

Original Article



The Effect of Pelvic Floor Muscle Strengthening Exercise on Urinary Incontinence and Quality of Life in Patients after Prostatectomy: a Randomized Clinical Trial

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ABSTRACT

Introduction: Urinary incontinence is a common problem after Prostatectomy that affects patients' life. Nurses can assist patients in improving urinary problems. This study aimed to assess the effects of pelvic floor muscle exercises on urinary incontinence and the quality of life in patients after Prostatectomy.

Methods: This randomized clinical trial was performed on 60 patients with suprapubic prostatectomy and urinary incontinence who had referred to urology department of Vali-e-Asr Hospital in Tehran. The subjects were selected and randomly divided into control and intervention groups. The control and intervention groups received standard care and pelvic floor muscles exercises after surgery, respectively. The data were gathered in the course of seven days; one, two and three months after surgery, using three questionnaires and a check list for the evaluation of urinary incontinence and assessing Quality of Life. The data were then analyzed, using SPSS ver.13, and statistical tests such as t-test, ANOVA and Chi- square.

Results: The quality of life and urinary incontinence score before intervention were not significant between two groups. The findings showed that there was a statistically significant difference between two groups in the average scores of urinary incontinence and the quality of life after intervention.

Conclusion: Pelvic muscles exercises reduced urinary incontinence and enhanced quality of life. It's recommended as a non-pharmacologic, non-invasive way to control urinary incontinence. Patients with adequate cognitive and mental abilities can easily be trained on pelvic floor muscle exercises.

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Introduction

Benign Prostate Hypertrophy (BPH) is the most common benign tumor in men, becoming more prevalent as men grow. More than 50% of men over 50 and 90% of patients over 80 years of age suffer from BPH.¹⁻³ The incidence rate of prostate cancer is reported to be 33% in Iran, which varies across different populations of the country.⁴

BPH is currently being treated through either medication or surgery, depending on the patient's condition.⁵ For the medication treatment, anticholinergic and anti- muscarinic medications such as Oxybutynin and Detrusitol are used, which might be associated with certain side-effects including, constipation, dizziness, urinary retention, and skin rashes.^{6,7} The surgical treatment, on the other hand, involves prostatectomy, widely applied in prostate diseases, in particular prostate cancer and benign prostate hypertrophy.^{8,9} It imposes huge expenses on the patient and the national healthcare system.¹⁰

Despite the improved surgical techniques, the procedure is associated with a number of complications such as, bleeding, urinary incontinence and sexual impotence. Urinary incontinence is one of the most discomforting complications of prostatectomy.¹¹⁻¹³

Studies have shown that most men suffer from urinary incontinence, having undergone prostatectomy and after

the removal of the urinary catheter.¹⁴ Around 87-88% of patients experience urinary incontinence for 6 months after the surgery and 44-45% for as long as one year.¹⁵

Many patients experience moderate to severe degrees of urinary incontinence in the first week following surgery, and some suffer from this complication for months or even years after surgery. Urinary incontinence might cause embarrassment, loss of self-esteem, impaired mental well-being, anxiety, relationship and sexual problems and social isolation. It also has a dramatic effect on the patients' physical, social and emotional indicators and activities, thereby creating an embarrassing situation and ultimately leading to the social isolation of the individual. This complication is critical to Muslims who believe in ritual purity. 10,17,18

Social isolation can affect the patient's general health, and might even cause diseases such as osteoporosis, hypertension, heart disease, depression and anxiety, thus reducing an individual's quality of life.^{19,20} Nursing care for this complication is based on the principle that urinary incontinence is not inevitably disease-dependent and is often reversible and curable.²¹ Pelvic floor muscles exercise is a non-medicinal, non-invasive and cost-effective method of controlling urinary disorders in these patients who can easily be trained by the medical personnel, including nurses, to perform it.^{3,18,22,23}

As nurses are in direct and constant contact with patients, it appears reasonable that they play an important role in helping patients accept non-medicinal treatments.²⁴

