Early Recovery of Urinary Continence After Radical Prostatectomy Using Early Pelvic Floor Electrical Stimulation and Biofeedback Associated Treatment

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Abbreviations and Acronyms

BF = biofeedback

FES = pelvic floor electrical stimulation

ICS = International Continence Society

PME = pelvic floor muscle exercise

PPI = post-prostatectomy incontinence

RP = radical prostatectomy

UI = urinary incontinence

Submitted for publication August 12, 2008.

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Purpose: We analyzed the benefit of the early combined use of functional pelvic floor electrical stimulation and biofeedback in terms of time to recovery and rate of continence after radical prostatectomy.

Materials and Methods: A total of 60 consecutive patients who underwent radical prostatectomy were included in the study. Patients were prospectively randomized to a treatment group (group 1) vs a control group (group 2). In group 1 a program of pelvic floor electrical stimulation plus biofeedback began 7 days after catheter removal, twice a week for 6 weeks. Each of the 12 treatment sessions was composed of biofeedback (15 minutes) followed by pelvic floor electrical stimulation (20 minutes). The evaluation of continence was performed at time 0, at 2 and 4 weeks, and at 2, 3, 4, 5 and 6 months during followup. Evaluations were performed using the 24-hour pad test and the incontinence section of the International Continence Society questionnaire.

Results: The mean leakage weight became significantly lower ($p < 0.05$) in group 1 than in group 2 starting at 4 weeks until 6 months of followup. A significant difference ($p < 0.05$) between groups 1 and 2 in terms of percentage of continent patients was achieved from 4 weeks (63.3% group 1 and 30.0% group 2) to 6 months (96.7% group 1 and 66.7% group 2).

Conclusions: Early, noninvasive physical treatment with biofeedback and pelvic floor electrical stimulation has a significant positive impact on the early recovery of urinary continence after radical prostatectomy.

Key Words: urinary incontinence, prostatectomy, prostatic neoplasms, electric stimulation, biofeedback

THROUGH the improvement of anatomical knowledge and advancements of surgical technique in recent years, morbidity after radical prostatectomy for prostate cancer has consistently decreased. Nonetheless, RP remains one of the most important causes of iatrogenic incontinence in men. Reported prevalence rates of urinary incontinence after RP vary from 5% to more than 60% depending on the definition of UI in terms of timing as well as method of evaluation.[1,2] Postoperative UI has a significant impact on quality of life and the time of continence after the removal of the urethral catheter is one of the most frequently asked questions by the patient.[3] Peyromaure et al emphasized that early UI affects 30% to 50% of patients from 3 weeks to 6 months after RP.[4] The main causes of post-prostatectomy incontinence might be sphincteric insufficiency and/or bladder abnormalities.[5]

0022-5347/09/1814-1788/0
THE JOURNAL OF UROLOGY®

Vol. 181, 1788-1793, April 2009
Printed in U.S.A.
DOI:10.1016/j.juro.2008.11.104

Various noninvasive treatments for PPI have been analyzed in the literature.[6–10] Functional pelvic floor electrical stimulation has been reported as a possible conservative treatment for UI after RP.[2,7] FES can artificially stimulate the pudendal nerve and its branches to cause direct and reflex responses of the urethral and periurethral striated muscles.[7] An alternative noninvasive treatment is behavioral training using pelvic floor muscle exercises to increase the strength of the pelvic floor.[10] In the first phase for the correct contraction of these muscles the patient can learn the exercises using behavioral methods following verbal instructions or using biofeedback.[10]

There are several randomized studies on the role of these noninvasive methods in managing PPI.[6,10] However, as stated in the Cochrane 2007 review results remain uncertain.[2] In this prospective randomized study we analyzed the benefit of the early combined use of FES and BF as learning tools for PME in terms of time to recovery and rate of continence after RP.

MATERIALS AND METHODS

Population

Between June 2005 and June 2007 a total of 60 consecutive patients who underwent standard RP at our institution (1 surgeon, AS) for clinically localized prostate cancer were included in this study. Patient characteristics are described in table 1. Exclusion criteria were prior bladder or prostate surgery, prior urinary or fecal incontinence, neurogenic dysfunction, preoperative history of overactive bladder, psychiatric history or significant perioperative complications. None of these patients received radiotherapy after RP. No patient was prescribed anticholinergic drugs (or other drugs able to influence urinary continence) during the study. In all patients the catheter was removed 10 days after RP.

