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Original Article

Urinary incontinency after radical prostatectomy and effects of 1 month pre-operative biofeedback training

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Abstract: Background: Radical prostatectomy is one of the treatment choices in patients with prostate cancer. Urinary incontinency is a common complication of this surgery that could significantly influence on the quality of life (QOL) in patients. In the present study, we aimed to investigate the effects of pre-operative biofeedback training on this issue. Methods: This is a randomized controlled clinical trial that was performed in 2017-2021 on 240 patients that were candidates for radical prostatectomy. The demographic data of all patients including age and gender were collected. The patients were randomized into two groups each containing 120 patients. The first group of patients were visited by an experienced physiotherapist and he instructed them in pelvic floor muscle training (Kegel training) using biofeedback technique in a one-hour-long training class for one month before their surgery. The other group received no pelvic floor muscle training instructions. Presence of urinary incontinence was asked from all patients 24 hours, one week, one month, three months and six months after removal of the patients' urinary catheter. We used International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) long-form questionnaire to obtain data regarding urinary incontinence. By the means of this questionnaire, we evaluated patient's QOL. Results: The QOL of patients in the intervention group was significantly higher within 1 day, 1 week, 1 month and 3 months after the surgical operations compared to the control group ($P<0.05$). No significant differences were observed between groups at the 6 months after the surgeries ($P>0.05$). Conclusion: Biofeedback has significant short-term effects on the urinary incontinence immediately after the surgical operation. We also observed that biofeedback had no significant long-term effects.

Keywords: Radical prostatectomy, prostate cancer, biofeedback, urinary incontinency

Introduction

Prostate cancer is one of the most common cancers among men with prevalence rate of 109.8 per 100,000 men per year [1]. The 5-year survival rate of regional prostate cancer is almost 100% but this rate could decrease to 30% in patients with metastatic prostate cancer [2].

Treatment strategies for prostate cancer depend on various facto such as grade and stage of cancer, invasion and metastasis and the slow or fast growing characteristic of the cancer. These strategies include radical prostatectomy, radiotherapy and brachytherapy [3]. Radical prostatectomy is the most definite therapeutic option in patients with prostate cancer that is associated with higher survival rates compared to radiotherapy or other options. Radical prostatectomy is one of the standard therapeutic strategies for localized or locally advanced prostate cancer [4].

On the other hand, radical prostatectomy is associated with complications including bleeding, urinary tract infection, urinary incontinence, erectile dysfunction (impotence), narrowing of the urethra or bladder neck and formation of cysts containing lymph (lymphocele).

Like any other intervention, radical prostatectomy is associated with complications including bleeding, urinary tract infection, urinary incontinency and erectile dysfunction (impotence) [5]. Urinary incontinency is accounted as one of the most important complications that could results in significant reduction in quality of life (QOL) among patients undergoing radical prostatectomy [6].

The prevalence rate of urinary incontinency is reported to be almost 40% in patients undergoing radical prostatectomy due to prostate cancer [7]. Different treatments have been used for post-operative urinary incontinency including medical treatments, pelvic muscle physiotherapies or invasive treatments such as bulking agent injections, male slings or artificial sphincter administration [8].

Invasive treatments are usually initiated after 1 year following radical prostatectomy because most of the cases with urinary incontinency are ameliorated within 1 year. Biofeedback is one of the non-invasive treatment methods for urinary incontinency [9]. Previous studies have reported paradoxical results for influences of biofeedback on urinary incontinency after Radical prostatectomy. Some have reported that this strategy has no significant effects but most of these studies have investigated the post-operative effects of biofeedback in this field [10-12]. These controversial results could be due to two main issues: First, the effects of biofeedback could be initiated within 6-8 weeks; second, the urinary incontinency of some patients could ameliorate spontaneously within weeks after surgical procedures and as a result, the possibility of finding significant results is deceased [13]. These two issues could interact with each other that could lead to different therapeutic results.

