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Improvement of Continence Rate with Pelvic Floor Muscle Training Post-Prostatectomy: A Meta-Analysis of Randomized Controlled Trials

Key Words

Prostatectomy · Urinary incontinence · Pelvic floor muscle training · Biofeedback

Abstract

Objective: The aim of this meta-analysis was to evaluate the evidence of the effect of pelvic floor muscle training on urinary incontinence after radical prostatectomy. **Methods:** A bibliographic search was conducted in four databases. Studies were grouped according to the intervention program (muscle training versus control and individual home-based versus physiotherapist-guided muscle training). **Results:** Eight studies were selected for meta-analysis after satisfying the selection criteria. The data show that pelvic floor muscle training improves continence rate in the short (RR = 2.16; $p < 0.001$), medium (RR = 1.45; $p = 0.001$) and long term (RR = 1.23; $p = 0.019$) after surgery. The number of randomized controlled trials and the heterogeneity in the study population and type of pelvic floor muscle training were the main limitations. **Conclusion:** Programs including at least three sets of 10 repetitions of muscle training daily appear to improve continence rate after radical prostatectomy. Our

meta-analysis shows that muscle training programs for urinary incontinence provide similar results to those of physiotherapist-guided programs, therefore being more cost-effective.

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Introduction

Prostate cancer is the fourth most common cancer [1]. Radical prostatectomy is the treatment of choice for men with localized prostate cancer who have evidence of high or intermediate risk of disease progression [2]. Improvements in anatomical knowledge and surgical techniques have considerably reduced morbidity after radical prostatectomy [3]. Nevertheless, many patients suffer from moderate to severe urinary incontinence (UI) after surgery [4]. UI is defined by the International Continence Society as any involuntary loss of urine [5]. This loss of bladder control becomes a physical, emotional, psychosocial and economic problem [6, 7]. The etiology of UI after radical prostatectomy is not entirely known, although studies indicate that it could be a result of direct

damage to the external urethral sphincter [8] and/or bladder abnormalities, especially detrusor overactivity with decreased bladder compliance [9].

Most radical prostatectomy patients experience some incontinence immediately after catheter removal [10]. In some men, continence can be achieved as early as a few weeks after surgery, but for others it may take 12 months to recover [10]. A prevalence of 4–76% at 1 year has been reported [4, 11]. Since most patients regain urinary control in the year following surgery, invasive treatments are not indicated during this period [3]. Thus, conservative treatment is the first-choice treatment during this phase [12]. This includes pelvic floor muscle training (PFMT), with or without biofeedback, to help increase urethral closure pressure during exertion episodes. However, the value of the various approaches to conservative management of incontinence after radical prostatectomy remains uncertain [13]. Thus, the aim of this meta-analysis was to evaluate the evidence on the effect of PFMT on UI after radical prostatectomy.

Methods

The review was performed according to the PRISMA statement [14].

Data Sources and Searches

A literature search was performed on databases from CENTRAL, ClinicalTrials.gov, EMBASE, PubMed (MEDLINE), Web of Knowledge, and Physiotherapy Evidence Database (PEDro) in order to identify scientific articles published up to August 2014. The search was limited to articles published in Spanish, English and French. The references of relevant articles were reviewed to identify those articles that met the selection criteria but had not been identified during the primary search. The key words entered in the search were: ('prostate' OR 'prostatic hyperplasia' OR 'prostatic neoplasm' OR 'postprostatectomy') AND 'urinary incontinence' AND ('conservative' OR 'biofeedback' OR 'exercise' OR 'rehabilitation' OR 'behavioral').

Study Selection

The inclusion criteria were: (i) patients diagnosed with prostate cancer subjected to radical prostatectomy; (ii) patients without UI prior to surgery, who experienced urine loss after the same; (iii) type of study: randomized controlled trials (RCTs); (iv) type of intervention: aftercare programs of PFMT, excluding studies that included pharmacological, surgical or orthopedic treatment in some of their groups; (v) outcome measure: continence rate; (vi) methodological assessment of the study according to PEDro scale above 4 [15, 16].

Data Extraction and Quality Assessment

The search for, selection and evaluation of the articles and data extraction were performed independently by two reviewers (R.A.F. and M.T.M.C.). Any possible discrepancies were resolved by con-

sensus. In the case of failure to reach consensus the final decision was made by a third reviewer (A.F.M.). The information obtained from the reviewed literature was compiled by the first two reviewers. These two reviewers independently extracted the following data from each selected article: (i) characteristics of the study subjects (sample size, age); (ii) treatment planning (duration and frequency); (iii) treatment characteristics (type and parameters); (iv) evaluation results (type of test, time of evaluation and continence rate).

