RESEARCH ARTICLE

Assessment of Physical Therapy Strategies for Recovery of Urinary Continence after Prostatectomy

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Abstract

Introduction: Urinary incontinence is a complication of radical prostatectomy. Pelvic floor exercises can facilitate recovery of continence after surgery; however, there is not sufficient evidence that physical therapy with biofeedback training is effective, particularly with respect to providing a faster recovery. **Objective:** To analyze the application of physical therapy techniques in the recovery of urinary incontinence after prostatectomy. **Methodology:** A randomized clinical trial was conducted from April to October 2015 with patients undergoing radical prostatectomy up to three months after surgery at the Santa Casa de Misericordia in Northeastern Brazil. The physical therapy intervention consisted of up to eight individual sessions. Patients were randomized into the intervention group, which performed exercises and received biofeedback training, and the control group, which performed exercises alone. Participants were assessed before, during and after treatment. The initial assessment included a structured instrument addressing sociodemographic and urological data. Frequencies were calculated for all variables and comparisons were checked by the Mann-Whitney test and for correlation significance. **Results:** The study included 13 patients aged 54-74 years, the majority undergoing retropubic surgery with mild urinary incontinence [11 (84.6%)]. There was a significant difference in the outcome of the pad test before (p=0.070) and after (p=0.015) treatment between the groups, but the reduction of urinary loss and the time to recovery of continence were equivalent for both groups. **Conclusion:** Both interventions provided improvement in the degree of incontinence within two months of treatment.

Keywords: Prostatectomy- prostate cancer- pelvic floor- urinary incontinence

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Introduction

With the world population aging, cancer has become an increasingly important concern in the Public Health sector. According to the Instituto Nacional de Câncer – INCA (Brazil's National Cancer Institute), prostate cancer (PC) – among the various oncological diseases – has shown an increasing incidence rate worldwide. It is the second most common cancer in men worldwide, with about 1.1 million new cases according to 2012 global estimates (Ferlay et al., 2012). Moreover, with the increase in life expectancy worldwide, a 60% increase in the number of new cases is expected. According to 2016 estimates of cancer incidence in Brazil, 61,200 new cases of PC are expected for the year 2016, with an estimated risk of 61.8 new cases per 100,000 men in the country and 57.5 new cases per 100,000 men in the state of Ceará (Brazil, 2015).

Given that PC is notably recognized as a public health problem, actions involving cancer consist of early diagnosis and adequate therapeutic approach to prevent disability. In this context, surgical treatment is an approach that leads to complications that affect the quality of life (QoL) of patients – for instance, urinary incontinence (UI). Men who develop UI after prostatectomy should be treated through conservative methods in the first year, and the surgical treatment should be indicated only in cases of severe urinary loss in the first 12 months postoperatively (Agostinho and Bertotto, 2014).

Physical therapy interventions after prostatectomy should be the first choice of treatment and may include pelvic floor exercises (PFE), electrical stimulation (ES), biofeedback training (BFB) and also behavioral therapy (BT), which involves educational actions. However, there is still no consensus on the right time to begin PF training after surgery nor on the amount and type of exercises to be performed, i.e., there is not a clear protocol to be followed (Marchiori et al., 2010).

PFE or PFMT (pelvic floor muscle training) are the main physical therapy interventions for the treatment of UI with grade A recommendation (Abrams, 2009) in several countries with good results (Filocamo et al., 2005; Manassero et al., 2007; Centemero et al., 2010).

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Performing exercises associated with biofeedback requires active participation of the patient and specialized equipment to convert the physiological signals into visual or auditory signals and also a trained practitioner to guide the therapy (Seleme et al., 2009). This intervention has been used to promote the recovery of continence after prostatectomy with good levels of evidence (Van Kampen et al., 2000; Floratos et al., 2002; Ribeiro et al., 2010).

Thus, the present study aimed to analyze the impact of physical therapy techniques on the recovery of urinary continence after prostatectomy assessed through 1-hour pad test.

Materials and Methods

Population

A prospective, randomized intervention study was conducted in a Pelvic Floor Physical Therapy Clinic of the city of Fortaleza, Ceará, Northeastern Brazil, to compare PFE plus biofeedback training versus PFE only. Study participants were men with urinary incontinence (loss > 2g) after retropubic or laparoscopic prostatectomy for clinically localized cancer between April and October 2015. The study included 13 patients with a mean age of 63.9 (54-74 years) up to three months postoperatively.