Treatment

Patients were enrolled in a prospective, randomized fashion into a treatment (group 1) or a control group (group 2). All patients signed an informed consent before randomization. The control group (group 2) was not given FES, BF or formal education of PME after catheter removal. They received the usual instruction to conduct PME, which included verbal instruction (how to correctly and selectively contract the anal sphincter while relaxing the abdominal muscles) by the urologist, and written examples of exercises (Kegel exercises) at the catheter removal visit and during followup visits.

Patients in group 1 were included in an early BF + FES program that began 7 days after catheter removal. This program was performed in all cases by the same clinician (GM). Patients in group 1 met the clinician twice a week for 6 weeks. Each of the 12 treatment sessions was homogeneously composed of a first part with BF (15 minutes) followed by a second part with FES (20 minutes). Thus, each session lasted 35 minutes. Patients were placed in a supine decubitus position. For FES a surface electrode (InCare™) was inserted into the anus and pulsed at 30 Hz (first 10 minutes) and 50 Hz (second 10 minutes) square

Table 1. *Patient characteristics at time 0*

	Group 1	Group 2	p Value (2-tailed t test)
No. pts	30	30	—
Pt age:			>0.05
Mean ± SD	61.86 ± 3.26	61.43 ± 3.60	
Median (range)	63 (56–67)	62.50	
Preop prostate specific antigen (ng/ml):			>0.05
Mean ± SD	8.05 ± 1.49	8.57 ± 1.93	
Median (range)	7.85 (5.40–12.0)	8.50 (4.0–12.30)	
No. pathological stage (%):			>0.05
pT2pN0	24 (80.0)	25 (83.30)	
pT3pN0	6 (20.0)	5 (16.70)	
No. pathological Gleason score (%):			>0.05
7 (3 + 4) or Less	20 (66.7)	22 (73.3)	
7 (4 + 3) or Greater	10 (33.3)	8 (26.7)	
No. nerve sparing procedure (%):			>0.05
Yes (unilat or bilat)	20 (66.7)	20 (66.7)	
No	10 (33.3)	10 (33.3)	
Postop prostate specific antigen (ng/ml):			>0.05
Mean ± SD	0.05 ± 0.04	0.04 ± 0.03	
Median (range)	0.04 (0.01–0.14)	0.04 (0.01–0.10)	
Catheter removal (days)	10	10	—
Leakage wt/24 hrs (gm):			>0.05
Mean ± SD	291.0 ± 311.98	290.0 ± 299.46	
Median (range)	217.50 (20.0–1,500.0)	215.0 (20.0–1,400.0)	
Prostate vol (cc):			>0.05
Mean ± SD	49.76 ± 6.70	48.13 ± 6.60	
Median (range)	50.0 (35–64)	46.0 (37–65)	

waves at a 300 μs pulse duration and a maximal output current of 24 mA. Stimulation up to the maximal tolerable level was given. The intensity was adequate to induce visual lifting of the levator ani and pubococcygeus muscle, considering the level of comfort of the patient.[7]

For biofeedback a 2-channel electromyographic BF apparatus (Reactive Biofeedback, BEAC, Stradella, Italy) was used, with 1 channel for perineal and the other for abdominal muscles, and the signal received through surface electrodes.[10] During the initial 2 to 3 sessions a strong emphasis was placed on the specificity of muscle contraction (contraction of pelvic muscles with minimum activity of abdominal muscles). During the following sessions, the exercises were designed to increase the power and endurance of the pelvic floor muscles. Verbal guidance of the contractions was also used to instruct the patient how to correctly continue the exercises at home. Initially the patients performed these exercises while supine but later also when sitting or standing, during normal daily activities.

Outcome Assessment

In groups 1 and 2 the evaluation of PPI was performed after randomization at time 0 (7 days after catheter removal), during followup at 2 and 4 weeks, and 2, 3, 4, 5 and 6 months after removing the catheter. UI was objectively assessed using the 24-hour pad test and the number of pads used (primary outcome). Objectively continence was defined as no pad use (pad weight gain during the test of 2 gm or less).[7,11] Subjective evaluation (secondary outcome) was made using the incontinence section of the ICS-male questionnaire.[6,12] Moreover, patients were asked to keep a voiding diary including the number of incontinence episodes, the number and volume of voids and the number of pads used. Because urodynamic studies are invasive they were avoided and used only in patients with UI after the 6-month followup (according to ICS standards).[1,13] At a 12-month interval the percentage of continent (no pad use) cases was also reported.

