TURKISH JOURNAL OF UROLOGY
Turk J Urol 2021; 47(5): 436–441 • DOI: 10.5152/tud.2021.21096
NEUROUROLOGY
Clinical Trial

Comparison of the effect of the pelvic floor muscle biofeedback prior or postradical prostatectomy on urinary incontinence: A randomized controlled trial

Farzad Allameh[1], Seyed Mansoor Rayegani[2], Mohammadreza Razzaghi[3], Amir Reza Abedi[4], Amirhossein Rahavian[5], Atefeh Javadi[2], Saeed Montazeri[2]

Cite this article as: Allameh F, Rayegani SM, Razzaghi M, Abedi AR, Rahavian A, Javadi A, Montazeri S. Comparison of the effect of the pelvic floor muscle biofeedback prior or postradical prostatectomy on urinary incontinence: A randomized controlled trial. *Turk J Urol.* 2021; 47(5): 436-441.

ABSTRACT

Objective: This study aimed to evaluate the pre- and postoperative effects of pelvic floor muscle training (PFMT) and the biofeedback method on the management of urinary incontinence (UI) in patients who underwent radical prostatectomy (RP).

Material and Methods: Fifty-seven patients were enrolled in this study from September 2019 to July 2020. They were randomly divided into three groups each of 19 patients: two case groups (biofeedback before and after RP) and a control group. All patients underwent RP, followed by PFMT and 24-hour pad use instructions after the postoperative removal of the Foley catheter. Then, the rate of patient-reported pads/day usage was recorded and compared among the three groups at the end of the 1st, 3rd, and 6th months of catheter removal.

Results: Compared with the control group (only 15%), 63 and 52% of the patients who used pre- or postoperative treatment interventions, respectively, regained urinary continence during the first postoperative period, showing significant downward rates of pads/day use ($P = .01$ and .001, respectively). However, the results were not significant between the two case groups.

Conclusion: Our study revealed that applying the biofeedback method for pelvic floor muscles could be an efficient interventional approach in patients with UI, leading to the earlier regaining of continence following RP.

Keywords: Biofeedback; pelvic floor muscle training; radical prostatectomy; urinary incontinence.

[1]Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[2]Physical Medicine and Rehabilitation Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[3]Laser Application in Medical Sciences Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[4]Department of Urology, Shohada-e-Tajrish Hospital, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[5]Andrology Research Center, Yazd Reproductive Sciences Institute, Shahid Sadoughi University of Medical Science, Yazd, Iran

Submitted: 06.04.2021
Accepted: 26.08.2021

Corresponding Author: Saeed Montazeri
E-mail: saeed.montazeri89@gmail.com

Available online at www.turkishjournalofurology.com

Introduction

Urinary incontinence (UI) is one of the most bothersome complications of radical prostatectomy (RP).[1] Despite improvements in surgical equipment and techniques, it still has a relatively high prevalence[2–4] and is regarded as one of the main causes of deterioration in patients' quality of life.[5] Although various explanations, including detrusor overactivity and injuries to urinary sphincter, detrusor, and pelvic floor muscle, have been proposed for the occurrence of postprostatectomy incontinence (PPI), its pathophysiology remains largely unknow.[6] Continence recovery after RP relies on the training of bladder to hold larger urinary volumes, striated urinary sphincter function to compensate for the reduced smooth muscle function, and also compensation by the puborectalis and bulbocavernosus muscles in case the striated urinary sphincter is affected by surgery.[5,7] Multidisciplinary treatment approaches determined by physiotherapists and urologists are the standard of treatment for PPI.[8] The initial treatment of incontinence involves noninvasive behavioral therapies consisting of bladder training, diet modifications, and pelvic floor muscle

training (PFMT).[4,9] These methods are inexpensive, effective, and without any serious adverse effects.[10] PFMT is considered the physiotherapeutic modality of choice in PPI treatment. Various studies have explored the impact of PFMT on PPI and reported conflicting results.[1,4] Despite early optimistic outcomes, some studies have questioned its efficacy for PPI treatment.[11–13] The disparity between the available results is likely to be derived from variability in the assessment methods, the instructions given, and the PFMT type.[1] Some authors have proposed that biofeedback could result in a better PPI improvement.[14,15] There is growing evidence that PFMT can be more effective in the treatment of PPI if it is given as rehabilitation (starting before surgery) rather than rehabilitation (starting after surgery).[16] Thus, in the current trial, we aimed to further investigate the effects of preoperative or postoperative biofeedback and PFMT on the early achievement of urinary continence.

