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Effect of Pelvic Floor Electrical Stimulation and Biofeedback on the Recovery of Urinary Continence after Radical Prostatectomy

Radikal Prostatektomi Sonrası Üriner İnkontinansın Düzelmesinde Pelvik Tabanda Biofeedback ve Elektrik Stimülasyonunun Etkisi

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Summary

Objective: Urinary incontinence (UI) is one of the most distressing postoperative problems of radical prostatectomy (RP) and negatively affects the quality of life (QOL). We assessed the effect of pelvic muscle exercises (PME), electrical stimulation (ES) and biofeedback (BFB) on UI after RP.

Materials and Methods: 80 patients, who underwent RP, were randomized into three groups. Group I (n=26) received instructions about PME, group II (n=26) received ES and group III (n=28) received ES plus BFB. The treatment was started one week after catheter removal, twice a week for 12 weeks. The evaluation of continence was performed at time 0, 6, 12 weeks, and 24 weeks during follow-up, using the 24-hour pad test and the QOL using the incontinence impact questionnaire -7 (IIQ-7).

Results: The mean leakage weight became significantly lower ($p<0.05$) in group III than in groups II and I starting at 6 weeks until 24 weeks of follow-up. A significant difference ($p<0.05$) between the groups in terms of percentage of continent patients was achieved from 12 weeks (71.42%, 53.85% and 34.62%) to 24 weeks (96.43%, 76.92% and 65.38%) for groups III, II and I, respectively.

Conclusion: Early, noninvasive therapy with ES and BFB has a significant positive effect on the duration and the degree of UI and QOL. *Turk J Phys Med Rehab 2012;58:170-6.*

Key Words: Urinary incontinence; radical prostatectomy; electrical stimulation; biofeedback

Özet

Amaç: Üriner inkontinans (Üİ) radikal prostatektominin (RP) en sıkıntı verici ameliyat sonrası komplikasyonlarından olup, yaşam kalitesini (YK) olumsuz etkiler. Bu çalışmada pelvik kas egzersizleri (PKE), elektrik stimülasyonu (ES) ve biofeedback (BFB) uygulamasının RP sonrası Üİ üzerindeki etkisini araştırdık.

Gereç ve Yöntem: RP geçirmiş 80 hasta üç gruba randomize edildi. Grup I e (n=26) PKE, Grup II'ye (n=26) ES ve Grup III'e (n=28) ES artı BFB verildi. Kateterin çıkarılmasından bir hafta sonra başlanan tedavi on iki hafta boyunca haftada iki gün uygulandı. 0, 6, 12 ve 24. haftalardaki takip sırasında kontinans 24 saatlik ped testi ile yaşam kalitesi ise inkontinans etki anketi-7 (IIQ-7) ile değerlendirilmiştir.

Bulgular: Grup I de, altıncı haftadan başlayarak 24 üncü hafta takiplerine kadar görülen ortalama sızıntı miktarı Grup I ve II ye göre önemli ölçüde daha azdı. Gruplarda kontinans oranı bakımından 12. haftada (Grup III, II ve I için sırasıyla %71,42, %53,85 ve %34,62) ve 24 üncü haftada (%94,43, %76,92 ve %65,38) önemli farklara ulaşıldı.

Sonuç: ES ve BFB ile erken noninvaziv terapinin Üİ süresi ve derecesi ile YK üzerinde önemli bir etkisi bulunmaktadır. *Türk Fiz Tıp Rehab Derg 2012;58:170-6.*

Anahtar Kelimeler: Üriner inkontinans; radikal prostatektomi; elektrik stimülasyonu; biofeedback

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Introduction

Urinary Incontinence (UI) is a devastating complication after Radical Prostatectomy (RP) and negatively affects the quality of life (QOL) (1). UI develops in the majority of patients during the early postoperative days. Peyromaure et al. (2) emphasized that early UI affects 30% to 50% of patients from 3 weeks to 6 months after RP. Rates vary widely due to survey methods, the definition of incontinence and surgical technique. However, spontaneous improvement in continence status may occur up to one year after RP (3). The main causes of Post-Prostatectomy Incontinence (PPI) might be intrinsic sphincter deficiency, and/or detrusor overactivity and/or decreased bladder compliance (4).