The methodological quality of the selected studies was independently assessed by the two reviewers using the PEDro scale, whose reliability for quality assessment of randomized clinical trials has been demonstrated [17]. This scale includes 11 items, and each satisfied item (except for the first item) contributes 1 point to the total PEDro score (range 0–10 points). The first item relates to external validity and is omitted for the final score [17]. Studies with low quality assessment (from 0 to 4 points) [15, 16] were excluded from the review, because their lack of internal validity could have caused bias in the meta-analysis.

Data Synthesis and Analysis

Relative risk (RR) reductions and their 95% confidence intervals (CIs) were calculated. The DerSimonian-Laird random-effects model was used if there was evidence of heterogeneity between the studies, based on the χ^2 test for heterogeneity and the I^2 test. Otherwise the fixed-effects model (Mantel-Haenszel) was selected to summarize the pooled RR.

Heterogeneity Assessment

In order to quantify heterogeneity between the different studies, the Cochran Q statistic and I^2 statistic were used, with values of 25, 50 and 75% corresponding to low, moderate and high degrees of heterogeneity, respectively [18].

Sensitivity Analysis

A sensitivity analysis was conducted in order to check the reliability and robustness of the overall result. For this, the meta-analysis was replicated eliminating one of the included studies at each step, thus analyzing its influence on the overall result.

Publication Bias

The presence of publication bias was estimated using a funnel plot and Egger's test [19].

Results

Study Selection

Searching using the key words initially identified 671 studies. Duplicates, articles that did not meet the selection criteria and those with low methodological quality were excluded. Eight articles were eventually included in the review, two of them identified by manual search (fig. 1).

Characteristics of Studies and Treatments

The characteristics of the eight studies are detailed in table 1. They were grouped into two categories: PFMT

Table 1. Characteristics of the studies included in the meta-analysis

Study	EG	CG	Intervention characteristics	Control	PEDro
<i>PFMT versus control</i>					
Filocamo et al. [20]	150	150	PFMT home; 6 months; 3 sets daily; 10 contractions/set	none	5
Manassero et al. [21]	54	40	PFMT home; 12 months; 3–6 sets daily; 15 contractions/set	none	6
Goode et al. [22]	70	68	PFMT home; 2 months; 3 sets daily; 15 contractions/set	none	6
Van Kampen et al. [23]	50	52	PFMT home; 12 months; 90 contractions/day	none	7
<i>Physiotherapist-guided versus home-based PFMT</i>					
Moore et al. [24]	106	99	PFMT home + 1 session weekly; 6 months; 30 min/session; biofeedback	PFMT home	6
Overgard et al. [25]	42	43	PFMT home + 1 session weekly; 12 months; 45 min/session; intensive PFMT	PFMT home	5
Dubbelman et al. [26]	35	44	PFMT home + 9 sessions; 3 months; 30 min/session; muscle strength and proprioception	PFMT home	5
Glazener et al. [4]	205	206	PFMT home + 4 sessions; 3 months; biofeedback and intensive PFMT	PFMT home	7

EG = Exercise group; CG = control group.

Fig. 1. Flowchart of study selection.

Table 2. Values of pre- and post-test (percentage) for continence rate in the programs

Study	Continence rate												RR		
	EG						CG								
	1st trimester		2nd trimester		4th trimester		1st trimester		2nd trimester		4th trimester		1st	2nd	4th
	n	%	n	%	n	%	n	%	n	%	n	%			
<i>PFMT versus control</i>															
Filocamo et al. [20]	111	74.0	144	96.0	148	98.7	45	30.0	97	64.6	130	88.0	2.47*	1.48*	1.14
Manassero et al. [21]	25	46.3	36	66.7	45	83.4	9	22.5	16	40.0	19	47.5	2.06*	1.67*	1.75*
Goode et al. [22]	11	15.7	–	–	–	–	4	5.9	–	–	–	–	2.67	–	–
Van Kampen et al. [23]	45	88.0	48	95.0	48	95.0	29	56.0	40	77.0	43	81.0	1.61*	1.25*	1.16*
<i>Physiotherapist-guided versus home-based PFMT</i>															
Moore et al. [24]	30	32.0	41	47.0	53	60.0	23	28.0	37	50.0	47	64.0	1.22	1.03	1.05
Overgard et al. [25]	16	46.0	27	79.0	33	92.0	17	43.0	22	58.0	28	72.0	0.96	1.26	1.21*
Dubbelman et al. [26]	–	–	10	30.0	–	–	–	–	9	27.0	–	–	–	1.40	–
Glazener et al. [4]	–	–	–	–	48	24.0	–	–	–	–	44	23.0	–	–	1.10