Material and Methods

After the approval of this study granted in accordance with the declaration of Helsinki by the Ethical Committee of Shahid Beheshti University of Medical Sciences in August 2018 (Ethical code: IR.sbmu.unrc.rec.1397.20), it was registered in the Iranian Registry of Clinical Trials (IRCT) under the code: IRCT20200429047243N1. All the patients with the definitive diagnosis of prostate cancer, verified via Transrectal biopsy, referred to Shohada-e-Tajrish Hospital (a tertiary center in Tehran, IRAN) from September 2019 to July 2020, and who were candidates for RP, considered eligible to enroll in the study. We estimated that 19 patients were needed in each group to give the trial the approximate power of 85%. The subjects were assigned in three parallel groups in this single-blinded randomized control trial.

The patients with one or more of the following criteria were excluded from the study according to the same exclusion criteria applied by similar studies: those who were diagnosed with prostate cancer following transurethral resection of prostate, those who received pelvic radiotherapy regardless of their primary malignancy, spinal cord injury, and comorbidities that can affect urinary continence (such as diabetes mellitus, overactive bladder, and urethral stricture), history of pelvic or retroperitoneal surgery, and neurologic disorders (e.g., multiple sclerosis and seizures).[1,5,13] After obtaining an informed consent from all the patients, they were randomized into three groups with the allocation ration of 1:1:1 via a randomization software using a block randomization method, and then a sealed envelope was used to ensure the concealment of allocation.

Main Points

- Urinary incontinence is significantly lower once pelvic floor muscle training is used.
- The patients who underwent treatment by pelvic floor muscle training before or after surgery regained urinary continence more significantly during 1 months after catheter removal compared with the control group.
- Beginning the course of therapy prior to surgery could contribute to better learning of the exercise and eventually better practicing these trainings.

Intervention

In the first group, biofeedback was performed for pelvic floor muscles using MyoTrac Infiniti (Thought Technology Ltd., Canada) by a physiatrist for the duration of 30 minutes, twice a week for 2 weeks prior to the surgery. This group received nonfunctional probes after the surgery. The patients in the second group received nonfunctional probes prior to the surgery, but upon removing the Foley catheter, they underwent pelvic floor muscle biofeedback by a physiatrist for a duration of 30 minutes, twice a week for 2 weeks. The third group received nonfunctional probes before and after the surgery. Subsequently, using the Walsh technique,[17] all the patients underwent RP by one of three urologists. The Foley catheter was removed 2 weeks after the surgery, and they were instructed how to do the PFMT. In accordance with similar studies, all the participants were instructed to use pads, and the patient-reported 24-hour pad usage was recorded and compared between the three groups at 1 month and then 3 and 6 months after catheter removal.[14,18] They all used similar pads. The patients with 24-hour pad usage of one or less (either as a result of minimal urine leakage or for security if no leakage was present) were considered to be continent. Those with 24-hour pad usage of two or more were considered to be incontinent.[19] UI improvement was defined by 24-hour pad usage, and complete recovery was defined as the absence of UI. Moreover, the duration between catheter removal and achieving complete urinary continence was assessed for all of the patients. We lost one patient to COVID-19 in biofeedback prior to the surgery group. Additionally, we lost contact with one patient in the no-intervention group. These patients were excluded from the analysis of 6 months (Figure 1).