Therefore, in the present study, the aim of this study was to investigate the effects of pre-operative biofeedback initiation on urinary incontinency and QOL of patients undergoing radical prostatectomy especially the period after surgery the time that incontinence is more prevalent. The use of pre-operative biofeedback training and pelvic floor muscle training (PFMT) is a novel topic that could clarify the effects of this technique on urinary incontinency after radical prostatectomy.

Methods and material

Study design

This is a randomized controlled clinical trial that was performed in 2017-2021 in Urology Clinic of Imam Khomeini Hospital affiliated to Tehran University of Medical Sciences. The current study was conducted on 240 patients that were candidates for radical prostatectomy. The study protocol was approved by the Research Committee of Isfahan University of Medical Sciences and the Ethics committee has confirmed it (Ethics code: IR.TUMS.MEDICINE.REC.1391.261, Iranian Registry of Clinical Trials (RCT) code: IRCT20170716035104N3).

Inclusion and exclusion criteria

The inclusion criteria were age 50 to 75 years, diagnosis of localized or locally advanced prostate cancer by the means of biopsy, and standard metastases work up being a candidate for radical prostatectomy and signing the written informed consent to participate in this study. The exclusion criteria were uncontrolled diabetes mellitus, previous neurologic diseases, severe urinary incontinence before surgery, causes of neurologic bladder, inability of nerve sparing during surgery, irregular post-operation visits, patient's will to exit the study.

Interventions

The patients who men the inclusion criteria entered the study. The demographic data of all patients including age and gender were collected. The patients were randomized into two groups using random allocation software each containing 120 patients. The first group of patients were visited by an experienced physiotherapist and he instructed them in pelvic floor muscle training (Kegel training) using biofeedback technique in a one-hour-long training class so they learned how they could exercise at home for one month before their surgery. The methods of Kegel training were similar to the recent paper by Urvaylıoğlu and colleagues in 2021 [14]. Besides, they were given a home exercise program and were recommended to begin exercising immediately after the trainings. For 30 days, these patients performed the exercises at home every day, two times for half an hour. The other group received no pelvic floor muscle training instructions.

Data gathering

Then, both groups of patients underwent open retropubic nerve-sparing radical prostatectomy, and standardized post-operative approaches were considered for them until discharge. In case control the patient encourage continue Kegel exercise after surgery. Presence of urinary incontinence was asked from all patients 24 hours, one week, one month, three months and six months after removal of the patients'

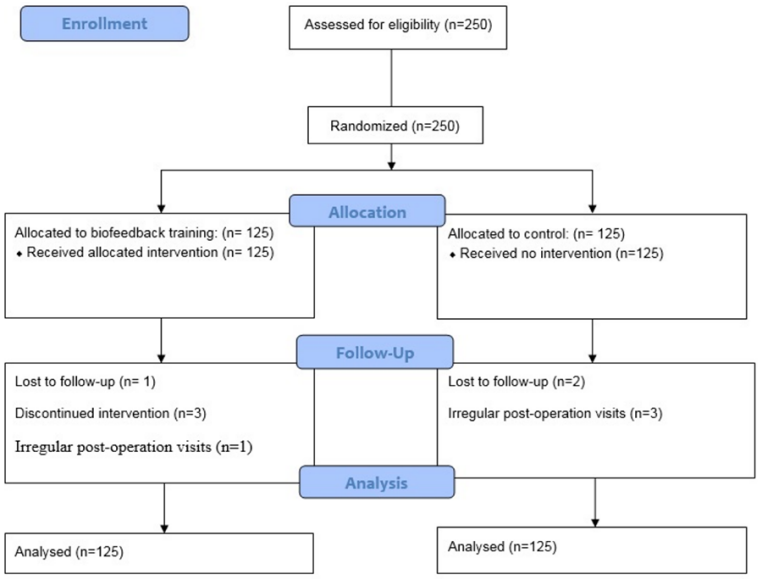

Figure 1. The CONSORT flow diagram of patients.

urinary catheter. We used International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) long-form questionnaire to obtain data regarding urinary incontinence. The reliability and validity of the Persian language version of this questionnaire was approved by Pourmomeny and colleagues in 2018 [15]. By the means of this questionnaire, we evaluated patient's QOL and lower scores of this questionnaire showed better QOL in patients.

