EARLY 3-MONTH TREATMENT WITH COMPREHENSIVE PHYSICALTHERAPY PROGRAM RESTORES CONTINENCE IN URINARYINCONTINENCE PATIENTS AFTER RADICAL PROSTATECTOMY:A RANDOMIZED CONTROLLED TRIAL

Abstract

Aims: The objective of this study is to ascertain whether an early three-month treatment with electrotherapy and biofeedback restores continence in urinary incontinence patients after radical prostatectomy (RP).

Methods: Design: The study performed a randomized, controlled trial of parallel and open groups. Configuration: Secondary care, urology department of a university hospital complex. Participants: Patients sent for RP due to prostate cancer (n = 60), 47 patients finally completed the study. Interventions: The treatment group (TG) received physiotherapy consisting of electrotherapy and biofeedback, 3 days a week for 3 months, while the control group (CG) received no specific treatment. Both groups received a guide to perform pelvic floor exercises at home. The measurement instruments used were the 1- and 24-hour pad tests and the International Consultation on In-continence Questionnaire Short-Form. The recording method used was a micturition (urinary) diary.

Results: he results of the 1-hour pad test (PT) show statistically significant differences between groups at 3 months (P = .001) and 6 months (P = .001), in favor of those in the TG. Sixty-four percent of patients in the TG recovered continence as against 9.1% in the CG after 3 months in the 1-hour PT, in line with the objective of this study.

Conclusions: An early physiotherapy program helps RP patients with urinary incontinence recover continence after 3 months. Moreover, they lead a better quality life.

Registration number of clinical trial- The study is registered in Assign ISRCTN to trial - standard fee Our Reference: 33075

Introduction

Prostate cancer is the second most diagnosed cancer in men worldwide and the first in Europe and Spain. Its early detection, thanks to the use of PSA and subsequent biopsy, caused the incidence rate to increase significantly in the 1990s (1) but led to significant decrease in mortality (2).

According to the latest data, prostate cancer currently has a high cure rate, where the relative survival at 5 years is almost 100%. This is because 90% of the cases are diagnosed in the localised stage, meaning that the cancer has not yet spread outside the prostate gland, which would explain the high survival rate (3).

Radical prostatectomy (RP) has become the "gold standard" to treat prostate cancer and seems to be the best method for cancer control in the long term. However, this procedure is not exempt from morbidity, since urinary incontinence affects patient's quality of life (4).

Data on urinary incontinence rates after RP are disparate and have been the source of controversy in recent years. Rodriguez Escobar (5) explains that the reason behind the wide range in incontinence incidence is the use of different definitions of continence and methods for quantifying it, where one can find definitions such as: "total control", "occasional leakage but without pad", and "less than one pad".

From a medical point of view, incontinence causes skin irritation, chronic dependence on catheters and urine collecting devices, and a significant increase in morbidity. The cost of this pathology (materials, nursing care, diagnostic tests, treatments, etc.) in the United States has been directly or indirectly estimated to be about 8 billion dollars a year (6).

The conservative treatment today for post-prostatectomy urinary incontinence includes training of the pelvic floor muscles, biofeedback (BF), and electro-stimulation.

The above must be combined with a proper life style that includes a decrease or elimination of caffeine, tobacco, performance of physical exercise and bladder training, creation of a voiding schedule, and gradually increasing voiding interval (7).

The objective of this study is to ascertain whether an early three-month treatment with electrotherapy (ET) and BF restores continence in radical prostatectomy patients with urinary incontinence.

Material and methods

A randomised controlled trial of parallel and open groups was carried out, to compare the efficacy of physiotherapy intervention in improving continence in patients who underwent radical prostatectomy due to prostate cancer.

The study is registered in Assign ISRCTN with reference ISRCTN48761809, https://doi.org/10.1186/ISRCTN48761809.

Power calculation was based in the study of Manassero et al (8) showing a 67% of continence at 3 months in patients undergoing RP in the group with physiotherapy treatmentand 22.5% in the control group (CG). Assuming a 95%confidence level, 80% potency and a 1:1 treatment andcontrol ratio, 56 patients would need to be included ineach of the groups. Assuming a percentage of losses duringthe follow-up of 20% of these groups should be 67.

Statistically significant results were achieved before reaching the calculated sample size, and therefore it was decided to stop the clinical trial (9).