There were several studies on the role of Pelvic Muscle Exercises (PME), Electrical Stimulation (ES), and biofeedback (BFB) (5-21). Of thesis studies, some showed better continence for PME group (3,6-13), while others did not show improvement (4,5,14-20). ES is one method, which may enhance the success of PME in patients with incontinence after RP (12,24). ES can artificially stimulate the pudendal nerve and its branches to cause direct and reflex responses of the urethral and periurethral striated muscles (12). However, the beneficial effect of ES plus PME on UI after RP needs to be verified by a randomized control trial. In addition, few studies did not show any significant benefit from PME and BFB compared with a control group (11). A recent Cochrane review stated that results remain uncertain. The discrepancies occur in the reported trials because of low to moderate quality of most studies, lack of randomization and lack of a control group, and the considerable variation in the interventions, populations and outcome measures (21).

In this prospective randomized, controlled trial, we analyzed the combined effects of ES and BFB enhanced PME on the recovery of UI and QQL after RP.

Materials and Methods

Subjects

From July 2007 to February 2010, a total of 95 patients who underwent RP for clinically localized prostate cancer at the National Institute of Urology and Nephrology were screened for this study. The operation was performed by four urologists without any knowledge concerning the outcome of randomization procedure. All patients were discharged with an indwelling catheter which was removed approximately 10 days (range 7-15 days) postoperatively. None of the patients were prescribed anticholinergic drugs or any drugs that influence continence during the study. Exclusion criteria were: (1) previous urethral, bladder or prostate surgery (6), (2) prior urinary or fecal incontinence, (3) neurogenic and psychiatric disorders, (4) preoperative urinary tract complications, (5) radiotherapy (7,9).

All patients signed an informed consent form before randomization. The patients were randomized into one control group and two treatment groups, using a computer generated random-number list placed in sealed envelopes. Following randomization, the subjects in each group were informed about the aims and perspectives of the study. One experienced physiotherapist delivered all therapy at the Physical Therapy Clinics at El-Materia Teaching Hospital, Cairo, Egypt. Treatment adherence monitored using patient-recorded diaries provided at the initial visit. At the time of this study, there was no Human Research Ethics Committee established in the faculty, but the study was approved by the postgraduate affairs and departmental committee. In order to have statistical power of 0.80 and $p<0.05$, it was calculated that 80 subjects were required to detect a 35% difference in improvement in self-reported urinary continence, and the sample size was increased to 95 to guard against the possible situation where some of the subjects would not complete the study.

Outcome Assessment

The evaluation of PPI was performed one week after catheter removal (W0), at 6 (W6) and 12 (W12) weeks of intervention. Follow-up assessment has been performed 24 weeks (W24) after removing the catheter.

The primary outcome measure was self-reported continence/incontinence using the 24-hour pad test. The definition of UI was according to the guidelines of the International Continence Society (ICS) where continence is defined as no need for wearing a pad (0 pads) (22). The 24-hours pad test is a standardized test using pre-weighed pads changed and weighed every 2 hours, with a chart of the frequency, volume and time of voids and the amount and type of fluid intake. The pad test is capable of detecting a one gram urine loss if the pads are placed in a sealed plastic bag (23).

The secondary outcome was the impact of incontinence on the QOL measured by the incontinence impact questionnaire-7(IIQ-7). The IIQ-7 has seven questions regarding the impact of UI on socializing, emotional health, physical activity and travel. Items are summarized to give a single score ranging from (0 "not at all") to 100 ("a great deal") (28). The IIQ-7 is reliable and valid in men with incontinence after RP (1). The IIQ-7 was translated into Arabic language that is easily understood by all Arabic speaking communities. The modified Arabic IIQ-7 (appendix) used in this study has a good test-retest reliability and validity to assess the impact of urinary incontinence on QOL (29). Because urodynamic studies are invasive, they were avoided and used only in patients with UI after the 6-month follow-up according to ICS standards (25).

Intervention

Patients in the control group were not given ES, BFB or formal education of PME after catheter removal. They received the usual instruction to conduct PME, which included verbal instruction (how to correctly and selectively contract the anal sphincter while relaxing the abdominal muscles), by the physiotherapist, and written examples of exercises (Kegel exercises) at the catheter removal visit and during follow-up visits. The patients received an informative booklet with these instructions. The patients performed three set of 15-20 contractions daily. The duration of each constriction was 3-5 seconds with a relaxation period of 6-10 seconds. Initially, the

patients practiced these exercises while supine but later when sitting, standing, squatting, and going up and down stairs. After that, patients were encouraged to practice the exercises before any effort or activity that might induce incontinence (sneezing, coughing, or lifting a weight).