Training pelvic floor muscle exercises can greatly contribute to the prevention and treatment of urinary incontinence. ¹⁹These exercises can be considered the basis of a therapeutic behavior aiming to correct disorders such as stress and urgent incontinences or their combination, constituting a frontline treatment. ^{5,6} Many studies have been conducted on the effectiveness of pelvic floor muscle exercises in reducing the degree of the severity of urinary incontinence in women in their reproductive ages, in their postpartum period, with stress incontinence and also the elderly. ^{21,25-27} Lucio et al., studied the effect of pelvic floor muscle exercise training on symptoms of the lower urinary tract dysfunction and quality of life in women with multiple sclerosis. ^{28,29}

However, despite the high prevalence of postprostatectomy urinary incontinence, very few studies have been conducted on the effect of these exercises on urinary incontinence and quality of life in such patients.

Considering the importance of nursing interventions in the treatment and care of patients after prostatectomy and the high prevalence of urinary incontinence in these patients and also the lack of research conducted on the effect of pelvic floor muscle exercises on incontinence and quality of life in patients after prostatectomy in Iran, and also given the few side-effects of such interventions, the current study was designed and conducted with the purpose of determining the effect of pelvic floor muscle strengthening exercises on urinary incontinence and quality of life in patients after prostatectomy.

Materials and methods

This study has been extracted from a master degree dissertation. The ethical permission for the study was granted by the Ethics Committee of the Tehran University of Medical Sciences where the researchers are employed (ethical code: 93/130/914). The purpose and procedures of the research were explained to the patients, and written informed consents were obtained from them prior to their participation. The patients were informed of their rights to terminate their participation at any time throughout the study without facing any sort of penalty or impact on their routine care during hospitalization.

They were assured that their names would not be disclosed, and they could request a report of the study findings. Also, this clinical trial has been registered in the required website of Registry of Clinical Trial at the Registration code of IRCT2014090519049N1.

The present research is a parallel randomized clinical trial with a control group conducted at the urology department of Vali-e-Asr NAJA Hospital, Tehran, Iran (October 2015 until December 2015). The study population consisted of sixty eligible males. The inclusion criteria were: being candidates for suprapubic prostatectomy, being between 50-75 of age, having no cognitive errors, having no urinary incontinence for other

medical disorders such as diabetes mellitus, or urinary tract infections, having received no training for exercises and not doing such exercises prior to the surgery. If they were unwilling to continue their participation in the study or the dosage of medicine affecting their urinary incontinence was changed, they were excluded from the study. The patients were first selected, using the convenience sampling method, and were then randomly divided into a control and an intervention group. The intervention meant training the patients in the intervention group to perform face-to-face pelvic floor muscle strengthening exercises prior to the surgery and by the use of training pamphlets.

These exercises involved a series of pelvic floor muscle contractions in various positions, including, the supine position with bent knees, the sitting position and the standing position.³⁰ The patients were initially advised to maintain contractions for 3 seconds, followed by 5 seconds of rest, and then to gradually increase the duration of contractions to 10 seconds. These exercises were performed 3 times per day from the moment of admission, lasting for 12 consecutive weeks, and gradually increasing to 100 contractions per day. The regular performance of exercises was monitored on a daily basis and continued for 3 months after the surgery.

It should be noted that the patients in the intervention group were assessed with respect to their urinary incontinence before the surgery, after they had undergone surgery and two days after the urinary catheter was removed. In cases where the assessments came out positive, their performing of pelvic floor muscle exercises was monitored on a daily basis; otherwise, and if they had no complaints about incontinence two days after the removal of the urinary catheter, they were excluded from the intervention group. The control group only received the ward's patient education trainings. (Figure 1)

