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The Effect of Pelvic Floor Muscle Training On Incontinence Problems After Radical Prostatectomy

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Abstract

The aim of the current study was to determine the effect of pelvic floor muscle exercises (PFME/Kegel) training administered to patients scheduled for robot-assisted radical prostatectomy on postprocedural incontinence problems.

This study was a randomized controlled trial. Pelvic floor muscle exercises were applied to the procedure group three times a day for 6 months. No exercises were applied to the control group. Incontinence and quality-of-life assessments of the 60 patients in the experimental and control groups were performed on months 0 (10 days after removal of the urinary catheter), 1, 3, and 6 through face-to-face and telephone interviews.

Total Incontinence Consultation on Incontinence-Short Form scores, which provide an objective criterion for the evaluation of individuals with incontinence problems, decreased over time. This decrease was statistically highly significant in the third and sixth months.

Pelvic muscle floor exercises are suitable for patients experiencing incontinence after radical prostatectomy.

Keywords

urinary incontinence, prostatectomy, muscle stretching exercises.

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Prostate cancer is one of the most common cancer types in men, and the prevalence increases with age (Vidmar et al., 2017). Although radical prostatectomy (RP) is considered the gold standard therapeutic option in patients with a life expectancy of more than 10 years for the treatment of organ-confined prostate cancer, post-RP complications are common (Sosnowski et al., 2011). Incontinence that may be encountered after RP is a surgical complication that significantly impairs quality of life (Hsu, Liao, Lai, & Tsai, 2016). While the postoperative incontinence rate is 1% in patients undergoing prostatectomy for benign reasons, a level of 2%–66% has been reported after RP (O'Callaghan et al., 2017).

Previous studies recommend that invasive methods for treating incontinence should be delayed for approximately 1 year (Ficarra et al., 2013; Frawley, Dean, Slade, & Hay-Smith, 2017). Behavioral therapeutic methods must always constitute the first step of treatment and must be primarily administered in eligible cases (Meyer, 2017). The treatment of incontinence therefore involves noninvasive behavioral therapeutic methods consisting of diet modification, bladder training, pelvic floor muscle exercises (PFME), biofeedback, and functional electrical stimulation. These methods are easily administered by health-care professionals. In addition to being inexpensive and effective, they involve no side effects (Santa Mina et al., 2014).

The aim of PFME, first defined by Arnold Kegel in 1948 as a behavioral therapeutic method for treating incontinence, is to enhance muscle volume and contraction strength in case of increased intra-abdominal

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pressure (Newman, 2014). While the physiological effects of PFME become visible after 2 weeks, symptoms are reported to decrease between 6 and 8 weeks, and significant improvement is observed by the sixth month (Chang, Lam, & Patel, 2016).

Previous studies have described incontinence problems that may occur postprocedurally in patients undergoing RP and have emphasized the positive effect PFME on these (Filocamo et al., 2005; MacDonald, Fink, Huckabay, Monga, & Wilt, 2007; Overgård, Angelsen, Lydersen, & Mørkved, 2008; Ribeiro et al., 2010; Tienforti et al., 2012; Lombraña, Izquierdo, Gómez, & Alcaraz, 2013). The purpose of this study was therefore to determine the effect on postprocedural incontinence problems (PFME/Kegel) training administered to patients scheduled for robot-assisted RP.

Methods

Participants and Procedure

The study was conducted from April 1, 2014, to January 1, 2015, in the Dr. Sadi Konuk Training and Research Hospital Urology Clinic, Istanbul, Turkey. A standard perioperative physiotherapy program, consisting of PFME and general physical activity, was applied. The training began in the preoperative period and involved both supervised and unsupervised contractions of the pelvic floor muscles in a range of functional positions. Continuous feedback regarding contraction techniques was given with the assistance of verbal and tactile pointers and real-time transabdominal ultrasound imaging. Transabdominal ultrasonography was performed approximately 1 cm above the urinary bladder and indicated sufficient pelvic floor muscle strength and contraction.

This experimental study was conducted to evaluate the effect of a 6-month Kegel exercise program (three sessions daily) on reducing incontinence after RP. The target population consisted of individuals diagnosed with localized prostate cancer.