EG = Experimental group; CG = control group. *p < 0.05.

versus controls [20–23] and PFMT at home versus PFMT guided by a physiotherapist [4, 24–26]. Four studies [20–23] compared performing PFMT exercises with a control group. The program duration varied between 2 and 12 months, with daily performance of three to six series of 10–15 repetitions. Meanwhile, four studies [4, 24–26] evaluated the effectiveness of PFMT programs in patients who attended regular sessions with a physiotherapist versus a control group including patients who received no additional information beyond the verbal or written instructions that all subjects in the study received immediately after surgery (all subjects in the studies performed PFMT exercises at home regardless of the group to which they were assigned). There was high variability in terms of the duration of these programs (between 3 and 12 months) and the number of sessions (between 9 and 48).

Methodological Quality of the Articles

The eight articles included in this meta-analysis had a mean score on the PEDro scale of 5.88 ± 0.84 (table 1).

Participants

A total of 1,552 men with a mean age of 64.56 ± 2.29 years who had undergone radical prostatectomy (retro-pubic, perineal or laparoscopic) participated. The average sample size of the groups was 89.00 ± 60.59 subjects in the exercise group and 87.75 ± 60.79 subjects in the control group (table 1).

Outcome Measure

The outcome measure considered for the meta-analysis was continence rate, defined as the percentage of subjects reaching continence by a certain time. Urinary continence was evaluated in the analyzed studies in one of four ways: the pad test (within 24 h [20, 21, 23] and 1 h [22]), the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) [9], the weekly bladder diary [22] and the number of compresses used [3, 10]. All have been validated for the assessment of UI [24, 25]. The studies evaluated the results in the short [3, 10, 20, 21, 23], medium [20, 21, 23–26] and long term [4, 20, 21, 23–25]. The mean follow-up time was 43.25 ± 16.90 weeks.

Summary of Results (Meta-Analysis)

In each treatment category the results of continence rates were separated into three quantitative analyses, one per trimester: short (≤ 12 weeks), medium (24 weeks) and long-term (≥ 48 weeks).

PFMT versus Control

The three short-term studies [20, 21, 23] observed significant improvements in the subjects' continence rates (74.0 vs. 30.0%, $p < 0.001$; 46.3 vs. 22.5%, $p = 0.03$; 88.0 vs. 56.0%, $p = 0.001$). Meanwhile, the remaining study [22] found no difference. Overall, the results of the meta-analysis showed the benefits of PFMT on subjects' incontinence (RR = 2.16; 95% CI 1.79–2.60; $p < 0.001$; $I^2 = 12\%$) (table 2, fig. 2).

Fig. 2. Effects of PFMT on continence rate. EG = Experimental group; CG = control group.

The three medium-term trials [20, 21, 23] collected data on continence rate, but only two [20, 21] showed significant improvements (96.0 vs. 64.6%, $p < 0.001$; 66.7 vs. 40.0%, $p = 0.01$). The meta-analysis also showed a significant change after 6 months of treatment (RR = 1.45; 95% CI 1.31–1.60; $p < 0.001$; $I^2 = 49\%$) (table 2, fig. 2).

Finally, these same three RCTs evaluated the outcome at 12 months. Only one RCT [21] identified statistically significant differences (83.4 vs. 47.5%, $p < 0.01$), while the remaining studies [20, 23] observed similar continence rates. The meta-analysis (random-effects model) also showed statistically significant differences between groups (RR = 1.23; 95% CI 1.04–1.47; $p = 0.019$; $I^2 = 76\%$) (table 2, fig. 2).

Physiotherapist-Guided versus Home-Based PFMT

The results of the meta-analysis for the short, medium and long term showed no significant improvements in continence rate in either group (table 2, fig. 3).

Sensitivity Analysis

After performing the sensitivity analysis for each of the established groups and the different analyses, the results remained statistically significant in terms of continence rate of the participating subjects.

Publication Bias

PFMT versus control: No publication bias was observed in the first ($p = 0.46$), second ($p = 0.34$) and fourth trimester ($p = 0.28$). Physiotherapist-guided versus home-based PFMT: After examining publication bias in the second and fourth trimester, the results showed no significant difference ($p = 0.27$ and $p = 0.19$, respectively).