The sample consisted of 60 patients (two groups of 30 patients each) who underwent RP surgery at the Complejo Hospitalario Universitario de Vigo. Only RP patients with stress incontinence who consented to participate in the study were included, those with neurological pathology, such as advanced Parkinson's disease, multiple sclerosis with deterioration of cognitive or sensitive abilities or with muscular weakness were excluded. Also excluded were patients with other serious illnesses such

as cancer, severe chronic obstructive pulmonary disease, severe pulmonary hypertension, etc., patients with pacemakers, patients treated with muscle relaxants, and patients with previous urinary incontinence. Five patients from the control group declined participation upon learning that they would not be part of the experimental group, while one had to receive chemotherapy and two had urinary continence. In the experimental group, three patients manifested urinary continence and two received chemotherapy. Finally, as shown in Figure 1, the sample consisted of 47 males, 25 from the treatment group (TG), and 22 from the CG

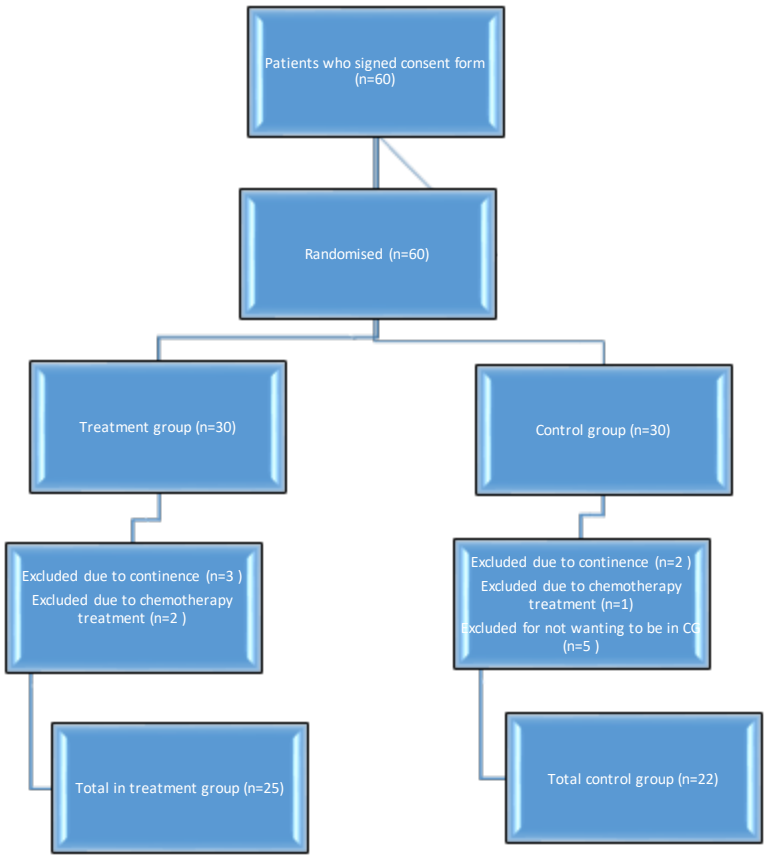

Figure 1- Study flow chart of thepatients in the study. Number of patients (n)

All patients signed the informed consent form approved by the Regional Committee on ethics and research of Galicia (IBAC) prior to participation in any of the study procedures.

Patients, doctors, and evaluators were not blinded for treatment. We expect no limitation of results since the main outcome variables are completely objective. All patients were subject to the same measurements and evaluations, irrespective of the group to which they belonged.

The urinary catheter was removed 3 weeks after RP and patients were subject to physiotherapy protocol 4 weeks after surgery.

The measurement instruments used were the 1 and 24-hour pad tests, following recommendations of the International Continence Society (IC) and the International Consultation on Incontinence Questionnaire Short-Form (ICIQ-SF) validated for the Spanish language. Moreover, the recording method used was a micturition diary.

Measurements were carried out at the start of treatment, and after 1, 2, 3 and 6 months. Initial measurement and treatment, in the case of the experimental group, began 7 days after catheter removal since immediate measurements may not be representative of later urinary incontinence.

The treatment group received physiotherapy consisting of electrotherapy and BF, 3 days a week for 3 months, while the CG did not receive any specific treatment, but both groups received a printed guide to perform pelvic floor exercises (PFEs) at home.