Data regarding the frequency of urinary incontinence and QOL of patients were collected and compared between two groups.

Statistical analysis

The study data were analyzed using IBM SPSS Statistics for Windows version 24.0. Armonk, NY: IBM Corp. Quantitative data were analyzed using the independent t-test, Bonferroni post-hoc test, and repeated measurements ANOVA. To demonstrate data, we used the mean and standard deviation in the form of figure and table. The significance level was defined as *P*-value <0.05.

Results

Study population

In this study, 250 patients were candidates to participate in this study and were divided into 2 groups each containing 125 patients. After the surgical procedures, 10 patients were excluded (5 in each group) due to: losing the follow-up (n=3), discontinuation of intervention (n=3), and irregular post-operation visits (n=4). At the end, data of 240 men were analyzed. The CONSORT flow diagram of patients is illustrated in **Figure 1**.

Demographic data

The age ranged from 50 to 70 years (mean ± standard deviation: 62.84±6.20) in the control group, and 50 to 73 years in the intervention group (mean ± standard deviation: 63.25±6.34). There was no statistically significant difference between the two groups regarding their age (*P*-value =0.33).

Our data showed that the frequency of incontinency was 19.2% (24 cases) in the intervention group and 34.4% (43 cases) in the control group. These differences were statistically significant (P<0.001).

Assessments of QOL

Table 1 demonstrates the findings of post-operative QOL of both intervention and control group patients, from one day to six months after the removal of their urinary catheter. We showed that the QOL score of patients in the intervention group was significantly lower within 1 day, 1 week, 1 month and 3 months after the surgical operations compared to the control group showing a better QOL (P<0.05). No significant differences were observed between groups at the 6 months after the surgeries (P>0.05). According to the findings displayed in **Figure 2**, patients' quality of life after pelvic floor muscle training in the intervention group was significantly higher compared to the control group at all times.

Discussion

Almost all patients that undergo radical prostatectomy are at the risks of urinary incontinence. The main cause of urinary incontinence in

Table 1. Quality of life of patients undergoing prostatectomy in evaluated times and their comparison in control and intervention group

Variable (Mean ± SD)	After one day	After one week	After one month	After three months	After six months	*P*-value**
Control	22.78±5.18	21.40±5.00	19.05±5.25	18.05±6.41	16.48±6.10	<0.001
Intervention	20.78±5.54	17.15±5.12	14.15±4.86	14.13±5.65	13.18±5.19	<0.001
P-value*	0.10	<0.001	<0.001	0.005	0.01	

*Independent t-test results. **Repeated measures ANOVA.

