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Effectiveness of Early Pelvic Floor Rehabilitation Treatment for Post-Prostatectomy Incontinence

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Abstract

Purpose: Urinary incontinence after radical prostatectomy is a significant clinical problem. In this prospective study we investigate the effectiveness of early pelvic floor muscle training (PFMT) on a large population, that had undergone radical retropubic prostatectomy (RRP) at our department.

Methods: 300 consecutive patients who had undergone RRP for clinically confined prostate cancer were randomized in two groups after catheter removal. One group of 150 patients took part in a structured PFMT program. This began before discharge and consisted of Kegel exercises. The remaining 150 patients constituted the control group, they were not formally instructed in PFMT.

Incontinence was assessed objectively using the 1 hour and 24 hour pad test, as well as with the ICS-Male questionnaire. All patients who were incontinent after 6 months underwent urodynamic evaluation.

Results: In the treated group, 19% (29 patients) achieved continence after 1 month, and 94.6% (146 patients) after 6 months. In the control group 8% (12 patients) achieved continence after 1 month, and 65% (97 patients) after 6 months ($p < 0.001$). Patient age did not correlate with continence in the control group ($p > 0.05$), although a significant correlation was revealed within the treated group ($p < 0.01$). Overall, 93.3% of the total population achieved continence after one year.

Conclusions: After RRP an early supportive rehabilitation program like PFMT significantly reduces continence recovery time.

Keywords: Urinary incontinence; Radical prostatectomy; Pelvic floor training; Physiotherapy

1. Introduction

Radical prostatectomy is a major procedure and the most effective treatment for curing early stage prostate cancer [1]. The surgical approach of completely excising the prostate, as defined by Walsh et al., provides optimal cancer control while maintaining continence and sexual potency. Nonetheless many patients suffer from moderate to severe urinary incontinence during the first post-operative weeks, and for some patients incontinence persists for several months and even years [2–4]. Radical prostatectomy is the most important cause of iatrogenic incontinence in men. Incontinence compromises the quality of life to a degree directly proportional to its duration [5,6].

The cause of post-prostatectomy incontinence (PPI) might be due to intrinsic sphincter deficiency (ISD) and/or detrusor overactivity (DO) and/or decreased bladder compliance [7,8]. The incidence of incontinence after radical prostatectomy, reported in the literature ranges from 6% to 87% [5,6].

Physiotherapy, in particular pelvic floor muscle training (PFMT), is the most commonly recommended conservative treatment for PPI [9]. PFMT may improve

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the capacity to increase urethral closure during stress episodes. The International Consultation on Incontinence (ICI) in 2001, assessed PFMT as beneficial in PPI treatment, although randomized controlled trials in large samples are necessary to identify its real value and to assess the correct time to initiate rehabilitation. Few authors consider early rehabilitation plans for recovering continence after radical prostatectomy [6,9–11]. A recent review demonstrates that PFMT is better than no treatment, because it can reduce the frequency of incontinence episodes by 54–72% [12]. There isn't a definition of PFMT on PPI treatment, moreover any benefits from such conservative management have not been sufficiently studied. Only few articles note the natural recovery of continence [6,9].

The aim of this prospective study is to evaluate the benefits of PFMT on a large population that underwent standard radical retropubic prostatectomy (RRP) at our department.

2. Materials and methods

From January 2000 to January 2004 we enrolled 300 consecutive patients who had undergone standard RRP for clinical stage T1 or T2 prostate cancer.

Exclusion criteria included prior bladder or prostate surgery, prior urinary or faecal incontinence, neurogenic dysfunction of the lower urinary tract, and a preoperative history of overactive bladder.

The enrolled patients were randomized in two homogeneous groups: a treatment group A and control group B (Table 1). The 150 group A patients (mean age 65.0 years; median 65 ± 4.79; range 51–75) took part in an early pelvic floor rehabilitation program that began when the catheter was removed. This program included Kegel exercises only, no rectal electrical stimulation or biofeedback were performed [13]. The other 150 patients of group B (mean age of 66.8 years; median 68 ± 5.33; range 45–75) had no formal training in PFMT after catheter removal. All patients signed an informed consent form explaining the nature of the study, which had been previously approved by the Ethics Committee of our Institution.