The sample size was calculated before the procedure using Russ G-Power analysis software. Significance was set at an alpha level of 0.05, with a statistical power of .95 ($1 - ß$). A sample size of 64 was determined total for groups sufficient to establish a 37% difference. Participants were informed about the study and gave written informed consent to take part. Sixty patients, 30 in the experimental group and 30 in the control group (Figure 1), met the inclusion criteria and were evaluated at months 0 (10 days after urinary catheter removal), 1, 3, and 6 (Tienforti et al., 2012). The training was given 1 week before hospitalization (the day of arrival at the clinic), on the day of hospitalization, 1 and 2 days after surgery, and on removal of the urinary catheter at 10 days postoperatively.

Inclusion criteria. Inclusion criteria were a diagnosis of stable localized prostate cancer (stage T1 and T2 and Gleason score 2–4) as defined by the relevant guidelines use of the bilateral nerve sparing technique, absence of urinary incontinence before surgery, BMI < 30, an elementary school level of education such as to permit completion of the study forms, age 30–75 years, and voluntary participation in the study.

Instruments

Personal information form. This form contained 11 questions designed to collect information about subjects' sociodemographic characteristics and relevant medical histories.

Incontinence Diagnosis Questionnaire. This form contained 14 questions designed to collect information about numbers of episodes of incontinence, and their frequency and type.

Incontinence Assessment Scale—International Consultation on Incontinence Questionnaire Short-Form (ICIQ-SF). The first three of the four questions in the ICIQ-SF are intended to elicit data concerning the frequency, level, and impact of urinary incontinence. The total possible score ranges from 0 to 21, higher scores indicating greater severity of urinary incontinence. In the final question, participants indicate those activities during which urine leakage occurs from a range of alternatives, including coughing or sneezing, and during physical activity or exercise. No assistance was provided by the authors or any medical personnel during completion of the questionnaire.

Pelvic Floor Muscle Exercise Guide. This was prepared by one of the authors and contained PFME techniques and rules for application.

Data Collection

Subjects undergoing preoperative PFME training received one to four sessions before RP, each approximately 1 hr in duration. Detailed histories were taken, and comorbidity was evaluated during the first session. Anatomically exact models and diagrams were used to outline the architecture and functions of the bladder, urethra, and pelvic floor muscles. Subjects were instructed how to activate the pelvic floor muscles in various functional positions, such as lying down and standing upright. Feedback was given to subjects through transabdominal ultrasound imaging. Superior displacement of the bladder base exceeding 1 cm was regarded as indicating successful activation of the pelvic floor muscles. Activation of the superficial abdominal muscles was reduced by means of visual and tactile pointers, which also helped ensure that subjects did not hold their breath during pelvic floor activation.

Repeated activations (20 contractions, each lasting 10 s) of the pelvic floor muscles were performed under supervision in sitting, standing, and supine positions, during all preoperative sessions. Patients were also advised to repeat the exercises every day at home, as well as while performing normal day-to-day activities, including raising objects, squatting on the ground, and coughing. Patients performed a home program of 60 contractions per day and were instructed regarding contracting the pelvic floor muscles while coughing and sitting down or rising from a chair. They were asked to color in three squares in their diaries (each square representing 20 contractions). The subjects were also given additional written material and diagrams covering the PFME program (Mungovan, Huijbers, Hirschhorn, & Patel, 2014).

The authors monitored the control group (the group not performing PFME). Control Group Procedures: The patients in the control group were given information about the study in advance, and informed consent was obtained from each individual. We administered the same questionnaire to both groups; however, the control group did not receive PFME training. Members of the control group were given only breathing exercises and any questions they might have about the operation. In the last week of the study, the participants completed the questionnaire and ICIQ-SF assessment scale once again. When the data collection process ended, we taught the members of the control group how to perform the Kegel exercises.

The primary outcome measure was the self-reported recovery of continence 6 months after catheter removal. Continence was strictly defined as an ICIQ-UI score of zero. The secondary outcome measures were score of incontinence scale and number of pads used per week.

Data Analysis Plan

Statistical analyses were performed on Number Cruncher Statistical System 2007 & Power Analysis and Sample Size 2008 Statistical Software (Utah, USA). Student's *t* test was used to compare normally distributed variables between the two groups for quantitative and descriptive data (mean, standard deviation, median, frequency, level, minimum and maximum). Pearson's χ^2 test, Fisher's exact test, the Fisher-Freeman-Halton test, and Yates' continuity correction test (Yates-corrected χ^2) were applied for the comparison of qualitative data. Significance levels were set at $p < .01$ and $p < .05$.