Statistical Analysis

The study was designed to have an 80% power to detect a difference in improvement rates for a 2-tailed test with 5% type I error. The 2-tailed t test was used to compare variables between the 2 groups. Fisher's exact test was used to verify differences in the proportion of patients in the 2 groups who were continent at various followup intervals. Univariate (Pearson's correlation coefficient) and multivariate (Cox proportional hazards regression) analysis of the risk factors for incontinence (age, prostate volume, stage, nerve sparing technique) were performed and p values less than 0.05 were considered statistically significant. SigmaStat® and SigmaPlot® 9.0 statistical software was used.

RESULTS

A total of 60 cases were included in the evaluation, and were randomly assigned to treatment (group 1) and control (group 2) groups. At time 0 no significant differences between the 2 groups were present (table 1). All patients were evaluable for the entire followup and all in group 1 completed the BF + FES program. No complications were found in any patients and, in particular, in group 1 no patients complained of discomfort or irritation from the probe.

At time 0 the mean leakage weight for 24 hours was 291.0 ± 311.98 gm (median 217.50, range 20.0 to 1,500.0) in group 1 and 290.0 ± 299.46 gm (median 215.0, range 20.0 to 1,400.0) in group 2 ($p = 0.9234$) (table 1). Mean leakage weight became significantly lower ($p < 0.05$) in group 1 than in group 2 starting from visit 2 through visit 7 (fig. 1 and table 2). A significant difference ($p < 0.05$) between groups 1 and 2 in terms of the percentage of continent patients was achieved from visit 2 to visit 7 (fig. 2, and tables 3 and 4). Mean time to regain continence was 8.0 ± 6.49 weeks (median 4, range 2 to 20) in group 1 and 13.88 ± 8.32 weeks (median 16, range 2 to 24) in group 2 ($p = 0.003$). In both groups patient age, prostate volume and nerve sparing procedure were significantly associated with rate and time of continence achievement (Pearson's coefficients $p < 0.001$, $p < 0.001$ and $p < 0.0005$, respectively). On multivar-

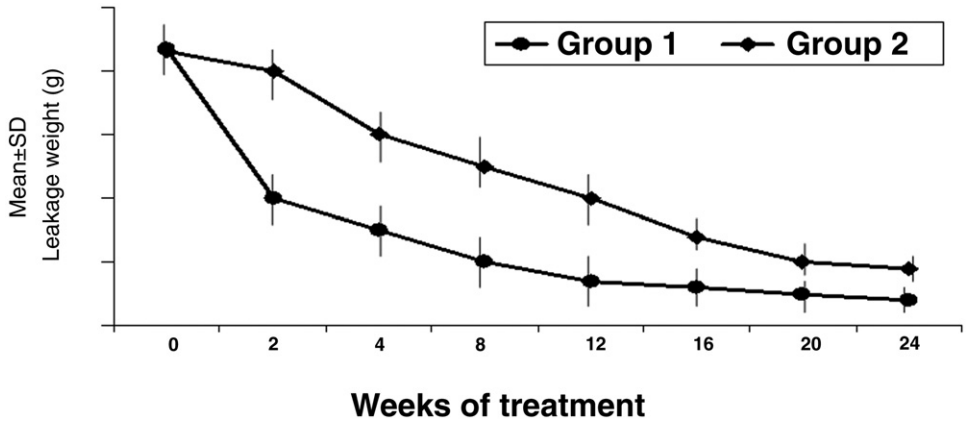

Figure 1. Leakage weight (24-hour) in 2 groups at various followup intervals

Table 2. *Mean leakage weight*

	Group 1	Group 2	p Value
Time 0:			
Mean ± SD	291.0 ± 311.98	290.0 ± 299.46	0.9234
Median (range)	217.50 (20.0–1,500.0)	215.0 (20.0–1,400.0)	
Visit 1 (2 wks):			
Mean ± SD	163.0 ± 145.87	261.70 ± 286.57	0.1783
Median (range)	100.0 (0–450.0)	200.0 (10.0–1,300.0)	
Visit 2 (4 wks):			
Mean ± SD	42.50 ± 72.30	197.70 ± 196.53	0.0004
Median (range)	7.50 (0–300.0)	150.0 (0–800.0)	
Visit 3 (8 wks):			
Mean ± SD	34.0 ± 58.52	172.67 ± 180.40	0.0008
Median (range)	0 (0–240.0)	125.0 (0–760.0)	
Visit 4 (12 wks):			
Mean ± SD	16.67 ± 30.55	136.67 ± 152.62	0.0001
Median (range)	0 (0–120.0)	100.0 (0–700.0)	
Visit 5 (16 wks):			
Mean ± SD	26.30 ± 44.20	80.17 ± 99.07	0.0279
Median (range)	0 (0–150.0)	55.0 (0–500.0)	
Visit 6 (20 wks):			
Mean ± SD	4.17 ± 14.92	40.83 ± 73.53	0.0003
Median (range)	0 (0–80.0)	25.0 (0–400.0)	
Visit 7 (24 wks):			
Mean ± SD	3.47 ± 14.67	27.83 ± 55.98	0.0004
Median (range)	0 (0–80.0)	10.0 (0–300.0)	