Urinary loss was assessed using 1-hour pad test. For the test, patients wore a pre-weighed pad and drank 500 ml of water. A series of activities was performed to provoke leakage: getting up and sitting; coughing; walking; bending over; and washing hands in running water. After performing the activities the pad was re-weighed. The difference in the weight before and after estimates the amount of lost urine and is classified into: no UI (<2g); mild UI (2 to 9.9g); moderate UI (10 to 49.9g) and severe UI (> 50g) (Smither et al., 2007).

Exclusion criteria were: men with altered cognitive status and/or neurological disorders that prevented understanding or had an impact on urinary control before surgery; men with previous history of bladder or prostate surgery or who had undergone pelvic radiotherapy; men with cardiac pacemakers or metal implants in the hip or lower limb and with advanced hemorrhoidal disease or rectal prolapsed; and those unable or unwilling to participate in the study.

Participants were randomly assigned to two groups: control (n=6) and intervention (n=7). All the patients gave their written consent before randomization. The intervention group performed PFE plus biofeedback and the control group performed only PFE. The study was approved by the Research Ethics Committee of the University of Fortaleza (UNIFOR) under Opinion No. 35977214.0.0000.5052 and authorized by the Urology Department of the Santa Casa de Misericórdia de Fortaleza hospital.

Intervention

All the patients were assessed in the first consultation and received information on the urinary tract and a structured program of exercises to be performed at home and underwent the 1-hour pad test. The physical therapy intervention started in the second consultation.

Patients in the intervention group performed PFE plus biofeedback once a week during eight weeks in a clinic using a manometry BFB equipment (Ibramed, Barueri, São Paulo, Brasil). An anal probe was placed and inflated with 15 ml of air. Placed in the right lateral decubitus, patients performed quick contractions and then sustained contractions followed by a time for rest, totaling 20 minutes. After that, active exercises were carried out by asking the patient to contract the anus as if trying to avoid passing gas. The physical therapy intervention for the control group consisted of active exercises performed in the clinic only. All the participants received oral and written instructions on exercises to be performed at home daily while sitting, lying and standing.

Assessment of outcomes

The assessment of both groups was performed by the same researcher at time 0, and in the fifth and ninth consultation. The UI assessed using the 1-hour pad test. Patients were considered continent if urine leakage was < 2g.

During the physical therapy sessions, none of the patients presented or reported any discomfort, irritation or any other problem relating to the treatment procedures.

Statistical analysis

The data were entered and analyzed using the SPSS (Statistical Package for the Social Sciences), version 19.0. (SPSS Inc., Chicago, IL, USA) and are described in numbers in the ordinal scale and simple frequency. The comparison of variables between groups was performed using the Mann-Whitney test and the correlation significance test was used to verify the significance between two numeric variables.

Results

In all, 20 patients were assessed. Of these, four were excluded for the following reasons: postoperative period >3 months; patient with hip prosthesis and continent

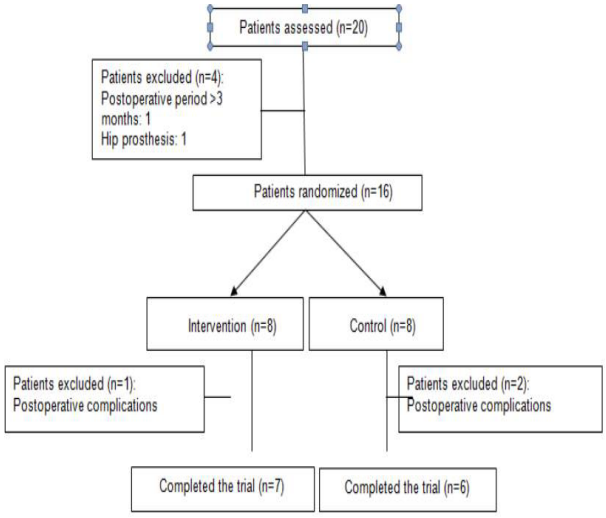

Figure 1. Flowchart of Patients in the Various Stages of the Study

Table 1. Clinical Variables of Participants. Fortaleza, Ceará, 2015.