Ethical Considerations

Written approval from the local Ethical Committee and written consent from the host institution were obtained before the study began. Patients scheduled for RP in both groups received information concerning the training program and the aim and content of the study. Written informed consent was obtained from all participants before any study procedures commenced. Prior written permission (via e-mail) was also obtained from Bülent ÇETİNEL to use the Turkish-language adaptation of the ICIQ-SF.

Results

The mean age of the experimental group (n = 30) was 63.00 ± 8.61 years and that of the control group (n = 30) was 59.93 ± 6.98. Mean body mass index (BMI) was 26.4 in the experimental group and 25.8 in the control group, the difference being statistically significant ($p < .05$; Table 1).

A significant difference was observed in the number of incontinence pads used in the first month between the groups ($p < .01$). Significantly more members of the experimental group reported using "1–3 pads per week" or "4–6 per week" while more members of the control group used "more than 5 per week" ($p < .01$).

The numbers of pads used in the two groups also differed significantly in the sixth month ($p < .01$), with more members of the experimental group reporting "I do not use pads" or "I use 1–3 per week," while significantly more members of the control group reported using "1–3 per week" or "3–4 per day" (Table 2).

In terms of type of post-RP incontinence, 68% (n = 41) of patients in both groups suffered from stress, 25% (n = 15) from urge incontinence, and 7% (n = 4) from mixed type incontinence (Table 3).

The control group (14.27 ± 3.25) scored significantly higher at month 3 than the experimental group (9.03 ± 3.55) ($p < .01$). At month 6, the mean control group score (14.63 ± 3.02) was again significantly higher than that of the experimental group (6.17 ± 2.85; $p < .01$; Table 4).

Table 1. Group-Based Evaluation of Identifying Characteristics.

		Experimental	Control	
		Mean ± *SD*	Mean ± *SD*	*p*
Age (year)		63.00 ± 8.61	59.93 ± 6.98	[a].135
≤ 45 (*n*)		1 (3.3)	0	
BMI		26.4	25.8	[a].010*
		23.9–29.4	22.8–27.7	
Smoker	**Yes**	12 (40.0)	14 (46.7)	[b].602
	No	18 (60.0)	16 (53.3)	
Alcohol consumption	**Yes**	5 (16.7)	5 (16.7)	[c]1.000
	No	25 (83.3)	25 (83.3)	
Pathological stage, n	**pT1c**	2 (6.7)	3 (10.0)	
	pT2a	7 (23.3)	6 (20.0)	
	pT2b	5 (16.7)	3 (10.0)	
	pT2c	16 (53.3)	18 (60.0)	
Surgical margins, *n*	**Positive**	9 (30.0)	4 (13.3)	
	Negative	21 (70.0)	26 (86.7)	
Gleason score, n	**2**	9 (30.0)	11 (36.7)	
	3	17 (56.7)	14 (46.6)	
	4	4 (13.3)	5 (16.7)	
Perineural invasion	**Yes**	8 (26.7)	5 (16.7)	
	No	22 (73.3)	25 (83.3)	

Note. [a]Student's *t* test; [b]Pearson's χ^2 test; [c]Fisher's Exact test; [d]Fisher Freeman Halton test.
$*p < .05$. $**p < .01$.

Table 2. Group-Based Evaluation of Numbers of Pads Used.

		Experimental	Control	
Number of pads used		*n* (%)	*n* (%)	*p*
	None used	3 (10.0)	4 (13.3)	
Month 0	**1–3 per week**	9 (30.0)	8 (26.7)	
	4–6 per week	12 (40.0)	9 (30.0)	[a].07
	1–2 per day	4 (13.3)	4 (13.3)	
	3–4 per day	2 (6.67)	2 (6.67)	
	>5 per day	0	3 (10.0)	
Month 1	**I don't use**	6 (20.0)	2 (6.7)	[a].008**
	1–3 per week	7 (23.3)	1 (3.3)	
	4–6 per week	11 (36.7)	4 (13.3)	
	1–2 per day	3 (10.0)	4 (13.3)	
	3–4 per day	2 (6.7)	2 (6.7)	
	>5 per day	1 (3.3)	17 (56.7)	
Month 3	**None used**	7 (23.3)	1 (3.3)	[a].095
	1–3 per week	16 (53.3)	12 (40.0)	
	4–6 per week	5 (16.7)	6 (20.0)	
	1–2 per day	2 (6.7)	5 (16.7)	
	3–4 per day	0	6 (20.0)	
Month 6	**None used**	15 (50.0)	1 (3.3)	[a].001**
	1–3 per week	11 (36.7)	9 (30.0)	
	4–6 per week	4 (13.3)	6 (20.0)	
	1–2 per day	0	5 (16.7)	
	3–4 per day	0	9 (30.0)	

Note. [a]Fisher Freeman Halton test.
*Ten days after catheter removal. $**p < .01$.