iate analysis BF + FES treatment demonstrated a significant ($p < 0.0001$) and independent ability to positively influence the rate and time of continence achievement.

At the end of the followup (visit 7 at 6 months) 3.3% (1 patient) in group 1 and 33.3% (10 patients) in group 2 remained incontinent (1 or more pads, urine loss greater than 2 gm). Therefore, the objective continence rate 6 months after randomization was 96.7% in group 1 and 66.7% in group 2. All incontinent patients at visit 7 underwent urodynamic evaluation that showed sphincter deficiency in 0 of 1 in group 1 and in 8 of 10 in group 2, detrusor overactivity in 1 of 1 in group 1 and in 2 of 10 in group 2. All patients with detrusor overactivity responded to antimuscarinic therapy. After 1 year 96.6% (58 of 60 patients) of the total study population achieved continence with no difference between the 2 groups.

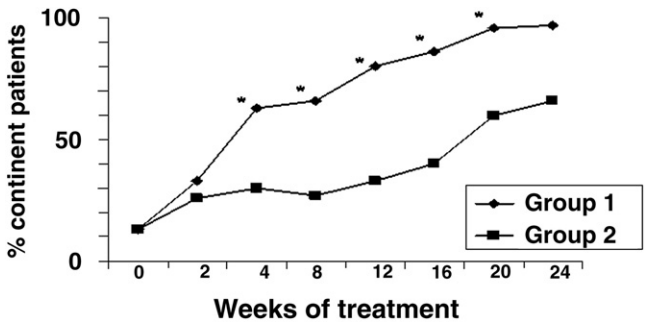

Figure 2. Percent of continent patients at various followup intervals. Asterisk indicates $p < 0.05$.

DISCUSSION

As shown by previous studies urinary incontinence after RP is mainly determined by a sphincteric deficiency caused by anatomical and functional changes during surgery.[5] Therefore, as a noninvasive treatment behavioral training using PME seems to be a logical approach.[2,6,8] Kegel first proposed PME to improve urinary control[14] and various recent studies have analyzed the role of PME in PPI.[6,8] Parekh et al studied 38 RP cases randomly assigned to PME before and after surgery vs control.[8] A greater fraction of the treatment group regained urinary continence earlier compared with the control group at 3 months ($p < 0.05$). Filocamo et al analyzed 300 patients treated with RP randomly assigned to early PME (at catheter removal) vs controls.[6] A significantly ($p < 0.001$)

Table 3. *Continence*

	No. Group 1 (%)	No. Group 2 (%)
Time 0	4 (13.3)	4 (13.3)
Visit 1 (2 wks)	10 (33.3)	8 (26.7)
Visit 2 (4 wks)	19 (63.3)	9 (30.0)
Visit 3 (8 wks)	20 (66.7)	8 (26.7)
Visit 4 (12 wks)	24 (80.0)	10 (33.3)
Visit 5 (16 wks)	26 (86.7)	12 (40.0)
Visit 6 (20 wks)	29 (96.7)	18 (60.0)
Visit 7 (24 wks)	29 (96.7)	20 (66.7)

Table 4. *ICS-male questionnaire about incontinence*

	No. Completely Dry	No. Occasional Leakage	No. 2 Pads	No. 3 Pads or More
Time 0:				
Group 1	0	4	11	15
Group 2	0	4	12	14
Visit 1 (2 wks):				
Group 1	3	7	7	13
Group 2	0	8	8	14
Visit 2 (4 wks):				
Group 1	14	5	9	2
Group 2	4	5	6	15
Visit 3 (8 wks):				
Group 1	16	4	8	2
Group 2	7	1	9	13
Visit 4 (12 wks):				
Group 1	19	5	6	0
Group 2	7	3	10	10
Visit 5 (16 wks):				
Group 1	17	9	4	0
Group 2	6	6	17	1
Visit 6 (20 wks):				
Group 1	24	5	1	0
Group 2	10	8	11	1
Visit 7 (24 wks):				
Group 1	27	2	1	0
Group 2	10	10	9	1

greater percentage of patients in the treated group vs controls achieved continence after 6 months (94.6% vs 65.0%) (after 1 month 19% vs 8%). The main result of these studies was that early use of PME has a significant effect on the early recovery of continence after RP. On the contrary Franke et al reported that PME did not affect the return of continence within 6 months after RP.[15] Floratos et al found similar (91%) objective continence rates at 6 months after RP using electromyographic BF or verbal instruction for PME.[10]