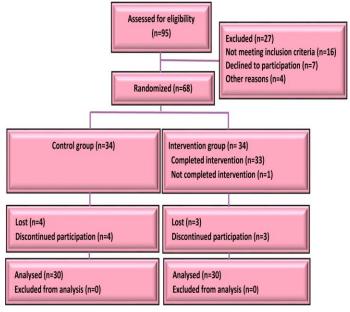


Figure 1. Flow chart of the study

The data collection tool consisted of a 3-part questionnaire and a checklist. The first part of the questionnaire contained the patients' personal information and was completed by them on the first day of admission. The validity of the demographic questionnaire and the check list was checked, using the face content validity (CVI) method; therefore, 10 faculty members approved it. The validity and reliability of the questionnaires were confirmed. The urinary incontinence Consultation questionnaire: International Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) had a validity of 0.88 and a reliability of 0.75.31,32 The validity of the quality of life questionnaire (I-QOL) had already been confirmed and used and was 0.85 while its reliability was calculated to be 0.88.28,33 The second part was the ICIQ-UI SF which assessed the patients' degree of incontinence and included 4 items:

1- the frequency of urine leakage (with the score ranging from 0 to 5), 2-degree of incontinence (with the score ranging from 0 to 6), 3-the timing of urine leakage,4-the effect of urine leakage on the patient's quality of life (with the score ranging from 0 to 10) on the frequency of urine leakage (with the score ranging from 0 to 5), degree of incontinence (with the score ranging from 0 to 6), the timing of urine leakage and the effect of urine leakage on the patient's quality of life (with the score ranging from 0 to 10). The overall score of the questionnaire varied from 0 to 21. In the end, the scores obtained in each dimension and the overall scores were compared before and after the intervention. The third questionnaire was the quality of life questionnaire I-QOL with 22 items in the 3 dimensions of psychological effects, avoidance behaviors and social effects. The scores were based on a 5-point Likert scale from 0 to 4, with 0 implying that urinary disorders had had no serious effects on the patients' quality of life as far as their health was concerned, and 4 indicating the extreme effects of urinary disorders on the patients' quality of life as far as their health was concerned. The questionnaires were filled out by the patients on the day of admission. If the patient confirmed their urinary incontinence two days after the removal of the urinary catheter, both control and intervention groups filled out the questionnaires of ICIQ-UI SF and QOL again. The patients completed these questionnaires on several occasions again, including 7 days, one month, two months and three months after the surgery. Selfreport checklists were distributed among the patients so that the frequency of muscle contractions could be recorded at every session, and the total number of muscle contractions along with the overall duration of exercise could be recorded per day for further support and follow-up of the training program. Over the course of the study, the researcher visited the urology clinic once a week to resolve potential problems and ensure the patients' adherence to the training program, and was also in touch with the patients over the phone every day to ensure the correct completion of the self-report checklists. To this end, the questionnaire scores obtained before and

after the intervention were compared against each other and their results were analyzed.

The data were analyzed, using SPSS (version 13.0, Chicago, IL, USA) and the normality of the variables was assessed using the Kolmogorov Smirnov test. Additionally, Chi-square tests were used for assessing the similarity of both groups in terms of the demographic characteristics. An independent t-test was used to compare the mean scores between the two groups, the repeated measure to compare the scores throughout the stages in each group. The level of statistical significance was set at P<0.001.

Results

The results showed that the control and the intervention groups were homogeneous and did not reveal statistically significant differences in terms of age distribution, Body Mass Index (BMI), employment status, economic status, type of insurance, having access to help with routine tasks and the duration of the disease.

However, there were statistically significant differences between them in terms of educational background (Table 1). Before surgery, nearly 40% of the control group and 60% of the intervention group had experienced urinary incontinence.

Table 1. Demographic variables of the participants

Variable	Intervention N (%)	Control N (%)	Р
Marital status	IN (70)	14 (70)	0.73
Single	7 (23.35)	8 (26.70)	
Married	23 (76.65)	22 (73.30)	
Educational level			0.01*
Illiterate	7 (23.35)	22 (73.30)	
Primary education	7 (23.35)	3 (10.05)	
High school education	3 (10.05)	3 (10.05)	
Academic education	13 (43.25)	2 (6.60)	
Job status			0.64
Employee	19 (63.33)	16 (53.35)	
Self-employment	6 (20.01)	10 (33.35)	
Unemployed	5 (16.66)	4 (13.30)	
Age (year)€	53.53(21.49)	51.23(20.62)	0.53