Statistical Analysis

Statistical analysis was carried out employing Statistical Package for the Social Sciences (SPSS) version 22.0 (IBM SPSS Corp.; Armonk, NY, USA). A *P*-value less than .05 was considered as statistically significant. The quantitative data were reported as mean ± SD. The comparison within the groups was evaluated with the paired-samples t-test, and the comparison

Turk J Urol 2021; 47(5): 436-441
DOI: 10.5152/tud.2021.21096

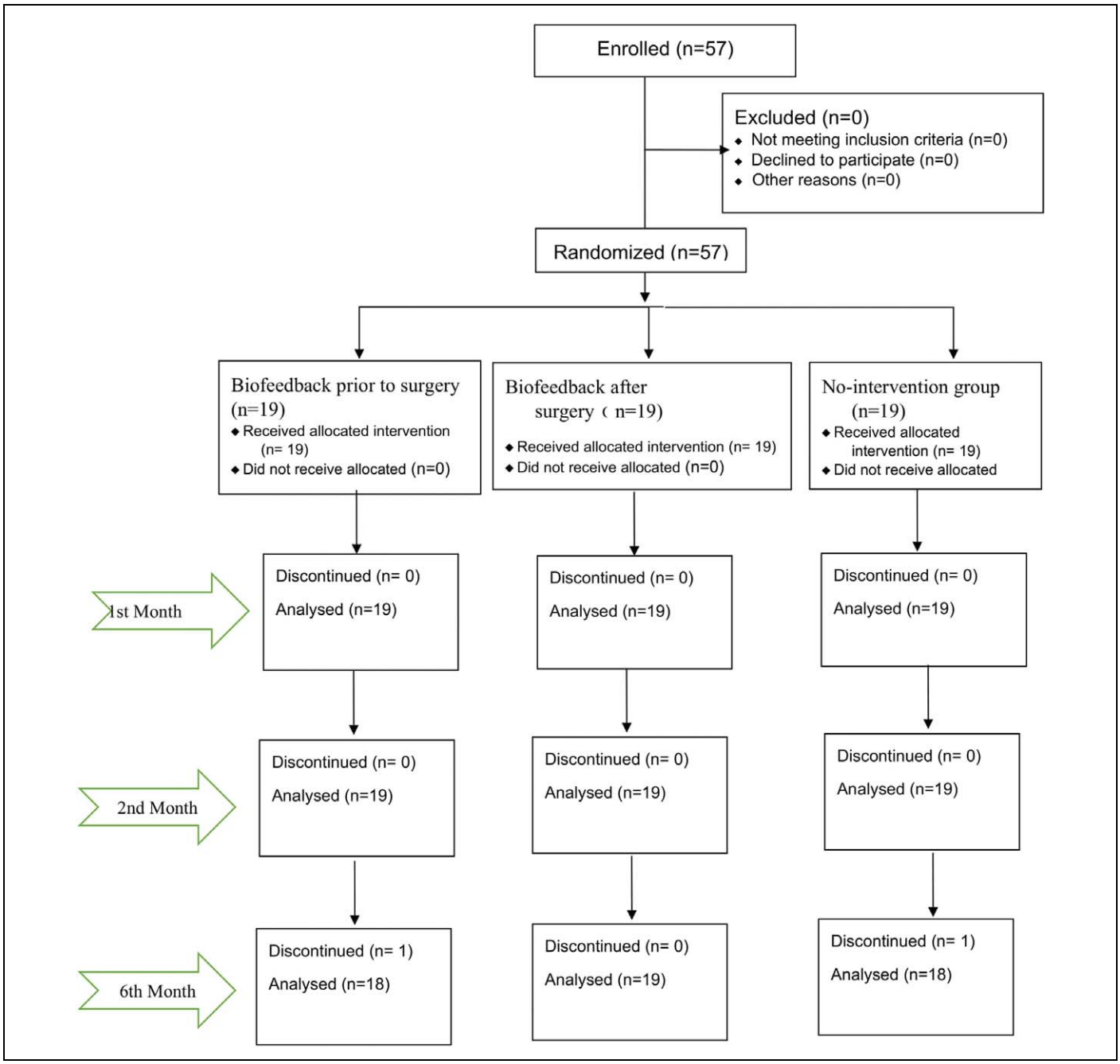

Figure 1. Flow diagram illustrating progress of patients screened for the trial.

between the groups was assessed by the repeated measures ANOVA.