Variables	Control Group n=6		Intenrvention Group n=7		´p value
	F	%	F	%	
Type of surgery					
Radical retropubic prostatectomy	5	38.5	5	38.5	1
Laparoscopic radical prostatectomy	1	7.7	2	15.3	
Prostate weight					
Up to 30 g	0	0.0	2	15.3	0.301
Between 31 and 40 g	2	15.3	0	0	
Between 41 and 50 g	2	15.3	4	30.8	
>50 g	2	15.3	1	7.7	
Gleason score					
6 (3:3)	0	0.0	3	23.2	0.041
7 (4:3)	3	23.2	0	0	
7 (3:4)	3	23.2	2	15.3	
9 (4:5)	0	0.0	2	15.3	
Time spent with catheter postoperatively (days)					
Up to 15 days	2	15.3	4	30.8	0.79
Between 10 and 15 days	2	15.3	2	15.3	
More than 15 days	2	15.3	1	7.7	
Time elapsed between the surgery and the start of physical therapy					
Up to 30 days	2	15.3	2	15.3	1
From 31 to 60 days	1	7.7	1	7.7	
From 61 to 90 days	3	23.2	4	30.8	
Number of physical therapy sessions held					
5 sessions	2	15.3	3	23.2	1
8 sessions	4	30.8	4	30.8	

Source, Research data. Fisher's Exact Test

patient (pad test <2 g). The remaining 16 patients were randomly assigned to the treatment group (n=8) and control (n=8). The study excluded three patients who presented urethral stricture and needed to receive a catheter again. A total of 13 patients completed the trial, including six in the control group and 7 in the treatment group (Figure 1).

The groups were similar in age, with a mean of 63.9 years (54-74); however, there was a prevalence of individuals aged 60 to 70 years (n=9, 69.3%). The mean age was 65.6 years (58-70) for the treatment group and 62 years (54-74) for the control group. Regarding other demographic data, participants were predominantly white (n=7; 53.8%), married (n=9, 69.3%), had an adequate nutritional diagnosis (n=7, 54%), low education (n=8; 61.8%) and were retired (n=6; 46.1%). Additionally, nearly half of the participants received up to two minimum wages (n=6; 46.2%).

The groups presented homogeneous sociodemographic characteristics and no statistical significance was found for the variables: age, race, education, occupation and income between the two groups.

In Table 1 it can be seen that there was a prevalence of retropubic surgery in both groups. The prostate weight ranged between 41 and 50g and there was no statistical significance. On the other hand, the most prevalent score obtained using the Gleason grading system (in which scores are obtained according to the microscopic appearance of PC, where higher scores are associated with worse prognosis) was 7(3:4). Most participants used a catheter for up to 15 days, received late physical therapy treatment and received eight sessions.

According to Table 2, nine out of the 13 incontinent patients became continent after treatment (69.2%) and

Table 2. Classification of UI According to the Pad-Test before and after Treatment. Fortaleza, Ceará, 2015.

Groups	Pad-Test 1 h	No UI	Mild	Moderate	Severe	p value
Intervention Group	Before treatment	0	6	1	0	0.070
	After treatment	4	3	0	0	
Control Group	Before treatment	0	5	0	1	0.015
	After treatment	5	1	0	0	

Source, Research data. Fisher's Exact Test

Table 3. Distribution of the Occurrence of Nocturia before and after Treatment. Fortaleza, Ceará, 2015.

GROUPS	Nocturia	0-1	2-3	3-4	>4	p value
Intervention Group	Before treatment	0	0	6	1	0.009
	After treatment	5	1	1	0	
Control Group	Before treatment	1	0	3	2	0.156
	After treatment	2	3	1	0	

Source, Research data. Fisher's Exact Test

Table 4. Distribution of Patients Using Pads before and after Treatment. Fortaleza, Ceará, 2015.

Groups	Use of Pads	Never or Occasionally	1-2 day	3-4 day	>4 day	p value
Intervention Group	Before treatment	2	4	0	1	0.021
	After treatment	7	0	0	0	
Control Group	Before treatment	0	3	3	0	0.002
	After treatment	6	0	0	0	

Source, Research data. Fisher's Exact Test

four remained with mild UI (30.8%), with losses very close to the cutoff established in the methodology. In the statistical analysis, it was found that there was a significant difference between pre and post-treatment in both groups (p=0.070; p=0.015).

Nocturia, defined as the need to wake two or more times at night only to urinate (Moreno, 2009), is a common condition after surgery and was present in 12 patients (92.3%) at the beginning of treatment. Table 3 shows that, after the physical therapy intervention, six patients (46.1%) maintained this frequency. With regard to this symptom, a statistically significant difference was found between pre and post-treatment only for the EB group (p=0.009).

The analysis of the number of patients using pads to contain urinary losses found that 11 (84.6%) individuals used such feature (diapers or pads). A statistically significant decrease in both groups (p=0.021; p=0.002) was found for this variable. At the end of treatment, all participants reported no or occasional use of pads (Table 4).

Discussion

Although there is a consensus on the benefits of the use of PFE for UI treatment, yet there is no scientific evidence to prove the effectiveness of the performance of exercises plus biofeedback. This finding is highlighted in the Cochrane systematic review, which emphasizes that the effectiveness of the conservative treatment of UI after RP remains uncertain. However, in general, there is enough evidence to demonstrate the beneficial effects of PFMT (Anderson et al., 2015).