Table 3. Incontinence Type Distributions of Groups.

Type of incontinence (*N* = 60)	%
Stress incontinence	68
Mixed incontinence	25
Urge incontinence	7
Total	**100**

The control group (14.27 ± 3.25) scored significantly higher at month 3 than the experimental group (9.03 ± 3.55) [mean difference (95% CI) −5.233 [−6.996, −3.470], $p < .01$]. At month 6, the mean control group score (14.63 ± 3.02) was again significantly higher than that of the experimental group (6.17 ± 2.85) [mean difference (95% CI) −8.467 [−9.986, −6.947], ($p < .01$)].

Table 4. Total Mean ICIQ-SF Scores.

	Total		Experimental		Control		
ICIQ-SF	Min–Max	Mean ± *SD*	Min–Max	Mean ± *SD*	Min–Max	Mean ± *SD*	*p*
Month 0*	2–4	2.11 ± 0.45	2–4	2.10 ± 0.40	2–4	2.13 ± 0.51	.973
Month 1	2–20	11.33 ± 4.20	2–20	11.10 ± 5.04	6–19	11.57 ± 3.2	.911
Month 3	2–21	11.65 ± 4.28	2–19	9.03 ± 3.55	8–21	14.27 ± 3.25	.001**
Month 6	2–20	10.40 ± 5.16	2–11	6.17 ± 2.85	8–20	14.63 ± 3.02	.001**

Note. *Ten days after catheter removal. **$p < .01$.