Patients in the ES group were included in the ES program that began one week after catheter removal. Treatment time was set for 15 minutes, twice weekly for 12 consecutive weeks. Stimulation parameters were 50 Hz square wave with a 300 µs pulse width with output current of maximum tolerable intensity (26). The sites of electrode application were placed symmetrically on the skin surface over 2nd through 4th sacral outflow, where the lateral border of each electrode placed over the posterior superior iliac crest, and the inside border located one finger width from the midline (27).

Patients in the BFB group were included in an early ES+BFB that began one week after catheter removal. Patients received the treatment twice weekly for 12 weeks. Each of the 24 treatment sessions was homogeneously composed of a first part with BFB (15 minutes) followed by a second part with ES (15 minutes). For BFB, a 2-channel electromyographic BFB apparatus (Reactive Biofeedback, BEAC, Stradella, Italy), was used with one channel for perineal, and the other for abdominal muscles and the signal received through surface electrodes (9,10). In the right lateral decubitus position, patients practiced 3 series of 10 rapid contractions to improve the phasic musculature component. Then, patients practiced 3 sustained contractions of 5, 7 or 10 seconds depending on ability to maintain the contraction of the pelvic floor muscle tonic component. Subjects were then placed in the supine position, with hips flexed to approximately 60 degrees, to practice 10 contractions during prolonged expiration, avoiding the Valsalva maneuver (28).

All patients were given a diary logbook to complete on a daily basis during the intervention period. They were asked to maintain a daily self-report of their daily exercise activities. The content of the logbooks did not differ between active laser and placebo groups.

All variables are described in terms of mean and Standard Deviation (SD) or range and proportions. ANOVA was used with normally distributed variables otherwise, Friedman and the Wilcoxon's nonparametric tests. Alpha level of <0.05 was considered statistically significant. Statistical analysis was done using a statistical package for social science (SPSS Inc., Chicago, IL), version 11.0.

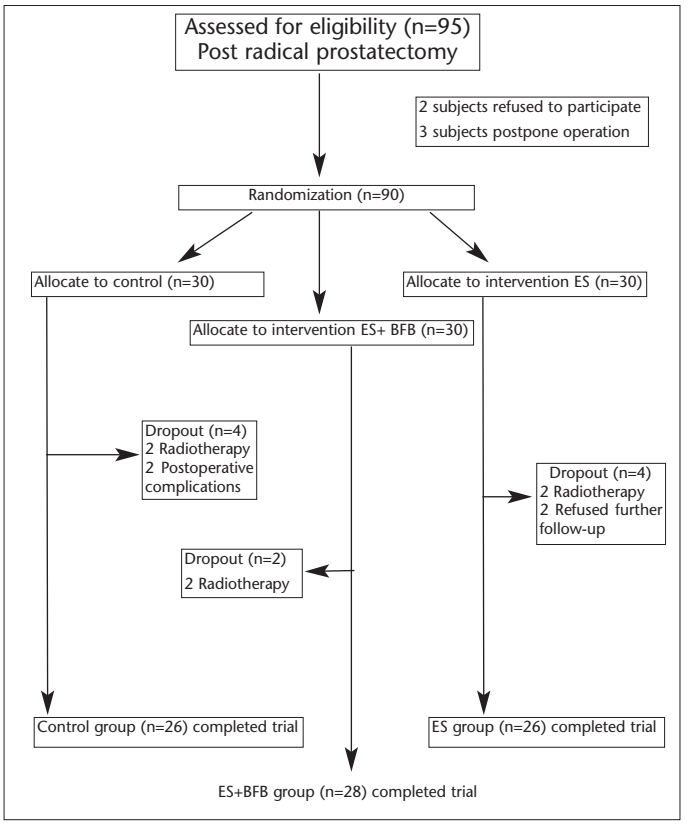

Figure 1. Study flow chart.