In their first treatment session group A patients, learned how to exercise a dominant pelvic muscle contraction while in supine position without contracting antagonist abdominal, gluteal or adductor muscles. In this phase we taught the patients by various methods, including verbal explanations, palpation, and visualization of the contraction at the base of the penis with a mirror. We evaluated the contraction by digital anal control. A score of 0–5 was given. At home for ten days the patients performed daily 3 sets of exercises: they alternated 10 contractions lasting 5 seconds with 10 seconds of muscular relaxation. In the second treatment session we taught PFMT in all positions: sitting, standing, squatting, and going up and down stairs. Then we invited the patients to identify all movements that could cause incontinence, and asked them to perform the new series of exercises at home for seven days. At the third treatment session we invited the patients to practice PFM contraction only before any effort or activity that might induce incontinence (sneezing, coughing, or lifting a weight). All patients were asked to compute a bladder diary to record any urine leakage, and were counselled to prevent this by increasing the frequency of micturition. This program of easy exercises was followed by patients at home for 6 months or longer, if required.

Follow-up included controls at 1, 3, 6, and 12 months with objective and subjective evaluation of incontinence. Incontinence was assessed objectively using the 1 hour and 24 hour pad test. Incontinence was measured by the number of pads used daily (1 precautionary pad signified continence). Subjective evaluation was made by the incontinence section of the International Continence Society (ICS)-male questionnaire [14,15]. All patients who were incontinent after 6 months underwent urodynamic evaluation according to ICS standards [16].

The two-tailed *t* test was used to compare preoperative PSA, the nerve sparing procedure, and time to catheter removal between the treated and control groups. Fisher's exact test was employed to verify differences in the proportion of patients in the two groups who were continent at 1, 3, 6, and 12 months. Furthermore, univariate correlation between patient age, nerve sparing procedure and continence was tested with Pearson's product moment coefficient. Moreover a multivariate analysis of the risk factors for incontinence including age and nerve sparing procedure was conducted using the Cox proportional hazards regression analysis.

3. Results

The two patient groups were homogeneous with respect to preoperative PSA level, numbers of nerve sparing versus non-nerve sparing operations, and catheterization periods (Table 1).

After 1 month continence was achieved by 29 patients (19.3%) of group A as opposed to 12 (8%) patients of group B ($p = 0.006$). After 3 months the numbers were 111 (74%) patients of group A and 45 (30%) of group B ($p < 0.00001$), whereas after 6 months the numbers were 144 (96%) and 97 (64.6%) respectively ($p < 0.00001$) (Fig. 1, Table 2).

Table 1
Patient characteristics

	Group A (150 pts)	Group B (150 pts)	
Mean pre-operative PSA level (ng/ml)	8.13 (range 4.7–12.9)	8.11 (range 3.5–11.9)	$p = 0.68$
Nerve-sparing surgery (uni or bilateral)	95 pts	88 pts	$p = 0.40$
Catheter removal (days)	8.3 (range 7–16)	8.4 (range 7–15)	$p = 0.64$

Two-tailed *t* test to compare PSA level, nerve sparing surgery, and catheter removal between group A and B.

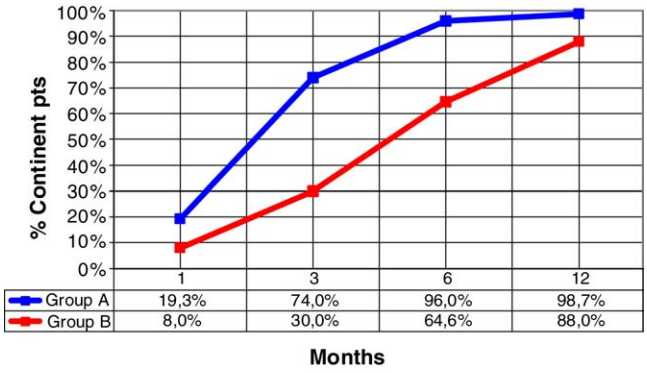

Fig. 1. Percentage of patients achieving continence of group A and B at 1, 3, 6, and 12 months after RRP.