Discussion

This meta-analysis aimed to assess the improvement in urinary continence rate by strengthening the pelvic floor muscles after radical prostatectomy. The results show the effect of PFMT programs on recovery from UI after radical prostatectomy in men in terms of continence rate. The results also support the use of strengthening programs performed by the patient at home after brief guidance. Thus, PFMT is able to reduce continence acquisition time in prostatectomy patients as well as to increase the number of patients cured [20, 21, 23], which can help overcome the physical, psychosocial and emotional problems derived from loss of bladder control in the months following surgery. In the following, the discussion will be presented separately for the two types of

Fig. 3. Effects of home-based PFMT (EG2) versus PFMT guided by physiotherapist (EG1) on continence rate.

intervention: (i) muscle training versus control group and (ii) physiotherapist-guided versus home-based PFMT.

PFMT versus Control

The effectiveness of PFMT in men receiving radical prostatectomy has been a controversial issue [27]. This meta-analysis shows an improvement in continence rate after a PFMT program compared to the control group (RR = 2.16 in the short term, RR = 1.45 in the medium term and RR = 1.23 in the long term) (fig. 2). However, the heterogeneity of the studies (in the short and medium term) makes it necessary to interpret these results with caution. The working methodology was very similar in the four studies included in the meta-analysis [20–23]. Although part of the success of these programs could be attributed to the frequency of performing strengthening exercises [20], there is no scientific evidence on the exact number of repetitions that should be performed to improve muscle mass, strength and endurance [28]. Data from this meta-analysis suggest that three series including 10 repetitions performed daily might be sufficient to improve continence rate.

Only one study [22] failed to obtain statistically significant short-term reductions in incontinence rate. However, it did obtain a clinically relevant improvement according to the ICIQ-UI SF questionnaire. These discrepancies in results may be due primarily to the fact that

PFMT was started an average of 4–5 years after prostate surgery (unlike in the other three studies [20, 21, 23] where treatment began between 7 and 10 days after the withdrawal of the urethral catheter); this might suggest that programs should start as soon as possible after surgery. Our meta-analysis showed that PFMT increases the number of continent patients at the end of the first year after surgery. The differences in the results obtained by the studies [20, 21, 23] may be explained by the duration of the strengthening programs (6, 12 and 12 months, respectively). The results of the first study [20] are similar to those reported by other authors [23], who concluded that the difference between the study groups progressively decreased after 1 year. Furthermore, our data show that PFMT is not only effective in reducing continence acquisition time after prostatectomy, but also in improving resistance to incontinence in a larger number of patients.

Physiotherapist-Guided versus Home-Based PFMT

There is no evidence of the benefit of adding sessions guided by a physiotherapist to the daily exercises performed by the patients at home [29]. Only one study noted a subjective improvement in the self-reported severity of UI and in the quality of life levels [30]. This meta-analysis found no change in continence rate between subjects who performed PFMT individually at home and those who also received regular sessions guided by a physio-

therapist (fig. 3). The working methodology varied among the four studies analyzed [4, 24–26], but they all involved a daily exercise routine. Despite the variability in the number and frequency of clinic visits performed in the RCTs, there is little evidence that more visits result in a higher continence rate [13].

It should be emphasized that in one study [10] significant differences in continence rate were observed at 12 months, contradicting other authors who have reported an improved tendency in continence rate after 1 year [8]. This discrepancy may be attributed to differences in adherence to the exercise program (91.4 vs. 55.0% and 64.7 vs. 41.7% in the exercise and control group, respectively). Therefore, the results of this meta-analysis indicate that PFMT programs guided by a physiotherapist have no greater effectiveness than PFMT programs performed by subjects at home, as long as they are supported by verbal and written instructions provided by the healthcare professional. The latter approach has a higher cost-effectiveness advantage, contributing to saving financial and human resources in the healthcare system [4, 24].

The present meta-analysis had some limitations. First, the number of RCTs included was small, although their homogeneity was optimized by the stringency of the inclusion criteria. Second, the large variations in the type of PFMT (duration, intensity, etc.) performed in the interventions could have influenced UI rates. Finally, the study population was heterogeneous.

PFMT appears to be effective for improving continence after prostatectomy, especially when started as soon as possible after surgery. Specifically, three sets daily of 10 repetitions seem to be beneficial in this regard. Meanwhile, PFMT performed at home produces similar results to PFMT with sessions guided by a physiotherapist, with the associated cost benefits. According to the Oxford Centre for Evidence-Based Medicine [31], we believed that our results could be considered to be at a '1a' level of evidence and at an 'A' grade level of recommendation. However, additional trials are needed to confirm the utility of PFMT combined with other conservative treatment options (e.g. electrical stimulation).

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