Results

Participant Flow

Figure 1 is a patient participant flow chart. 95 patients met the eligibility criteria. Data were available for 90 patients who were randomized into three groups. There were 10 patients who did not complete the trial because they could not attend the ambulatory schedule for various reasons. A total of 80 patients completed the trial, included 26 in the control group, 26 in the ES group and 28 in the ES+BFB group. As shown in Table 1, all groups were homogeneous with respect to the demographic, pathological and operative characteristics.

Self Report Incontinence Rate:

One week after W0, the mean leakage weight was similar in all groups (χ^2=1.89, p>0.05). There were a significances at W6 (χ^2= 28.15, p<0.05), W12 (χ^2= 16.19, p<0.05) and W24 (χ^2= 2.89, p<0.05). Between-group comparisons revealed that, the mean leakage weight decreased significantly (p<0.05) in the ES+BFB group than in the ES and control groups at W6, W12, and W24, respectively. A significance difference was observed between the ES group and the control group at W6, and W12 and non-significance at W24 (Table 2).

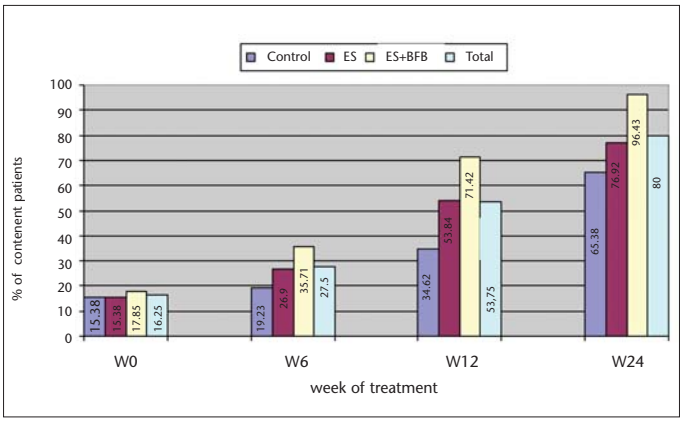

Figure 2. Comparasion of control and EsS groups.

After catheter removal, the continence rates were similar (p>0.05) between the groups. The overall continence rates were increased to 27.5% and 73.75% at W6 and W12, respectively. There was a significant (p<0.05) increase in continence rate in the ES+BFB group (35.71% and 71.42%) compared to that in the control and ES groups (19.23% and 34.62%) and (26.9% and 53.85%) at W6 and W12, respectively. The overall continence rates were increased to 80% at W24. Continence rate was significantly (p<0.05) increased in the ES+BFB group (96.43%) compared to that in the ES and control groups (76.92% and (65.38%, respectively). There was no significant difference between the control and ES groups (p>0.05) (Figure 2).

At W24, there were 1 patient (3.57%) in the ES+BFB group, 6 patients (23.07%) in the ES group, and 9 patients (34.62%) in the control group remained incontinent (1 or more pads, urine loss greater than 2 gm). All incontinent patients underwent urodynamic evaluation that showed a sphincter deficiency in 1 of 1 in the ES+BFB group, in 3 of 6 in the ES group and in 7 of 9 in the control group. Detrusor over activity detected in 3 of 6 in the ES group, and in 2 of 9 in the control group.

Quality of Life on IIQ-7

There were no significant differences in terms of QQL as measured by the modified IIQ-7 (p>0.05), between the groups at baseline (W0). A significant change in the overall QQL was demonstrated (p<0.05) at W6, W12 (p<0.04) and W24 (p<0.05) compared to baseline. We found significant improvement on the recorded impact of IU at each time of measurement within each group compared to baseline, with greater improvement observed in the ES+BFB group compared to the control and ES groups. A non significant difference was observed between the ES and the control groups, Table 3.

Discussion

Urinary incontinence after radical prostatectomy has many causes; the main factor seems to be insufficiency of the sphincteric mechanism and/or bladder abnormalities caused by the anatomical and functional changes during surgery such as direct surgical trauma, neural injury, and decreased elasticity of the bladder neck (3,30). Thus, different therapeutic approaches, such as PME, ES and BFB have been used, although discrepancies occur in the reported efficacy of conservative treatment for incontinence.