Table 2
ICS-Male questionnaire about incontinence

Group	1 Month		3 Months		6 Months		12 Months	
	A	B	A	B	A	B	A	B
Completely dry	5	3	35	21	115	48	134	101
Occasional leakage	24	9	76	24	29	49	14	29
2 Pads	38	53	31	42	3	43	0	10
3 Pads or more	83	85	8	63	3	10	2	8
Total	150	150	150	150	150	150	150	148

In group A, patient age correlated significantly with continence 3 to 6 months after surgery, whereas there was no correlation at any time in group B (Fig. 2). Nerve sparing procedure was associated with a better continence outcome than non-nerve sparing (Pearson's product moment coefficient $p = 0.0002$). Multivariate analysis demonstrated that the interaction of nerve sparing surgery with lower patient age had a positive effect on continence at any time during the follow-up for both groups ($p = 0.001$). All but 2 patients of group B, who dropped out during controls, were followed for at least 12 months.

Six patients (4%) of group A presented incontinence after 6 months and underwent urodynamic evaluation. 2 of these had ISD and DO (mixed incontinence), 2 others presented DO only (urge incontinence). Additionally 53 patients (35.3%) in group B underwent urodynamic evaluation for incontinence. 7 of them showed ISD and DO, and 3 others DO only. All patients with DO responded to antimuscarinic therapy.

After 1 year 2 (1.3%) of the 150 in group A patients and 18 (12.1%) of the 148 group B patients were incontinent. Overall 93.3% of the total study population achieved continence after one year. Two (1.3%) and 3 (2%) patients of group A and B respectively with severe stress urinary incontinence underwent implantation of an artificial urinary sphincter an average of 17 months (range 15–19) after surgery. In 6 (4%) and 4 (2.7%) patients of the treated and control group respectively we observed the development of symptomatic post-operative anastomotic stricture that required endoscopic treatment.

4. Discussion

Urinary incontinence after RRP determines a significant by reduced global quality of life score [17]. Most urodynamic studies have shown that PPI is associated with ISD, and bladder dysfunction is rarely the only cause of this incontinence [18].

Bladder neck preservation during radical prostatectomy has been advocated for improving urinary continence, but there are many controversial issues on this approach [19,20].

Treatment modalities include behavioural, pharmacological and surgical therapy. Pelvic floor exercises represent an attractive option. Pelvic floor training is defined as repetitive selective voluntary contraction and relaxation of specific pelvic floor muscles [21]. Data from a Cochrane review demonstrate that PFMT is better than no treatment in regard to the duration of incontinence, PFMT reduces the frequency of incontinence episodes by 54–72% [12]. Rehabilitation aims

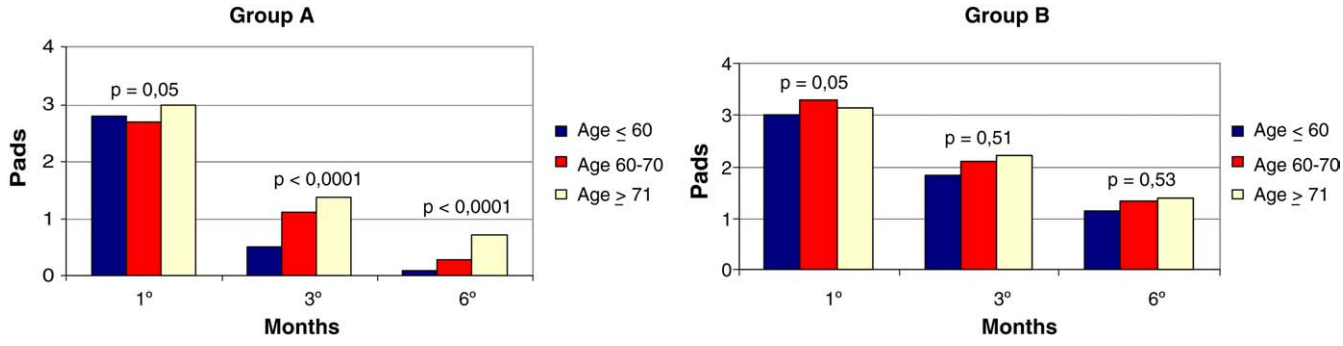

Fig. 2. Correlation between age and continence in group A and B at 1, 3, and 6 months.