Results

From September 2019 to July 2020, 57 patients were enrolled in the study, and they were randomly assigned into three groups each of 19 patients: "biofeedback prior to surgery" group, the "biofeedback after surgery" group, and the "no-intervention" group. Figure 1 illustrates the flow diagram of the patients screened for the trial.

The mean age of the participants was 69.4 ± 6.4 years. The mean prostate volume was 37.1 ± 11.1 g. The analysis showed

Table 1. Mean Age, Prostate Volume, and Gleason Score of Patients

Groups (Amount)	Mean Age (years)	BMI	Smoking	Mean Prostate Volume (g)	Gleason Score 6	7	8
All (57)	69.4 ± 6.4	24.1 ± 2.0	18	37.1 ± 11.3	18	29	10
Biofeedback prior to surgery (19)	69 ± 5.7	24.2 ± 2.1	5	34.9 ± 11	5	10	4
Biofeedback after surgery (19)	68.4 ± 6.9	23.9 ± 2.0	7	35.6 ± 12.3	7	9	3
No-intervention group (19)	70.6 ± 6.8	24.4 ± 1.9	6	40.8 ± 10.2	6	10	3
P-value	.56	.62	.12	.21		.95	

P values of less than .05 were regarded as statistically significant.

Table 2. Mean Pad/Day between Three Groups at 1, 3, and 6 Months after Catheter Removal

Groups	Pad/Day After One Month	Pad/Day After 3 Months	Pad/Day After 6 Months
Biofeedback prior to surgery	2 ± 0.7	0.9 ± 0.5	0.4 ± 0.5
Biofeedback after surgery	2 ± 0.7	1.1 ± 0.6	0.47 ± 0.5
No-intervention group	1.9 ± 0.6	1.4 ± 0.5	0.9 ± 0.4
P-value	.86	.01	.00

P-values of less than .05 were regarded as statistically significant.

no significant differences between the means. Table 1 depicts the baseline demographic and clinical characteristics of the groups.

The mean 24-hour pad usage indicated no significant differences between the three groups at 1 month (*P*-value: .86), but after 3 and 6 months, 24-hour pad usage was significantly higher in the group with no intervention compared to that in the case groups although the comparison between the two case groups showed no significant differences. Table 2 represents the mean 24-hour pad usage among the three groups at 1, 3, and 6 months after catheter removal.

Twelve (63%) patients in the first group who underwent intervention prior to surgery and 10 patients (52%) in the second group, who underwent intervention after surgery, showed urinary continence 1 month after the catheter removal. Compared with the control group with no intervention (15%), these results were statistically significant) *P*-value: .012). Three months after the catheter removal, these amounts were 18 (94%), 17 (89%), and 10 (52%) in the prior to surgery, after surgery, and no-intervention groups, respectively, which was statistically significant (*P*-value: .01). At 6 months, these were 17 (94%), 18 (94%), and 15 (83%), respectively, which was not statistically significant (*P*-value: .2).

The patients in the control group regained their continence 50.7 ± 6.1 days after the catheter removal, which was significantly different from the other two groups: 35 ± 8.7 and 31.3 ± 6.5 days in the prior to surgery and after surgery groups, respectively (*P*-value: .00); meanwhile, the differences between the undermentioned groups were not significant (*P*-value: .27).

Discussion

UI is known to be a bothersome complication of RP.[20] Multidisciplinary treatment approaches, particularly noninvasive behavioral therapies including PFMT, are important aspects of PPI treatment. However, the short- and long-term effects of PFMT on PPI are still debatable.[12,21]

We conducted this study to assess the effects of biofeedback on patients' PPI in the course of 6 months. The rationale for PFMT is that voluntary contractions of selected pelvic floor muscles may result in an improvement in their strength, which, in turn, could result in their effectiveness during intra-abdominal pressure periods.[12] In our study, at 3 and 6 months, the mean 24-hour pad usage was significantly lower in the case groups compared with that in the control group (with *P*-values of .01 and .001, respectively); however, the differences were not significant

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between the case groups (treatment prior to or after surgery). Sixty-three percent of the patients who underwent treatment before surgery and 52% of those who received treatment after surgery regained urinary continence during 1 month after catheter removal. This was as low as 15% in the control group, which showed a significant difference (*P*-value: .012).