The intervention consisted of a first awareness phase where patients received basic notions of anatomy, functioning of the musculature and the process of urination, and were then given recommendations on control of liquid intake, limitation of substances such as coffee, alcohol, etc. and instructions on how to fill in the urinary diary. Moreover, they were trained to perform a reliable contraction, that is to say, perform contraction of the pelvic floor muscles, by avoiding parasitic contractions of buttocks, abdominals, adductor muscles, etc. This phase was adapted to each patient since getting quality contraction is of utmost importance here.

Patients received ET every alternate day, that is, for 15 minutes 3 days a week, with square wave pulses of 20 Hz, 300ns pulse duration and maximum intensity of 24 mA. This was because the literature review indicates this to be the type of electro-stimulation that gets best results.

Electromyography BF: the duration of treatment with BF was approximately 30 minutes every day and patient gradually exercised for strength, endurance and speed to obtain the objectives.

PFEs should be in line with the patient's muscular condition, and hence should vary in terms of force of contraction, duration of contraction, pause times, speed and position adopted by adapting to the muscle condition of each patient. These exercises were done at home three times/day spread over several sets.

Statistical analysis:

Data were analysed with SPSS version 22. The Shapiro-Wilk test was used to check the distribution of sample normality. The descriptive statistics of the quantitative variables are provided through the mean and standard deviation, while qualitative variables are expressed as percentages. The Wilconson test compared the results of urinary incontinence between the two groups at the start of treatment, after 1, 2 and 3 months. A p value of .05 was considered as statistically significant.

Results

The relationship between the treatment and CGs at baseline and prior to start of treatment did not show significant differences in any of the measurement instruments

used: 1-hour pad test (p=0.641), 24-hour pad test (p=0.983) and ICIQ-SF (p=0.079) (Table 1).

The results of the 1-hour pad test show statistically significant differences between groups at 3 months (p=.001) and 6 months (p=.001) in favor of the treatment group (Table 1). Figure 2 shows the evolution of urine loss by group and time.

Table 1.Contrast of medians between groups in PT1h, PT24 h and ICQSF

Variable	Time	N (TG)	Mean +- te (EG)	n(CG)	Mean +- te (CG)	IC95	P value
1-hour PT	Start	25	72.48±19.24	22	61.09±15.64	-11.39[-60.29, 37.51]	0,741
	1 month	25	26.76±6.43	22	56.00±16.26	29.24[-5.79, 64.27]	0,162
	2 months	25	13.12±4.10	21	51.67±15.77	38.55[5.62, 71.47]	0,069
	3 months	25	4.64±1.83	20	35.30±9.91	30.66[10.19, 51.13]	<0.001*
	6 months	23	0.70±0.35	18	19.50±7.34	18.80[3.75, 33.86]	<0.001*
24-Hour PT	Start	25	465.48±99.23	22	443.91±93.16	-21.57[-289.81,	0,983
	1 month	25	258.60±66.65	22	352.64±111.65	246.67]	0,565
	2 months	25	128.64±38.98	21	276.38±81.28	94.04[-164.11, 352.18]	0,242
	3 months	25	27.32±11.69	20	196.70±65.40	147.74[-32.30, 327.78]	0.003*
	6 months	23	4.00±1.50	18	107.78±43.00	169.38[34.38, 304.38]	<0.001*
						103.78[15.58, 191.97]	
ICQSF	Start	25	13.48±0.80	22	15.36±0.70	1.88[-0.20, 3.97]	0,079
	1 month	25	12.32±0.66	22	13.77±0.68	1.45[-0.42, 3.32]	0,102
	2 months	25	9.28±0.86	21	12.48±0.93	3.20[0.69, 5.70]	0.011*
	3 months	25	5.68±0.86	20	12.20±0.77	6.52[4.24, 8.80]	<0.001*
	6 months	23	3.87±0.84	18	9.94±1.12	6.07[3.31, 8.84]	<0.001*

	6 months						

Note: The P value refers to the difference between the groups. *P < .05.Abbreviations: CG, control group; CI, confident interval; ISIO-SF, International Consultation on Incontinence Questionnaire Short-Form; n, number ofpatients; PT, pad test; te, typical error; TG, treatment group.