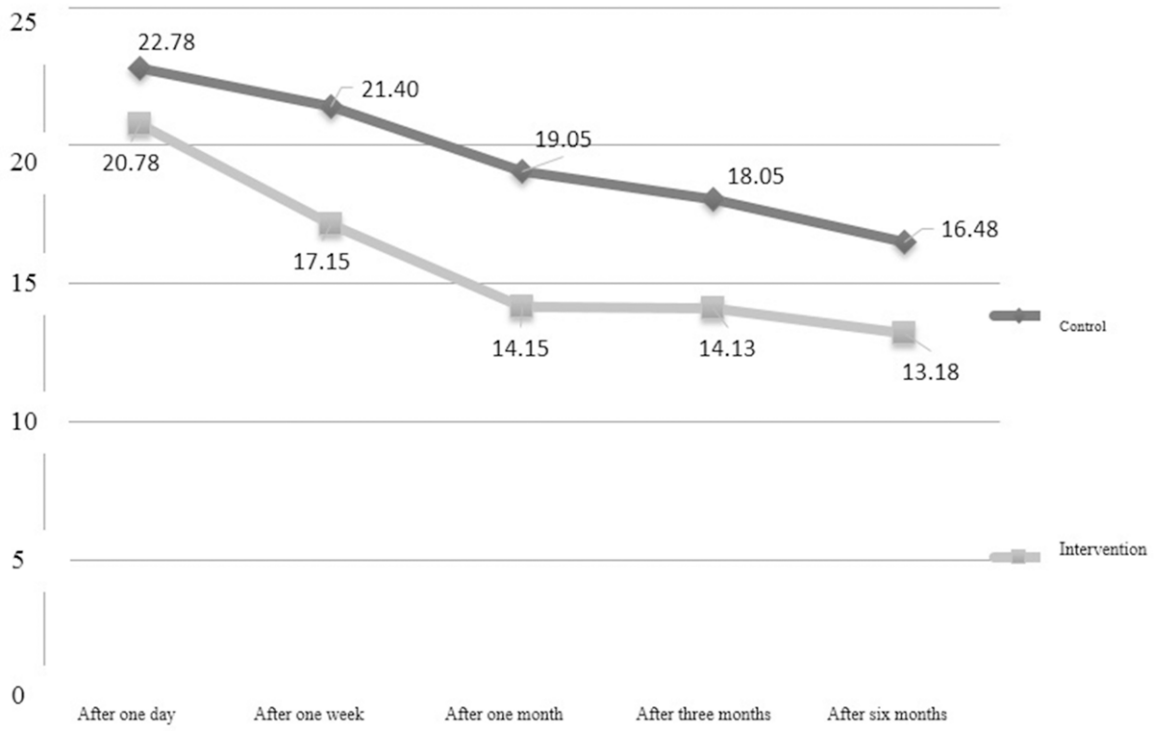

Figure 2. Comparison of patients' quality of life scores between the control and intervention group during different periods.

these patients is intra-operative damage to the urethral sphincter. Epidemiologic studies have claimed that urinary incontinence could occur in almost 20% of patients which is highly associated with decreased QOL. Some other studies have indicated that urinary incontinence could be observed in 44.4% to 50% of patients [16, 17] that is considered as an important issue in patients. We indicated that the patients in the intervention group had significantly lower incidence of urinary incontinence that highlights the effectiveness of these treatments.

The urinary incontinence could adversely affects the patient's QOL [18] and based on studies, this issue could cause heavy socio-economic burden on healthcare system [19]. As a result, special attentions have been given to this issue in recent research. Efforts have been made to prevent and treat urinary incontinence but it has been well established that the urinary incontinence following radical prostatectomy will ameliorate within 1 year after the surgeries. As a result, studies have investigated the effectiveness of treatment strategies to increase the QOL of patients within 1 year after radical prostatectomy.

There are various types of treatments for urinary incontinence after radical prostatectomy including pelvic floor exercises, supportive care, medications, neuromuscular electrical stimulation, surgery, injections, and devices, artificial sphincter and bulbourethral sling.

Most of these therapeutic strategies are invasive and are not performed within the first 1 year after the surgical operations [20, 21]. Biofeedback is one of the treatment strategies that could be initiated within 1 year after the surgical procedures [22].

Biofeedback is accounted as an important mind-body technique that involves controlling involuntary bodily functions. With the use of biofeedback training, the patients could be able to improve their body functions. During a biofeedback session, a therapist trains the patients to perform special muscle improvement movements. Biofeedback exercises for the pelvic floor muscles could be designed to improve the muscle strength, support urinary tract, prevent urinary leakage and improve the urgency.