FES has been described as the conservative treatment of UI after surgery.[2,7,16] Moore et al compared the advantageous effect of the association of FES and PME to PME alone in terms of PPI.[7] They did not perform early PME and FES, starting treatments only after 8 or more weeks from RP. In 58 cases analysis was limited to 12 weeks from baseline and demonstrated no significant ($p > 0.05$) differences in overall urine loss between the 2 groups.

Our study first analyzed the advantageous effect of early combined use of BF and FES on the early recovery of urinary continence after RP. The significance of our study is based on the prospective randomized assignment of treatment vs control, on the homogeneous characteristics of the 2 groups and on the objective evaluation of outcome assessment. In particular all patients underwent standard RP performed by the same surgeon (AS) and in all patients the catheter was removed after 10 days. Patients were considered continent when no pads were required and the weight gain of the pad during the test was 2 gm or less. A more objective evaluation of UI would be urodynamic evaluation. However, these investigations are invasive, especially soon after surgery, and they do not correlate better with subjective rates (overestimating clinically important UI rates).[10,17] Thus, in our study, as previously reported, urodynamics were postponed and used only in refractory cases after 6 months.[6] Daily pad use correlates better with actual leakage than does patient quantification of urine loss.[10,11]

Homogeneously all patients in group 1 started treatment early at 7 days after catheter removal and continued treatment for 12 sessions. BF and FES were performed in each session. The rationale for placing BF and FES in the same session is to perform the 3 consecutive steps in each session of 1) to emphasize the specificity of muscle contraction (BF), 2) to increase the power and endurance of pelvic floor muscles (BF), and 3) to artificially stimulate and increase the periurethral striated muscle (FES). This type of session also helps patients to better perform and continue exercises at home, thus improving the voluntary control of the pelvic floor and supporting the primary urethral closure mechanism.[6] If muscles work efficiently (BF + FES) it is easier for the patient to create an autonomic pelvic floor contraction to prevent stress events. Fatigue of the periurethral striated muscles is often the cause of increased urine loss during the second part of the day and this can be prevented by BF + FES sessions.

In our population we demonstrated a significant advantage of BF + FES treatment in terms of objective continence rates compared to the control group. It is not possible to estimate the exact contribution of each method to the final result, but BF and FES work together in this set-up. The benefit of this physical therapy is particularly evident in the early recovery of continence and in the reduction of urine leakage early at 4 weeks from the beginning of treatment. Benefits were already significant during treatment sessions (after the first 8 sessions) and are maintained after BF + FES end (6 weeks) to the 6-month control. If we compare our results (early combined use of BF + FES) with those of Filocamo et al (early use of PME) at the 1-month followup a higher percentage of continence was achieved using BF + FES (63.3%) than PME (19.3%), whereas the results were comparable at 3 months (80.0% vs 74.0%) and 6 months (96.7% vs 98.3%).[6] The initiation of the treatment program soon after surgery, when patients have not become accustomed to the idea of wearing a pad, contributes to these significant results and might also explain the complete treatment compliance. Consideration should also be given to initiating this therapy preoperatively to

determine whether there might be an additional benefit to learning and practicing pelvic floor exercises before surgery.[18] It is also important to emphasize the safety of this physical treatment. It is not harmful and does not compromise future treatment options. Prior studies have shown that patient age and surgical technique are important risk factors that affect the PPI rate.[1,19,20] In our population a younger patient age, a lower prostate volume and a nerve sparing procedure resulted in a positive effect on continence after RP. However, on multivariate analysis our treatment resulted in a significant and independent ability to positively influence the rate and time of the achievement of continence. Limitations of our study included no measurement of urinary control results in terms of improved quality of life and costs of health care.

CONCLUSIONS

Although advancements in surgical technique have improved the outcome of RP, we believe that early treatment with BF and FES has a significant, positive impact on the early recovery of urinary continence. It can represent a noninvasive and nonharmful method for all patients undergoing RP to reduce the duration and the degree of PPI.

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