In the present study, an exercise program was applied with and without BFB under the supervision of a physical therapist plus a home exercise program that led to satisfactory results in both groups (treatment and control) in order to verify the effectiveness in reducing the degree and duration of the UI after RP. Active PF exercises associated with BFB may facilitate positive outcomes compared to exercises alone. This advantage is justified by the learning of an effective contraction through the use of this technology (Tienfort et al., 2012; Ribeiro et al., 2010; Floratos et al., 2002).

The use of the BFB had advantages given its attractiveness and the fact that it is easy to understand, despite the hassle of using the anal probe. Patients undergoing this intervention struggled to perform well during exercises and were annoyed when they could not perform the exercises so perfectly. These findings are corroborated by Tienfortet al. (2012) when comparing a home exercise program versus the same program plus a monthly session of BFB for 6 months. These authors obtained significant improvement in episodes of urine loss (p=0.005) and use of pads per week (p=0.03) in the group using the BFB.

To check outcomes it is important to grade the incontinence of patients before and after treatment given that the self-reported continence status is an imprecise measure of urine loss. The definition of recovery of continence with losses <2g is compatible with the number of sessions established in the treatment protocol and has been adopted by different researchers using the 1-hour pad test (Van Kampen et al., 2000; Laurienzo et al., 2013; Rajkoswska-Labon et al., 2014).

In the present study, only eight sessions were carried out and they have provided positive results for both groups. This is supported by Smither et al. (2007) who assessed 203 patients and found a rapid decrease in the volume of urine loss during 18 weeks, with 37% of patients regaining continence (loss <1 g) within the first 6 weeks. Yamanishi et al. (2010) conducted a randomized study with 56 patients with severe incontinence (>200g/day) and found that 63% of patients in the treatment group recovered continence in only 3 months.

Nocturia, a common symptom after prostatectomy, was present in most participants. During follow-up, according to reports from some of the patients, a reduction in nocturia did not occur given that the act of waking up during the night to urinate has been a habit prior to surgery. The presence of nocturia, according to patients' self-reports was higher in the treatment group at the beginning of intervention and is consistent with findings from the study by Ribeiro et al. (2010).

The information obtained through the reports of patients (self-reported continence and use and quantity

of pads per day) was important and served as the basis for checking the coincidence or not with the test pad. This information, even with risk of misconceptions in the reports of patients, is a strategy used by different authors to determine whether a patient is continent or not after treatment (Tienfort et al., 2012; Ribeiro et al., 2010; Mariotti et al., 2009; Floratos et al., 2002; Van Kampen et al., 2000).

Results without significance such as those obtained in the study by Goode et al. (2011) involving 208 prostatectomized patients in a randomized clinical trial should be highlighted. According to these authors, the inclusion of BFB and ES did not improve the results compared to BT alone, i.e., there was no significant difference in the reduction of UI among treatment groups. Accordingly, Wille et al. (2003) compared treatment groups with the inclusion of BFB and found that there were no statistically significant differences in continence rate at 3 months (p=0.861) and 12 months (p=0.524). Also, a Dutch study by Floratos et al. (2002) did not find better results with the inclusion of BFB compared to exercises alone. For these authors, both treatments were effective.

The treatment strategies proposed were able to positively influence the time to recovery of continence while most studies propose a monitoring time longer than that of the present study (2-3 months); however, the monitoring of patients is commonly performed for six months (Tienfort et al., 2012; Mariotti et al., 2009; Floratos et al., 2002; Franke et al., 2000) and 12 months (Goode et al., 2011; Ribeiro et al., 2010; Wille et al., 2003) and present similar results.

Supporting these findings, Marchiori et al., (2010) in an Italian study found that the mean time to recovery of continence in the treatment group was 44±2 days vs 76±4 days in the control group, i.e., continence was achieved earlier by patients who performed physical therapy exercises under supervision. In an American study involving 125 patients, Burgio et al. (2006) found that the mean time to achieve continence in the group receiving BFB preoperatively and instructions for performing PF exercises was 3.5 months (p=0.04).

Although positive results regarding the recovery of UI after completion of physical therapy have been found in a small sample, there is a need for further studies with a larger number of participants to allow inference with greater reliability, which was considered a limitation of the present study.

Conclusion

The findings obtained suggest that the training with BFB contributes to the improvement of the degree of UI and to the early recovery of continence, improvement of nocturia and decreased use of pads in prostatectomized men.

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