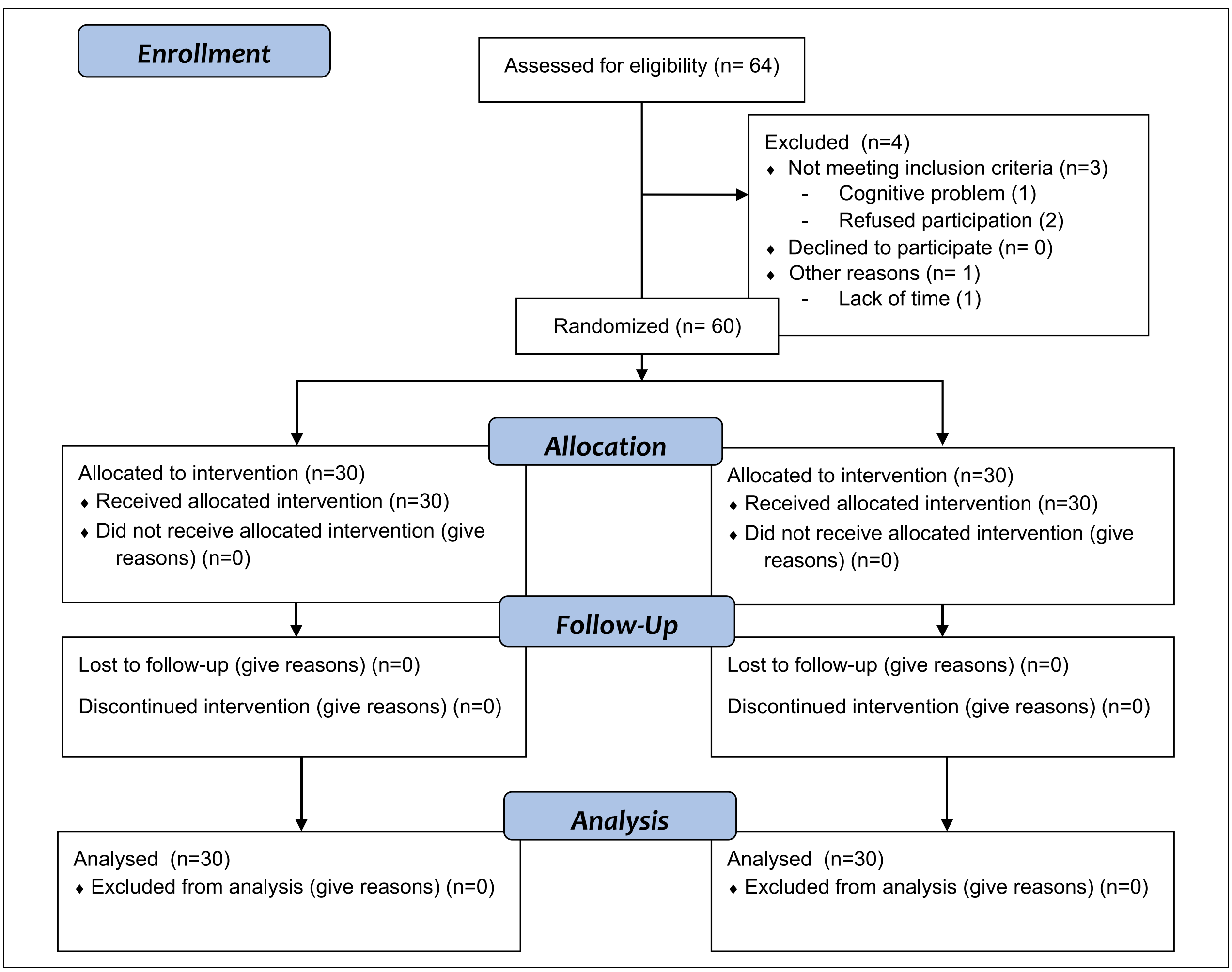

Figure 1. Consort diagram.

Discussion

Post-RP incontinence is a complication that significantly impairs quality of life and and one involving a high expectation of treatment expectation on the part of patients (O'Callaghan et al., 2017). Previous studies have reported that increased BMI also increases the risk of cancer and urinary incontinence (Chamie et al., 2013; Dickerman et al., 2017). Regular exercise and weight loss are associated with colon, rectum, pancreas, stomach, and prostate cancer. Studies have reported a particularly high risk of prostate cancer in male subjects with elevated leptin hormone, insulin, and IGF-1 (Nishimura et al., 2012; Sharma et al., 2014). Blewniewski, Markowski, Kliś, and Różański (2015) investigated stress urinary incontinence and obesity and reported that high BMI increases urinary incontinence (Blewniewski et al., 2015). Matsushita et al. (2015) investigated continence after RP and reported that high BMI has an adverse impact on continence (Matsushita et al., 2015).

In the current study, since the difference between the experimental and control groups was not significantly disfavorable to the experimental group, it does not constitute a risk to the credibility of the research. Since being overweight is an important risk factor for incontinence, the presence of subjects with higher BMI in the experimental group will be a useful factor in evaluating the effectiveness of PFME training.

Patients with incontinence problems may seek to disguise these using cloths or pads. For most patients, this can result in social phobia and lead to social isolation (How & Quah, 2013). Previous studies have emphasized that urinary incontinence and numbers of pads used can be reduced by increasing muscle strength with PFME training (Overgård et al., 2008; Ribeiro et al., 2010; Newman, 2014).

Geraerts et al. (2013) provided PFME training for an experimental group before and after surgery and for a control group on the day of catheter removal. No difference was observed between the two groups in terms of urinary incontinence rates measured using the 24-hr pad system.

In a single-center, randomized controlled study of 32 experimental and 34 control patients titled "efficiency of perioperative low-density pelvic floor muscle training program in improving recovery from continence after radical prostatectomy" by Tienforti et al. (2012), patients were given oral and written training on Kegel exercises and were evaluated on the first, third, and sixth months following catheter removal. At the third and sixth months, the number of pads used decreased, and ICIQ scores approached 0 at the sixth month (Tienforti et al., 2012).

Filocamo et al. (2005) evaluated a group that received PFME training after radical prostatectomy as "dry" at first, third, and sixth month evaluations (Filocamo et al., 2005). Mariotti et al. (2015) reported < 2 g pad test or no pad use in the 24 hr following training involving PFME and electrical stimulation (Mariotti et al., 2015). A study involving biofeedback and PFME training by Ribeiro et al. reported 96% recovery in the sixth month, and that no pads were thus used in the experimental group (Ribeiro et al., 2010). Patel, Yao, Andrew, Hirschhorn, and Mungovan (2013) performed sixth week and third month evaluations following PFME training given by four physiotherapists prior to RP. After 6 weeks, the 24-hr pad test results were < 9 g versus 17 g, p 50 g < .001, and urinary incontinence was significantly decreased. Continence also increased at the end of the third month ($p < .05$) (one pad used per day).