With regard to continence rates after 3 months in the 1-hour PT, and in relation to the objective of this study, 64% of patients in the TG recovered continence as against 9.1% in the CG.

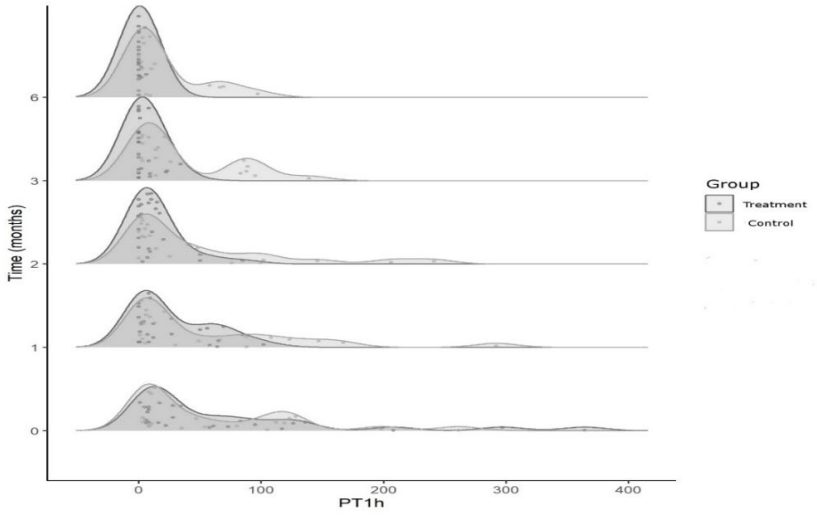

Figure 2. Evolution of urine loss bygroup and time in the 1-hour pad test (PT).

The results with the 24-hour pad test show significant differences between groups after 3 months (p= .003) and 6 months (p= .001), once again in favour of the treatment group (Table 1, Figure 3).

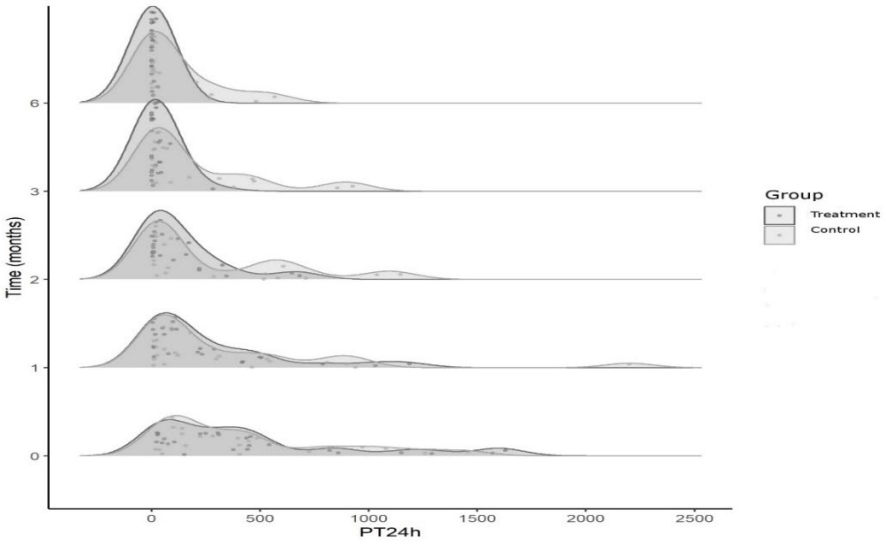

Figure 3. Evolution of urine loss by group and time in 24-hour PT. PT, pad test.

However, if we take into account continence rates at 3 months for the 24-hour pad test, the figure is 44% in the treatment group, which is lower than that seen in the 1-hour pad test. There is nevertheless evidence of difference between groups, since the control group reported a 4.5% continence rate.

Finally, the results of the ICIQ-SF scores show significant differences between groups at 2 months (p= .014), 3 months (p= .001) and 6 months (p= .0001), once again in favour of the treatment group (Table 1 and Figure 4).