In this study, the active BFB+ES group achieved continence significantly faster than the control group and the ES group suggesting that ES+BFB may promote early recovery of continence even in patients with severe IU after RP. The significance of our study is based on the prospective randomized assignment of treatments vs. control, on the homogeneous characteristics of the 3 groups and on the objective evaluation of outcome assessment. In particular, in all patients, the catheter was removed at 10 days and had severe UI with a mean leak of more than 650 gm. The patients were considered the continent when no pads were required and the weight gain of the pad during the test was 1 gm or less. A more objective evaluation of UI would be the urodynamic evaluation. However, these investigations are invasive, especially soon after surgery, and they do not correlate better with subjective rates (overestimating clinically important UI rates) (18,30). Thus, in the current study, and as previously reported, urodynamics was postponed and used only in refractory cases after 6 months (10). Homogeneously, all patients started treatment early at 7 days after catheter removal, with treatment schedule of only 2 sessions per week for 12 weeks.

Table 1. Baseline clinical characteristics of participants.

Characteristic	Group 1 (n = 26) mean± (SD)	Group 2 (n = 26) mean± (SD)	Group 3 (n = 28) mean± (SD)
Age (yr)	57.2±3.25	58.8±5.4	56.3±6.8
Body mass index (kg/m^2)	32.8±3.2	35±4.5	33.9±3.4
Prostate Specific Antigen (ng/ml)	10.7±9.1	9.8±6.6	8.13±4.7
Clinical stage %			
T1	57.69%	53.85%	57.14%
T2	26.93%	30.77%	28.57%
T3	15.38%	15.38%	14.28%
Nerve sparing %			
No nerve sparing	30.77%	34.62%	35.71%
Yes (Unilateral+ Bilateral)	69.23%	65.38%	64.29%
Operation time (minutes)	225±45	235±55	245±45
Blood loss (ml)	1067±576	1080±712	1073±760
Prostate weight (gm),	45.1±12.8	49.76 ±14.2	48.13±16.60
Pathological stage %			
pT2	79.92%	73.07%	78.57%
pT3	23.08%	26.93%	21.43%

There were no statistically significant differences between groups.

In this study, the BF+FES treatment showed a significance advantage in terms of objective continence rates compared to active ES and the control groups. It is impossible to estimate the exact contribution of each method to the result, but BFB and ES work together in this set up. The rationales for placing ES and BFB in the same session is to perform the three consecutive steps in each session: (1) to provide the patient with feedback on what is being trained to achieve the therapeutic outcome, when the patient is not able to contract the external sphincter in isolation, (2) to increase the power and endurance of pelvic floor muscles and (3) stimulate the periurethral striated muscle for neuro-modulation that affects the neural signaling that controls continence (31). This type of treatment helps patients to perform better and continue exercises at home, to improve the voluntary control of the pelvic floor and supports the primary urethral closure mechanism. If the muscles work efficiently (ES+BFB) it is easier for the patient to create an autonomic pelvic floor contraction to prevent stress events. Fatigue of the periurethral striated muscles is often the cause of increased urine loss during the day, and this can be prevented by ES+BFB treatments.

The results of the current study were supported by work of Filocamo et al. (7) where results were comparable after three months (74.0% vs. 71.42%) and six months (94.6% vs. 96.43%). Recently, Mariotti et al. (8) randomized 60 patients with UI after radical prostatectomy to a treatment group (ES plus BFB) and a control group (PME only), and they reported earlier recovery of continence in the treatment group. They demonstrated comparable continent rate at three months (80% vs 71.42%) and after six months (92.31% vs. 96.43%) for intervention groups. Thus, a significant additive effect of ES on PME compared with PMES alone has only been shown in this study, although it was not placebo-controlled and the subjects were consecutive patients undergoing RP in whom leakage

Table 2. Mean leakage weight.

Characteristic	Group 1 (n=26) Mean±SD	Group 2 (n=26) Mean±SD	Group 3 (n=28) Mean±SD
Baseline (W_0)	791.0±380.3	790.0±399.46	785±311.98
6- weeks (W_6)	533±316.53†	383.0±145.87†♠	263.0±145.87†*
12-week (W_{12})	260±216.53†	132.0±145.87†♠	83.0±145.87†*
24-week (W_{24})	123±116.53†	97.8±105.87†	36.0±95.87†*

* P<0.05, compared to group II (ES) and group I (control)
♠ P<0.05, compared to group I (control)
† p<0.05, compared to baseline within group

Table 3. Mean scores for quality of life on IIQ-7.