The rationales for starting PFMT prior to RP include: pelvic floor striated muscle mass and endurance increase, and neuromuscular reserve improvement. These potential beneficial effects could be conducive to compensation for the loss of striated and smooth muscles during RP. Furthermore, PFMT prior to RP provides the patients with necessary skills in beginning the exercise instantly after urinary catheter removal.[12,22] Our findings suggested a more beneficial role for the rehabilitation intervention as biofeedback; meanwhile, we also observed evidence for spontaneous recovery in the control group, especially with a longer follow-up period. Nevertheless, there was an increase in the recovery speed when earlier biofeedback programs were scheduled. The time duration before which the patient returns to continence is of utmost importance in preserving the patient's quality of life and psychological functions after RP.[23] In line with the results of our study, a review of seven studies showed a 36% improvement in the continence rates at 3 months for the men who performed preoperative PFMT compared with the control group; however, no significant differences were observed between the intervention and control groups concerning the continence rates 6 months following the surgery.[24]

A Cochrane review proposed that definite judgment regarding the role of conservative management, including PFMT, in the treatment of PPI cannot be made due to diversities in the populations and treatment protocols in addition to the low quality of most studies.[25] Various methodology differences could be seen in studies, including PFMT with or without biofeedback or electrical stimulation, the number of PFMT in a week, the duration of treatment, and the time of PFMT (before vs after the surgery). We believe these variables are the main explanations justifying the differences between the results of these studies.

In a meta-analysis of available articles in 2014, Fernández et al.[21] concluded that PFMT, especially if it is started soon after the surgery, is an effective method for improving continence after RP. They also stated that PFMT performed at home results in similar outcomes to PFMT guided by a physiotherapist while being more cost-effective. Several recent randomized control trials have found similar outcomes to those of our study. It was shown in a study by Oh et al.[14] that using biofeedback for PFMT, particularly in the postoperative period, may result in a more favorable outcomes regarding UI after RP compared with verbal instructions alone. Similar results were obtained in the study of Soto González et al.,[15] in which treating the patients with biofeedback and electrotherapy 3 days a week for 3 months resulted in a better improvement in UI compared with verbal instructions for PFMT alone. In another study, Milios et al.[1] concluded that intensive PFMT prior to RP may contribute to decreased prevalence of UI after surgery. Moreover, more rapid recovery has been observed as a result of more intense intervention.

There were several limitations to our study. First, although this study was powerful enough to draw conclusions, we may be able to demonstrate more definitive results with larger sample sizes. Second, based on the study design, selection bias and attribution bias are unlikely, yet there is room for information bias. Our data were solely dependent on the patient-reported 24-hours pad usage provided by the patients and/or their caregivers; thus, miscalculation is a possibility. Finally, the follow-up period was rather short; a longer follow-up period may result in different outcomes. Therefore, future studies with larger sample sizes may be required to further investigate biofeedback results on PPI.

In conclusion, with the advancement in surgical RP techniques, UI rates have significantly reduced, yet the rates still remain high. We propose that pre- or postoperative biofeedback of pelvic floor muscle is among the most effective interventions, which could help the patients for the earlier achievement of UI.

Ethics Committee Approval: Ethical committee approval was granted in accordance with the declaration of Helsinki by the Ethical Committee of Shahid Beheshti University of Medical Sciences in August 2018 (Ethical code: IR.sbmu.unrc.rec.1397.20).

Informed Consent: Verbal informed consent was obtained from all participants who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - F.A.; Design - S.M.R.; Data Collection and/or Processing - M.R.R., A.R.A.; Analysis and/or Interpretation - A.H.R., A.J.; Writing Manuscript - S.M.

Acknowledgments: The authors are grateful to the Shohada e Tajrish urology ward staff.

Conflict of Interest: The authors have no conflicts of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

Clinical Registration: This study was registered in Iranian Registry of Clinical Trials (IRCT) by the number of IRCT20200429047243N1.

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