A study was conducted by Ong and colleagues in Malaysia in 2015 on 40 patients and evaluated the effectiveness of biofeedback Kegel exercise on the stress urinary incontinence. This study showed that the pelvic muscle strength and the score of urinary incontinence improved significantly within 16 weeks of biofeedback Kegel exercise and suggested that these training should be considered as effective therapeutic methods [23]. Another study by Vickers and others evaluated the use of Kegel exercises and biofeedback among women with urinary incontinence. They mentioned that these trainings are almost hard to bear for patients but are also associated with significant improvements in urinary incontinence of patients [24]. In 2014, Park and Kang reviewed the previous clinical trials and assessed the effect of Kegel exercises on the management of stress urinary incontinence. They stated that Kegel exercises is one of the effective methods for managements of urinary incontinence by the mechanism of pelvic floor muscle exercise but also mentioned that more studies should be conducted on this issue [25].

There are also some evidence of the effects of Kegel exercises on urinary incontinence after radical prostatectomy. As Aydın Sayılan and colleagues showed, Kegel exercise and pelvic floor muscle training after radical prostatectomy could ameliorate urinary incontinence within the third and sixth month after the surgeries [26]. Another study by Pan and others showed that pelvic muscle training after radical prostatectomy might be helpful in reducing the urinary incontinence but also mentioned that some patients might not benefit from these trainings and as a result, their QOL might not improve [27]. Other studies have indicated that advanced pelvic floor muscle exercise could be a proper therapeutic option after radical prostatectomy but not all patients benefit from these training until 1 year after prostatectomy [28, 29]. Previous studies claimed that biofeedback exercises after radical prostatectomy might not be beneficial in all patients and suggested that other strategies should be made for the best therapeutic results.

Another study by Dijkstra-Eshuis and colleagues in 2013 assessed the effects of biofeedback on urinary incontinence after radical prostatectomy and declared that these treatments do not appear to be effective in the prevention of urinary incontinence and increasing the QOL of patients [30]. Kannan and colleagues showed that biofeedback and pelvic floor muscles exercise have no significant effects on the prevalence of urinary incontinence following radical prostatectomy [31]. Paradoxical results have also been reported about this issue in previous research [32-34].

We believe that due to the fact that urinary incontinence following radical prostatectomy could ameliorate without treatments within months after the surgeries [35, 36] and considering that biofeedback treatments require time for their effects to be appeared in patients and require high patient's compliance [37, 38], these controversies have been reported in former research. These issues make the assessments of biofeedback effects much complex and regarding the mentioned problems, here we designed this study to evaluate and assess the true effects of biofeedback on urinary incontinence by initiating the trainings almost 1 month before surgical procedures. This designs cause that the effects of biofeedback training appeared immediately after the surgeries and as we observed, the patients in the intervention group had lower incidence of urinary incontinence and better QOL.

In the present study, despite the previous surveys, we used biofeedback Kegel exercise 1 month before radical prostatectomy and showed significant improvements in urinary incontinence and QOL of patient within 3

months after the surgeries. After 6 months, no significant differences were observed in urinary incontinence among patients and both intervention and control groups had improvements in their symptoms and QOL. These data emphasize the effectiveness of pre-operative Kegel trainings on the urinary incontinence and QOL of patients within the first 3 months after the surgeries but these trainings have no significant effects on the final outcomes of patients. We recommend that surgeons should pay attention to the beneficial effects of Kegel trainings before radical prostatectomy. We believe that these trainings are suitable to perform and are cost-effective and therefore, should be suggested for patients.

The limitations of the current study were conducting the study in a single center and not evaluating the effects of Kegel trainings on other factors including sexual functions in patients. However, we believe that the large number of patients that were included in this study could make our data more reliable.

Conclusion

In the present study we showed that biofeedback has significant effects on the urinary incontinence immediately after the surgical operation and it should be noticed that these trainings have no effects on the anatomical disorders of the urinary sphincter but they mostly influence the functional disorders among patients. We also observed that biofeedback had no significant long-term effects but regarding the problems and decreased QOL and costs of urinary incontinence, we believe that these short-term effects have high clinical values and more attentions should be given to the use of pre-operative biofeedback trainings in patients.

Disclosure of conflict of interest

None.

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