Characteristic	Group 1 (n=26) Mean±SD	Group 2 (n=26) Mean±SD	Group 3 (n=28) Mean±SD	Total (80) Mean±SD
Baseline (W_0)	55±31	54±26	53±28	54±29
6- weeks (W_6)	40±23†	36±25†♦	26±25†*	33±25†
12-week (W_{12})	32±26†	29±28†♦	20±24†*	25±27†
24-week (W_{24})	25±26†	23±24†♦	15±25†*	21±24†

*P<0.05, compared to group 2 (ES) and group 1 (control)
♦P>0.05, compared to group 1 (control)
†p<0.05, compared to baseline within each group

Appendix: the Arabic IIQ-7.

	Not at all	Infrequently	Frequently	Almost always
1-Does urinary leak disrupt your prayer schedule?	not at all	makes me repeat rival cleansing for each prayer	make me repeat the prayer	I almost stoe praying
2-Does urinary leak affect your ability to do household chores (cooking, housecleaning)?				
3-Does urinary leak affect your ability to do physical recreational activities as walking, swimming, or other exercises?				
4-Does urinary leak affect your ability to do social activities outside your home (as visiting relative and neighbors)?				
5-Does urinary leak affect your ability to travel by bus or car for distance greater than 20 minutes away from home?				
6-Does your urinary leak cause you to experience frustration, sense of low self esteem and lost confidence?				
7-Dose your urinary leak affects your emotion health (nervousness, depression, etc.)?				

ranged widely from 20 to 1,500 gm daily, while in the current study all patients had severe incontinence. Moreover, Ribeiro et al. (28) studied 54 RP cases randomly assigned to PME BFB (n=26) and control groups (n=28) after catheter removal. Ribeiro et al. found that, the cumulative percentage of continent patients and duration of incontinence was shorter in the treatment group than in the control group with a median of 1 and 6 months, respectively. At 12 months postoperatively, 25 (96.15%) patients in the treatment group and 21 (75.0%) in the control group were continent ($p < 0.028$), which is similar to the results of the current study.

On the contrary, Franke et al. (5) reported that PME did not affect the return of continence within 6 months after RP. Floratos et al. (14) found similar (91%) objective continence rates at 6 months after RP using electromyographic BF or verbal instruction for PME. Moreover, Willes et al. (16) failed to observe a statistical significant difference in patients treated with PME, PME plus ES or ES plus BFB after 3 or 12 months. The results of the current study demonstrated higher percentage of continence rate in BFB+ES group when compared with the results of Willes et al. after three months (71.42% vs 53%) and during follow-up at six months in the current study vs 12 months in the work of Willes et al. (96.43% vs 88.6%). Considering that, their study may include minimal or mild cases of incontinence in which Pelvic Floor Muscle Training (PFMT) is enough to cure incontinence. Moore et al. (15) compared standard PFMT (verbal and written instructions), intensive PFMT and intensive PFMT plus rectal ES in 63 men with UI after RP. Incontinence improved in all 3 groups, and no differences were noted among the groups in terms of urine loss at 16 and 24 weeks.

In this study, an interesting aspect was the fact that QOL, measured by the IIQ-7, was better in the treatment groups and positively correlated with the improvement in continence throughout the 6 months after surgery. In 3 randomized controlled trials, PFMT after RP was evaluated using the IIQ-7 to assess patient QQL (2,9,15). In none of the studies, the QOL improved in the treatment group, even in one that revealed better continence in the treatment group. The authors suggested the possibility that men found ways to circumvent the impact of incontinence on well-being or confounded differences in incontinence with other QOL issues such as recovery from surgery, anxiety about cancer or sexual dysfunction (2). In the current study, despite the lack of a statistical difference, QOL was always numerically superior in the treatment group, indicating a trend for improved QOL that might be demonstrable had we included more patients in the study.

Conclusion

Although advancements in surgical technique have improved the outcome of RP, we believe that treatment with BFB+ES has a significant positive impact on the early recovery of UI. It can represent a noninvasive and non-harmful method for all patients undergoing RP to reduce the duration and the degree of PPI and improve quality of life.

Conflict of Interest:
Authors reported no conflicts of interest.

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