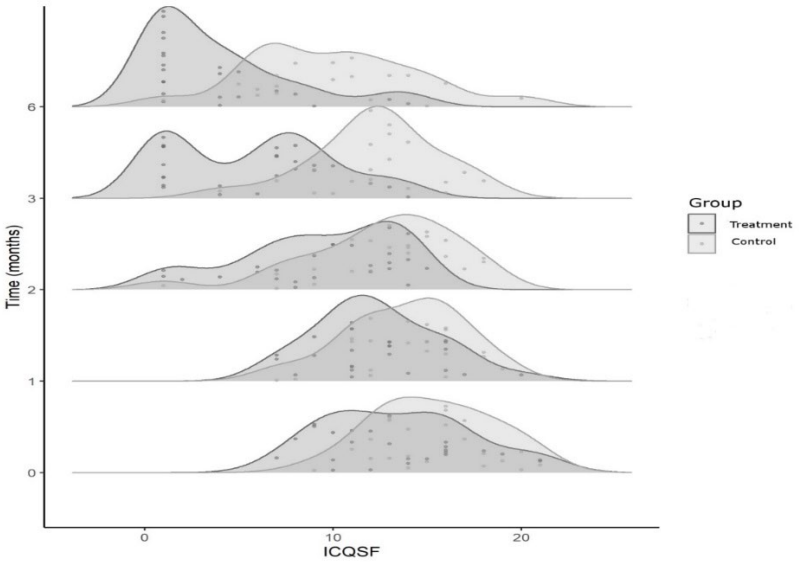

Figure 4. Evolution of urine loss bygroup and time in International Consultationon Incontinence Questionnaire Short-Form(ICIQ-SF).

Discussion

The results of the 1-hour pad test show statistically significant differences at 3 months, which was the deadline for achieving the continence objective in this study. Hence, a comparison of continence rates from the different studies for this period showed a large difference, where the best results were obtained by Kongtragul et al (10) and Van Kampen et al (11) at 95% and 88%, respectively. With regard to the intervention, worth mentioning is that Kongtragul et al (10) only used pelvic floor exercises (PFE) while Van Kampen et al (11) combined it with BF. Also noteworthy is the exercise intensity, since in Kongtragul et al (10) patients performed 240 contractions/day, while those of Van Kampen et al (11) only performed 90 contractions/day, which may explain the better results.

As shown in the section on results, the present study obtained 64% continence in the 1-hour pad test at 3 months, which is slightly lower than the one obtained in the mentioned studies, but it must be borne in mind that continence is defined as 0 g of loss. For studies using the same definition but with different tools (score 0 in the ICIQ and no loss recorded in the urinary diary), the rates were slightly lower such as 59.3% reported

by Centemero, 57.7% by Pedrialli, 50% by Tienforti, and 43.6% by Dijkstra-Eshuis. The first two authors performed interventions consisting of preoperative PFE and PFE+ Electrotherapy (ET) + BF, while the latter two authors performed interventions with BF + PFE.

The results with the 24-hour pad test show that there are significant differences between groups after 3 and 6 months, once again in favour of the treatment group. The continence rate at 3 months with this test in the present study was 44%. There is a group of authors who used this test and obtained similar continence rates of between 40-50% (8,12-14), and as can be seen, these rates are lower than those achieved with the 1-hour pad test.

Filocamo et al (15) and Cornel et al (16), respectively reported 74% and 70% continence at 3 months, which is the exception. However, it must be borne in mind that even though Filocamo et al (15) used the 24-hour pad test tool, they grouped patients who used one diaper/day under continence and this could clearly bias results. In the case of Cornel et al.(16) and Mariotti et al.(14), who obtained a rate of 63%, both classified continence as losses of less than or equal to 2 g, which could justify the higher rates when compared to the present study, which classifies continence as 0 g of loss or a completely dry pad.

On the other hand, Yamanishi et al (17) and Terzoni et al (18) achieved rates of around 63% but their definition of continence differs greatly from the rest of the studies (carried out in males). The former considered continence as ≤ 8 g, (the definition accepted at the time for females which took into account the weight of the vaginal flow) which cannot be applied in the case of males since it would skew this percentage. The latter included all patients with less than 10 g loss/day, which again prevents any comparison.

There seems to be a noticeable difference in rates depending on the pad test used. This coincides with a previous study conducted by Soto et al (19), where the discrepancy in continence rates depended on whether it was measured with the 1 or 24-hour pad test; a higher percentage of continence was observed for the 1-hour pad test. However, this fact would not alter the significant differences found between the study groups.