€ Mean (SD),*Statistically significant

Both the control group and the intervention group had reported their urinary leakage to have occurred most of the time seven days following the surgery [the Mean (SD) 14.76 (1.30) and 15.47 (2.16), respectively]. There were no significant differences between the two groups in this regard. However, one month after the surgery, both groups experienced urinary leakage just before reaching the bathroom or while putting on underwear [13.83 (1.58) and 11.90 (0.96)] in control and intervention group, respectively. Two months after surgery, the control group experienced urinary leakage quite frequently [the mean (SD) 13.53 (1.55)] while the intervention group only had this problem while putting on their underwear [the Mean (SD) 11.33 (0.55)]. Three months after surgery, the control group experienced urinary leakage either just before reaching the bathroom or while putting on their underwear [the Mean (SD) 13.07 (1.55)]. The intervention

group, however, no longer experienced this problem three months after the intervention [the Mean (SD) 9.90 (0.79)] (Table 2).

With respect to quality of life and its dimensions, the results showed, seven days after surgery, the subjects in

Table 2. The comparison of urinary incontinence in patients undergoing prostatectomy

Incontinence time	Intervention	Control	Р
	Mean(SD)	Mean(SD)	
7 days after surgery	15.47 (2.16)	14.76 (1.30)	0. 100
One month after surgery	11.90 (0.96)	13.83 (1.58)	0.001*
Two month after			
surgery	11.33 (0.55)	13.53 (1.55)	0.001*
Three month after surgery	9.90 (0.79)	13.07 (1.55)	0.001*

SD: Standard deviation ,*Statistically significant

both groups had a poor quality of life, with no significant differences existing between the two groups. However, one and two months after surgery, the quality of life was found to have improved in the intervention group, and three months after surgery, all members of this group seemed to be enjoying a very good quality of life.

As for the psychological dimension of the quality of life, no statistically significant difference was observed between the two groups seven days after surgery. However, the difference became statistically significant one, two and three months after the intervention (P=0.001), with the mean psychological dimension being greater in the intervention group.

As for the social effects and the avoidance behavior dimensions of quality of life, the difference between the two groups was statistically significant seven days after the intervention and also one, two and three months after surgery(P=0.001),and the mean avoidance behavior dimension was greater in the intervention group (Table 3).

Table 3. The comparison of the quality of life of patients undergoing prostatectomy

Intervention	Control	Р
Mean(SD)	Mean(SD)	
28.34 (5.05)	30.73 (8.81)	0.2
62.91 (3.22)	43.21 (13.54)	0.001*
89.18 (3.22)	47.00 (12.54)	0.001*
107.36 (2.57)	86.54 (14.84)	0.001*
	Mean(SD) 28.34 (5.05) 62.91 (3.22) 89.18 (3.22)	Mean(SD) Mean(SD) 28.34 (5.05) 30.73 (8.81) 62.91 (3.22) 43.21 (13.54) 89.18 (3.22) 47.00 (12.54)

SD: Standard deviation,*statistically significant

The results of examining the effect of urinary leakage on the quality of life showed a statistically significant difference between the two groups seven days after the intervention; however, there remained no statistically significant differences one month after the intervention.

Yet, two and three months after the intervention, the difference between the two groups was statistically significant once again (P=0.001). Additionally, the results did not seem to reveal statistically significant correlations between the patients' age group, BMI and the duration of

the disease and their urinary incontinence and the quality of life. ANOVA test showed Mean (SD) of UI and QoL are significantly reduced through multiple measurements after surgery in intervention group (respectively F=78.236, P<0.05 and F=2980.287, P<0.05) v.s control group (respectively F=13.758, P>0.05 and F=45.127, P>0.05).

