Recovery of Urinary Continence After Radical Prostatectomy Using Early vs Late Pelvic Floor Electrical Stimulation and Biofeedback-associated Treatment

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OBJECTIVE To compare the early vs late use of pelvic floor electrical stimulation (FES) plus biofeedback (BF) in terms of time to recovery and rate of continence after radical prostatectomy (RP).

MATERIALS AND METHODS Between April 2007 and April 2012, a total of 120 patients who underwent RP were prospectively included in the study. In group 1 (60 cases), we included patients who presented a urinary leakage weight ≥50 g for 24 hours, 14 days after catheter removal. In group 2 (60 cases), we included patients who continued to present a urinary leakage weight ≥50 g for 24 hours, 12 months after surgery. In both groups, patients were prospectively submitted to the same program of BF+FES.

RESULTS Mean leakage weight became significantly lower ($P < .002$) in group 1 than in group 2 starting from visit 1 (2 weeks) through visit 7 (24 weeks). However, a significant difference ($P < .05$) between the 2 groups in terms of percentage of continent patients was achieved only at 2 weeks (group 1 = 20%; group 2 = 0%) and 4 weeks (group 1 = 66.7%; group 2 = 46.7%). The objective continence rate 6 months after the beginning of treatment was 96.7% in group 1 and 91.7% in group 2.

CONCLUSION In our experience, the treatment with BF and FES has a significant positive effect on the recovery of urinary continence independently to the time in which it is used (early vs delayed). This protocol might represent a noninvasive method for all patients undergoing RP, also in a 12-month interval from surgery. UROLOGY 86: 115–121, 2015. © 2015 Elsevier Inc.

Despite relevant improvements in the surgical technique, radical prostatectomy (RP) remains one of the most important causes of iatrogenic incontinence in men. Reported prevalence rates of urinary incontinence (UI) after RP vary from 5% to >60% according to both the criteria used to define incontinence and the postoperative time of assessment.[1,2] The prevalence and severity of UI decreases with postoperative time: 8%-87% of patients have UI at 6 months postoperatively and 5%-44% at 12 months postoperatively.[3,4]

The etiology of post-RP UI is not completely understood, but it primarily results from sphincter insufficiency, detrusor overactivity, reduced bladder compliance, and decreased contractility.[5,6] Prognostic factors for post-RP UI include age, previous bladder surgery, nerve-sparing status, anastomotic stricture, and surgical experience.[7,8]

Various noninvasive treatments have been analyzed.[9,10] Pelvic floor muscle training (PFMT) is the most widely used noninvasive method of increasing pelvic floor muscle strength.[11,12] However, it can take several months to restore continence and some patients have persistent incontinence despite treatment.[5]

In a previous study[13] on cases submitted to RP, we compared the benefit of the early combined use of functional pelvic floor electrical stimulation (FES) and biofeedback (BF) with PFMT. Our analysis showed that the early (7 days after catheter removal) noninvasive treatment with FES+BF has a significant positive effect on the early recovery of urinary continence (at 4 weeks 63% continent with FES+BF vs 30% with PFMT) after surgery, also maintained in the long term (at 6 months 96.7% continent with FES+BF vs 66.7% with PFMT).

Post-RP UI has a significant negative effect on postoperative health-related quality of life. Therefore, conservative treatments with a potential to reduce early UI

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Table 1. Patient characteristics at baseline

Characteristic	Group 1	Group 2	*P* Value(2-Tailed *t* Test)
Number of patients	60	60	—
Age (y), mean ± SD; median and range	59.61 ± 4.03 (60); 50-67	59.28 ± 4.19 (60); 50-67	>.05
Preoperative PSA (ng/mL), mean ± SD; median and range	6.95 ± 2.40 (7.5); 3.5-12.0	6.97 ± 2.32 (7.7); 3.0-12.0	>.05
Pathologic stage, n			
pT2N0	54	55	>.05
pT3No	6	5	
Pathologic Gleason score, n			
7 (3+4) or less	48	46	>.05
7 (4+3) or greater	12	14	
Surgical technique RP, n			
Laparoscopic	20	22	>.05
Open	40	38	
Nerve-sparing procedure, %			
Yes (unilateral or bilateral)	42	44	>.05
No	18	16	
Postoperative PSA (ng/mL), mean ± SD; median and range	0.05 ± 0.03 (0.05); 0.01-0.1	0.04 ± 0.02 (0.04); 0.01-0.1	>.05
Catheter removal (d)	14	14	—
Leakage wt/24 h (g), mean ± SD; median and range	295.0 ± 141.03 (300); 50-700	322.5 ± 135.11 (300); 50-700	>.05
Prostate volume (cm^3), mean ± SD; median and range	46.91 ± 8.44 (45); 35-70	49.41 ± 7.65 (50); 35-70	>.05

PSA, prostate-specific antigen; RP, radical prostatectomy; SD, standard deviation.

are of relevant clinical interest. However, in the clinical practice, not always it is possible or the patient accepts an early physical treatment for UI, and a percentage of cases are managed only with verbal indications for exercises.

In cases with persistent UI after several months from RP, the choice of noninvasive procedures such as FES or BF could remain valid. We tried to evaluate whether the positive results on post-RP UI obtained with the combination of FES+BF in the early interval from surgery (<1 months) can be maintained also in cases with persistent UI after a long interval (12 months) from RP.

The aim of this prospective study was to analyze and to compare the early vs late use of FES+BF as a learning tool for pelvic floor muscle exercises in terms of time to recovery and rate of continence after RP.

MATERIALS AND METHODS

Population

Between April 2007 and April 2012, a total of 120 patients who underwent RP at our institution for clinically localized prostate cancer were included in the 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, and 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. Patients were divided into 2 groups. In group 1 (60 cases), we included patients submitted to RP who presented a urinary leakage weight ≥50 g for 24 hours, 14 days after catheter removal. All cases were considered for an early treatment that began 14 days after catheter removal.

In group 2 (60 cases), we included cases submitted to RP who continued to present a urinary leakage weight ≥50 g for 24 hours, 12 months after surgery. During this year, cases received only usual instructions to conduct pelvic muscle exercises (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).

Treatment

Patients were enrolled in a prospective analysis in both groups (1 and 2). All cases signed an informed consent before treatment and the protocol was approved by our internal ethical committee. In both groups, patients were submitted to the same program of BF+FES performed by the same clinician (G.M.). In group 1, the program started 14 days after catheter removal (early program), whereas in group 2, 12 months after surgery (late program). The BF+FES program was described in a previous article.[13] Patients 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 decubital position. For FES, a surface electrode was inserted into the anus and pulsed at 30 Hz (first 10 minutes) and 50 Hz (second 10 minutes) square waves at a 300-μs pulse duration and a maximal output current of 24 mA. The intensity was adequate to induce visual lifting of the levator ani and pubococcygeus muscle, considering the level of comfort of the patient.[14] For BF, a 2-channel electromyographic BF apparatus (Reactive Biofeedback; BEAC, Stradella, Italy) was used, with 1 channel for perineal and the other for abdominal muscle and the signal received through surface electrodes.[10] During the initial 2-3 sessions, a strong emphasis was placed on the specificity of muscle contraction (contraction of pelvic muscles with