to increase pelvic muscle strength and to improve voluntary control of the pelvic floor, allowed to support the primary urethral closure mechanism. Re-education programs favour isometric exercises to develop muscle tone. When the muscles work efficiently, the successive step is to create an automatic pelvic floor contraction to guard stress events. Eventually patients will not loose urine under stress, because skeletal muscles increase the closing pressure of the urethra, a relaxed patient will be incontinent if this reflex contraction is insufficient [6]. Fatigue of this striated muscle is the cause of increased loss of urine during the second half of the day. Efficacy of PFMT is dependent on the intensity of the training program, this is based on frequent exercising, and also interaction with a healthcare professional. There seems to be no additional benefit in combining PFMT with biofeedback or rectal electrical stimulation [22]. PFMT has the advantage of being, in any case, not harmful, nor does it compromise future treatment options. In our prospective study PFMT instruction initiated when the catheter was removed resulted in an earlier return to urinary continence. This benefit was significant after 3 months when 74% of the treated group regained continence while only 30% of the control group did ($p < 0.00001$). Differences between the two groups in incontinence remained high for the first 6 months, and then it decreased. In fact, at 12 months there was no statistically significant difference between the two groups. Rehabilitation seems to be most effective in the first four months after surgery, therefore therapy should start as soon as possible after the operation. Van Kampen et al. reported that the percentage of patients remaining incontinent was high in the first four months, and decreased to 14.4% at 1 year [6]. The International Consultation on Incontinence in 2001 evaluated the economic impact of urinary incontinence on society. The economic effects of incontinence include both direct (treatment and healthcare) and indirect costs, such as the loss of productivity because of morbidity or disability. Incontinence is more prevalent in the elderly, but it can also affect younger people. While most studies on the economics of incontinence focus on women, a recent American study demonstrated relatively little work loss associated with urinary incontinence in men. However, but the overall economic burden for male incontinence was estimated to be $ 29.4 billion in direct medical costs. Annual expenditures per person in men with urinary incontinence was more than double that in men without incontinence ($ 3,204 as opposed to $ 7,702) due to the cost of pads, condom drainage catheters and external devices, therefore treatment that reduces the duration and degree of urinary incontinence will also reduce economic impact on society [23].

Prior studies have shown that patient age and improved surgical technique are important risk decreasing factors for PPI. However, our data show that age was not a risk decreasing factor in the control group, but it was in the treated group, both at 3 and 6 months postoperatively ($p < 0.0001$) [24]. This may be because in the control group younger patients who did not receive formal instruction behaved like the elderly patients. Instead in the treated group, the younger men learned the exercises more easily than the elderly patients. We did not find any benefit of PFMT in severe incontinence, but surgical treatment for incontinence is generally not considered earlier than 12 months after operation. Two patients underwent implantation of an artificial urinary sphincter after 15 and 16 months.

Our data are in accord with previous reports that have shown that urodynamic investigations found DO and/or decreased compliance are rarely an isolated cause of PPI [18,25].

5. Conclusion

The majority of patients recover urinary control 1 year after surgery (93.3%) but this result can be achieved sooner with conscientious physical therapy. In the early post-operative period a supportive and educative approach is recommended to reduce the duration and the degree of urinary incontinence. We obtained consistent improvement or a complete cure (1 or 0 pad per day) after 6 and 12 months in 96% and 98.7% of cases of group A versus 64.6% and 88% in group B. We believe that early pelvic floor physiotherapy should be considered a good and safe method for treating incontinence after radical prostatectomy and so to improve quality of life. PFMT should be activated for all PPI patients, reserving urodynamic evaluation and invasive treatment only in those cases where it fails, such a posture conforms to ICI recommendations.

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