Discussion

The results obtained from comparing the degree of postprostatectomy urinary incontinence in patients 7 days, and one, two and three months after the training showed both groups to have moderate urinary incontinence 7 days after the surgery. However, one month after the intervention, the majority of the intervention group (90%) and only 40% of the control group had mild urinary incontinence. The second and third months after the intervention, however, the entire intervention group had a mild degree of urinary incontinence while no improvements were observed in the control group, (40% of the subjects) compared to the first month. These results show that performing the exercises and sticking to them can lead to even better results in the patients. The results of the present study seem to be in concordance with those of the studies conducted by Zhang et al., Shahali et al., Marchiori et al., Seyed Rasooli et al.9,20,34,35

They also emphasize better results can be achieved three months after constant exercise and increased duration and repeating of pelvic floor muscle exercises, and also believe them to be effective in improving the quality of life in patients. The assessments of the timing of urinary leakage showed that 7 days and one month after the intervention, the majority of the participants in both groups experienced leakage most of the time especially before reaching the bathroom or while putting on their underwear. Yet, two months after the intervention, the control group still experienced leakage quite frequently while the intervention group only experienced the problem while putting on their underwear. Three months after the intervention, the problem still persisted in the control group as severely as it did during the first and second months while the intervention group did not seem to be experiencing the urinary leakage problem anymore. These results are consistent with results obtained by Golmakani et al., who found wider changes in the timing of urinary leakage in the intervention group compared to those of the control group; however, they are inconsistent with results of the study by Seyed Rasooli et al., who found changes in the timing of leakage not to be statistically significant after the intervention (P=0.09).26,35 The inconsistent results might be due to the difference in the prevalence of incontinence types in the latter study's population of elderly women. The results revealed that the patients' quality of life had improved from poor to good, and persisted in only a small percentage of the control group 7 days, one, two and three months after the intervention; however, the improvements in the psychological, social

effects and avoidance behaviors dimensions had improved from poor to very good in the intervention group. In the present study, all dimensions of the quality of life changed significantly after the intervention. However, there have been other studies reporting the quality of life scores obtained after treatments and through general questionnaires not showing statistically significant differences in all dimensions.³⁶ This inconsistency might be due to the use of a quality of life questionnaire specifically designed for the patients with urinary incontinence. Furthermore, the results have underscored the effectiveness of training and persisting in the exercises in improving the quality of life and psychological reducing numerous and social complications of incontinence such as, shame and embarrassment, lack of pleasure in daily activities and social relations. Urinary incontinence has often been reported to cause embarrassing situations and have a dramatic effect on the patients' social and emotional activities and indicators, thus reducing their personal quality of life.20 It is also known to affect various social and psychological aspects of an individual's life, limiting their ability to find pleasure in daily activities, trips and personal relationships.¹ Pelvic floor muscle exercises thus made significant improvements in an individual's quality of life and their ability to participate in social activities and reduced the negative effects of urinary incontinence on their life.31,34 Not only did these exercises reduce urinary incontinence, they also improved the patients' quality of life and modified their life styles. One of the limitations of this study was the time limitation. Therefore, a longitudinal follow-up study with similar design to this study is recommended.

Conclusion

The results of current study showed that performing pelvic floor muscle exercises can reduce urinary incontinence and improve the quality of life in patients undergoing suprapubic prostatectomy. Therefore, given the sensitive and vital role of nurses in training patients, the present study aspires to be conducive to better use of non-medicinal approaches, and to improve the health and clinical status of patients. Patients with adequate cognitive and mental abilities can easily be trained on pelvic floor muscle exercises.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

Research Highlights

What is the current knowledge?

Pelvic floor muscle strengthening exercise in patients after supra-pubic prostatectomy reduces urinary incontinence and improves quality of life in such patients.

What is new here?

The nursing profession pays great attention to providing high quality and effective care that is conceptualized as evidence-based practice and in fact evokes evidence-based practice for a comprehensive understanding of the concept of best clinical practice.

Author's contributions

Study design; Manuscript writing; Technical and material support: SFJ; Study design; Data collection and analysis, Manuscript writing: MR; Manuscript writing; Technical and material support: VNS; Study design; Data analysis, Manuscript writing; Technical and material support: ShV.

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