in the same group.

Table 4. ICIQ-SF score among different groups during follow-up

Group	Pre Op	1st month po	3rd month po	6th month po	p value
G1	0.0 (0.0–18.0) aA	8.0 (1.0–21.0) aC	6.0 (0.0–21.0) aB	4.0 (0.0–21.0) aB	p<0.05
G2	0.0 (0.0–14.0) aA	11.0 (1.0–21.0) aC	6.0 (0.0–17.0) aB	3.0 (0.0–16.0) aAB	p<0.05
G3	0.0 (0.0–18.0) aA	11.0 (1.0–21.0) aC	5.5 (0.0–20.0) aB	4.0 (0.0–18.0) aAB	p<0.05
p value	p>0.05	p>0.05	p>0.05	p>0.05	

Different lower case letters indicate significant difference among the groups at the same time point. Different capital letters indicate significant difference among different time points in the same group.

Table 5. IIEF-5 score among different groups during follow-up

Group	Pre Op	1st month po	3rd month po	6th month po	p value
G1	20.0 (2.0–25.0) aC	3.0 (1.0–18.0) aA	5.5 (1.0–18.0) aB	7.0 (1.0–24.0) aB	p<0.05
G2	20.0 (1.0–25.0) aC	3.0 (1.0–24.0) aA	4.0 (1.0–25.0) aAB	6.0 (1.0–25.0) aB	p<0.05
G3	20.0 (2.0–25.0) aC	3.0 (1.0–24.0) aA	5.0 (1.0–24.0) aAB	6.0 (1.0–25.0) aB	p<0.05
p value	p>0.05	p>0.05	p>0.05	p>0.05	

Different lower case letters indicate significant difference among the groups at the same time point. Different capital letters indicate significant difference among different time points in the same group.

Table 6. IPSS score among different groups during follow-up

Group	Pre Op	1st month po	3rd month po	6th month po	p value
G1	8.0 (0.0–33.0) aB	8.0 (0.0–28.0) aB	6.5 (0.0–24.0) aAB	4.0 (0.0–18.0) aA	p<0.05
G2	9.0 (0.0–24.0) aB	8.0 (0.0–26.0) aB	7.0 (0.0–25.0) aAB	4.0 (0.0–23.0) aA	p<0.05
G3	6.5 (0.0–31.0) aB	6.0 (0.0–26.0) aB	4.0 (0.0–27.0) aAB	2.5 (0.0–27.0) aA	p<0.05
p value	p>0.05	p>0.05	p>0.05	p>0.05	

Different lower case letters indicate significant difference among the groups at the same time point. Different capital letters indicate significant difference among different time points in the same group.

In the evaluation of IPSS, there was a significant improvement in the sixth month evaluation in relation to preoperative in all groups (p<0.05). However, there was no significant difference between the groups, even at the end of follow-up: 4 (0–18), 4 (0–23) and 2.5 (0–27) in G1, G2 and G3, respectively (Table 6).

DISCUSSION

This study evaluated the impact of different forms of pelvic floor muscle rehabilitation in patients undergoing radical prostatectomy. Different types of physical therapy did not influence the recovery of urinary incontinence and erectile dysfunction. In all groups we observed an impairment of all studied variables (pelvic floor muscle strength, 1-hour Pad Test, ICIQ-SF and IIEF-5) except IPSS scores at 1 month after surgery with recovery at 3 months, sustained at 6 months for 1-hour Pad Test and pelvic floor muscle strength and at 6 months for ICIQ-SF, IIEF-5 and IPSS, regardless of the physiotherapeutic intervention.

Despite this, in agreement with other authors[12, 23] we have observed an association between recovery rates of urinary incontinence and increasing of pelvic floor muscle strength, suggesting an effect of pelvic floor muscles on urinary incontinence recovery, which was more complete than the erectile dysfunction recovery.

Nowadays, the role that pelvic floor muscle strength plays on the recovery of urinary incontinence and erectile dysfunction is still unclear. Perhaps the most important factor of these complications is the direct damage to the sphincter and vascular-nervous bundle during the radical prostatectomy. Although, we observed a weakness of perineal muscles in the first postoperative month in all groups, there were similar recovery rates in all groups.

The objective evaluation of urinary loss in the first month after radical prostatectomy found that most patients had moderate and severe urinary incontinence, with no significant difference among groups, demonstrating that these are homogeneous groups.

While our findings were coincident with the results observed in a meta-analysis by Zhu et al.[1], in which the authors concluded that the use of electrical stimulation associated with pelvic floor muscle training did not prevent urinary incontinence. A late benefit for pelvic floor muscle training was observed by other authors and the preoperative levels returning in the third month, maintained until the sixth month are in disagreement with other study[10] in which objective improvement in urinary incontinence post radical prostatectomy was observed earlier.

In erectile function, there was a significant worsening after surgery with no substantial recovery in all groups. Nevertheless, other authors[14, 24] have observed improvement in erectile function after physiotherapeutic treatment. Perhaps the main limitation of our study is in the fact that urinary incontinence did not improve in all groups, interfering with erectile dysfunction recovery since urinary incontinence can directly affect sexual relations attempts, and consequently, sexual satisfaction in this population.

We found a worsening in the quality of life (ICIQ-SF score) in the first month postoperatively in all groups, demonstrating the impact of surgery on the patients studied, with improvement attributed to the time effect. Yamanishi et al.[25] showed similar results in a controled study. Other authors have demonstrated the importance of using ICIQ-SF questionnaire validated in Portuguese to standardize the results obtained in relation of urinary incontinence influencing quality of life[26].

In the literature, some authors have used the IPSS score for evaluation of urinary symptoms in men after RP. Significant improvement at the end of follow-up compared to the pre-operative period was observed in our study, in agreement with other authors[27].

None of the patients involved in this study had previously performed any kind of physiotherapy for the pelvic floor muscles in their previous history. Perhaps a limitation to be considered in our study is the absence of an instrument to measure the patient's adherence to perform the exercises at home in the group that received only guidance for home exercises.

Although there is no knowledge of the patients nerve sparing, or use of PDE5 inhibitors postoperatively, there is no reason to believe that in the randomization such features might be unbalanced between study groups.

Our study is not without limitations, though prospective randomized, it is relativelly small and limited to the techniques used in the pelvic floor muscle trainnig. Further studies are necessary considering larger cohorts and different interventions.

Our results suggest that muscle strength recovery occurs independently of the therapy employed. The time factor seems to be the most important marker. Pelvic floor exercises or electrical stimulation also did not have an impact on the recovery of urinary continence and erectile function in our study.

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Conflict of interest

There are no conflicts of interest in the study.

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