The initial conditions of both groups in the present study were similar in terms of loss evidenced in all measurement instruments used. Moreover, based on the mean loss in grams reflected in the different studies, we can observe that they are quite similar for the 24-hour pad test, since they vary between 217 g and 287 g in most studies that refer to this variable (7,8,12,20–22). These data are below the median loss observed in the present study since it lies at 465.48±99.23 for the treatment group and 443.91±93.16 for the CG. Therefore, the level of severity of incontinence is greater in this sample. Yokoyama et al (23) reported losses of 680 g, which is a much higher figure than the medians in the rest of the studies, but it should be noted that this amount corresponds to the first day of urinary catheter withdrawal. Most studies performed measurements 1 week after catheter withdrawal, to obtain a more realistic measure of incontinence.

Authors that used the 1-hour pad test observed medians that lay between 28 g (24) and 40 g (25), and once again, our study indicates a higher severity level, since the mean is 72.48±19.24 g for the treatment group and 60.69±15.64 g for the control group.

This indicates that baseline losses are not homogeneous, thereby revealing differences in the initial severity of patients from the different studies, which may also affect the results obtained and prevent any comparison. It is striking that many studies do not specify the initial losses although they do use tests that include them (10,13,16,18,20,26–28).

The interventions that reported best results combined PFE + BF (11,16), BF + ET (20), but the intervention that obtained the best results is an intensive PFE program (10).

The ICIQ-SF results show significant differences at 2 months in favor of the intervention group, in studies that used this same questionnaire for assessment of urinary incontinence (13,17,21,29,30), where significant improvements were observed after the first month. At this point, it should be emphasised that this tool obtains improvements before those obtained objectively in the 1-hour and 24-hour pad tests. This could be due to the specific question related to quality of life, that is, the patient perceives an improvement even though it may not be significant. Earlier studies found discrepancies in the severity level determined by the ICIQ-SF and the pad tests, since they do not coincide much (31).

The most commonly used methods to treat urinary incontinence are ET, BF and PFE, which have been studied traditionally in the treatment of female incontinence but, as we shall see below, they have also been evaluated in the treatment of male urinary incontinence after RP.

Electrotherapy has shown its effectiveness in various studies (7,17,20,23,29,32), although most studies used a combination of ET + PFE to obtain better results (20,29). As an exception, Goode et al (33) reported that the addition of PFE to an ET program did not increase continence rates, but ET in this case was performed by the patient himself at home, which could affect the results. But what seems evident is that ET is the most appropriate treatment when muscle weakness is pronounced (34).

Many articles report that BF has been used in the treatment of male urinary incontinence (11,14,16,20,25,26,30,33,35–38) and the benefits of this therapy are that it facilitates learning of PFEs, giving the patient the possibility to conduct self-assessments, thereby increasing motivation towards treatment (39). There are diverse results after

application of BF, with positive result in the most of the studies (11,16,20,26,30,37), when used on its own or combined with other treatments.

A group of authors did not find benefits after addition of BF to their interventions. All these studies performed a total of 1 to 5 BF sessions (14,33,35,38) which may be the cause of the ineffectiveness of the technique since the number of sessions seems to be less than that required for obtaining good results. On the other hand, the effective studies had carried out between 1 to 2 sessions/week, over a 3 month interval (11,16,20,16,29,40,15,28,39). Many studies do not provide details of therapy implementation and hence cannot be reproduced.

Finally, PFE are the most widely used treatment for treating male urinary incontinence with good results in all studies that include them as sole treatment or compare them with placebo or no intervention.

The performance of PFES is considered as one of the most effective treatments today.

Although earlier literature reports that there is no established protocol on duration of contractions, resting time or the number of repetitions or sets, Garcia-Sanchez, after reviewing several articles related to therapeutic pelvic floor exercise, provides a protocol of 30 to 40 contractions four times/day. A maximum of 200 contractions/day and up to 300 contractions/day in athletic women (41) could justify the better results obtained with a more intensive program as seen above.

The fact is that patients who perform exercises at home cannot be controlled for adherence to the exercise program, which may affect treatment results.

Conclusion

An early physiotherapy program helps recover continence after 3 months in urinary incontinence patients that underwent RP. Moreover, these patients lead a better quality life.

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