In this study, no incontinence was initially observed in either group. In the first month, the number of pads used was statistically significantly higher in the experimental group. However, by the sixth month, the number of pads used was significantly lower in the experimental group ($p < .01$), in agreement with the findings of previous studies. This suggests that PFME training strengthens the muscles and that bladder control can thus be acquired.

Previous studies have emphasized the need to identify the type and severity of incontinence in the evaluation of patients with post-RP incontinence. Stress, urge, and mixed incontinence have been observed post RP (Lim, Liong, Leong, Khan, & Yuen, 2015; Fernández-Cuadros et al., 2016). Terzoni, Montanari, Mora, Ricci, and Destrebecq (2013) investigated whether pelvic floor muscle training or magnetic stimulation was more effective in preventing incontinence after RP, or whether no treatment should be provided. The most common form of incontinence was stress incontinence with a prevalence of 65%, followed by mixed type at 13%, and urge type incontinence at 5%. Ayhan, İyigün, Göktaş, and Hatipoğlu (2008) investigated the difficulties experienced by men after RP, and reported that 72.7% of patients experienced stress incontinence and that the social lives of 70.4% were adversely affected. Stress incontinence was observed in 41 of those patients (68%), mixed incontinence in 15 (25%), and urge incontinence in 4 (7%), consistent with this study' findings. In this research, the high incidence of stress incontinence is attributed to deficiencies in sphincter function after RP.

The ICIQ form has been described as a new scale that can be used in epidemiological research and in routine clinical evaluation of incontinence and quality of life (Karmakar, Mostafa, & Abdel-Fattah, 2017). Gotoh, Homma, Funahashi, Matsukawa, and Kato (2009) evaluated the scale's psychometric properties, and its reliability was confirmed by Çetinel (2005) in Turkey. Within the study, the internal consistency of the scale was 0.78, Kappa coefficients were 0.61 and 0.62, and correlation coefficients within the group were 0.90 and 0.91. For concurrent validity, the ICIQ-SF scores were compared with King's Health Questionnaire (KHQ) subscales and with both the 1-hr pad test and the number of daily incontinence attacks. The ICIQ-SF scale was identified to exhibit a more accurate trend. Japanese researchers have described the ICIQ-SF as a valid, reliable, and sensitive scale for patients with incontinence problems.

Pedriali et al. (2015) compared PFME with Pilates in 85 patients in terms of levels of incontinence after RP and concluded that the two methods were equally effective. A decrease in the amount of pads used and ICIQ-SF scores was observed with both procedures. Tienforti et al. (2012) reported an ICIQ-SF score of 0 at the end of the sixth month following PFME and biofeedback procedures.

PFME training given by Ribeiro et al. (2010) prior to RP resulted in a highly significant decrease in ICIQ-SF scores at the end of the sixth and twelfth months ($p < .001$).

ICIQ-SF scores in this study decreased in the experimental group but increased in the control group, and this decrease was statistically significant at the third and sixth months. This result, which is compatible with findings from the previous literature, may be interpreted as evidence that pelvic floor muscle training becomes effective when performed regularly over an extended period and that it reduces patients' incontinence problems.

Limitations

The principal limitation of the study was the relatively small sample, made up of subjects attending the Dr Sadi Konuk Research and Education Hospital Urology Clinic. The findings cannot therefore be extended to society in general.

Conclusion

This research was planned and conducted as a randomized controlled experimental study in order to determine the effect of pelvic floor muscle training on incontinence problems after RP. The number of pads used in the first month was highly statistically significant, with large numbers of patients responding "1–3 per week" and "4–6 per week" in the experimental group and ">5 per day" in the control group. The amount of the pads used in the sixth month was also highly statistically significant, with large numbers of patients responding "never" in the experimental group and responding "1–6 per week" and "3–4 per day" in the control group. Monthly ICIQ-SF scores decreased in the experimental group while increasing in the control group. This decrease was highly statistically significant in the third and sixth months.

Preoperative PFME is a treatment strategy significantly more effective than the standard care in improving recovery of continence in patients undergoing RP. Distinct improvements were observed in training parameters among the active treatment group compared to the controls. In particular, Kegel training promoted similar outcomes in the proportion of fully continent patients compared to pelvic floor muscle training third and sixth months after RP. It also achieved a higher rate of fully continent patients when compared to the control group in the short term. PFME may improve early continence and ICIQ-SF outcomes after RP. Further studies are now needed to corroborate our results.

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Declaration of Conflicting Interests

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