

ORIGINAL ARTICLE

Early postoperative pelvic-floor biofeedback improves erectile function in men undergoing radical prostatectomy: a prospective, randomized, controlled trial

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Erectile dysfunction (ED) and urinary incontinence are common complications following radical prostatectomy (RP). Although pelvic-floor biofeedback training (PFBT) may improve urinary continence following RP, its effects on the recovery of potency are unknown. Fifty-two patients selected for RP were prospectively randomized for a treatment group ($n = 26$) receiving PFBT once a week for 3 months and home exercises or a control group ($n = 26$), in which patients received verbal instructions to contract the pelvic floor. Erectile function (EF) was evaluated with the International Index of Erectile Function-5 (IIEF-5) before surgery and 1, 3, 6 and 12 months postoperatively. Patients were considered potent when they had a total IIEF-5 score > 20 . Continence status was assessed and defined as the use of no pads. Groups were comparable in terms of age, body mass index, diabetes, pathological tumor stage and neurovascular bundle preservation. A significant reduction in IIEF-5 scores was observed after surgery in both groups. In the treatment group, 8 (47.1%) patients recovered potency 12 months postoperatively, as opposed to 2 (12.5%) in the control group ($P = 0.032$). The absolute risk reduction was 34.6% (95% confidence interval (CI): 3.8–64%) and the number needed to treat was 3 (95% CI: 1.5–17.2). A strong association between recovery of potency and urinary continence was observed, with continent patients having a 5.4 higher chance of being potent ($P = 0.04$). Early PFBT appears to have a significant impact on the recovery of EF after RP. Urinary continence status was a good indicator of EF recovery, with continent patients having a higher chance of being potent.

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INTRODUCTION

Radical prostatectomy (RP) is a commonly performed surgery and the therapeutic option chosen by most patients with localized prostate cancer.¹ The most common long-term complications after prostatectomy (RP) are urinary incontinence and erectile dysfunction (ED).² ED is estimated to affect 26–100% of patients after surgery.^{3,4} The main cause of ED after RP is neurogenic, because of intraoperative injury to the neurovascular bundle.⁵ However, other mechanisms including arterial trauma and neuropraxia-associated structural alterations in corporal smooth muscle may also have a role.^{5,6} Age has consistently been shown to be a predictor of potency preservation following RP, with younger men having a significantly increased chance of regaining the ability to have adequate erections for intercourse than men older than 65 years. Other risk factor associated with ED following RP are coronary artery disease, diabetes mellitus, quality of preoperative erections and hypertension.⁷

ED has a negative effect on the quality of life of men and their sexual partners and its burden may persist long after cancer cure concerns have subsided.⁸ Recovery of erectile function (EF) can take up to 24 months after surgery and depends on the patient's age and preservation of the neurovascular bundles.⁹ Many authors consider it important not to wait inactively until EF is regained, as the lack of oxygenation of the corpora cavernosa may lead to involutional atrophy, because of the increasing fibrosis of the smooth muscle.^{10,11} The proposed rationale for post-RP penile

rehabilitation is to provide oxygenation to the corpora cavernosa, by increasing the arterial inflow, during the period when the cavernous nerves are recovering and avoid irreversible structural damage to the erectile tissue.¹² This is primarily based in the fact that men routinely experience nocturnal erections that are presumed to help preserve erectile tissue healthy even in the absence of sexual activity. After cavernous nerve injury, nocturnal erections are significantly diminished in number and rigidity and may even be completely absent for a prolonged period of time.¹⁰

Four modalities of treatment have been employed to improve the recovery of EF following RP: phosphodiesterase inhibitors (PDEi-5), intracorporeal injections, vacuum erectile devices and transurethral prostaglandin.¹³ These treatments may potentially hasten the recovery of EF, as they may provide better oxygenation of the corpora cavernosa, avoiding irreversible damage to the erectile tissue.¹⁴ There is sufficient evidence that oral PDEi-5 improve EF after RP.^{15–17} Intracorporeal injections, intraurethral prostaglandin and the use of vacuum erectile devices have also been used but their role in the recovery of spontaneous erections is either uncertain or limited because of its invasiveness and low acceptance by patients.^{11,18–20}

Pelvic-floor exercises have been used to improve urinary continence following RP, with good results.^{21,22} There are some evidences that they may improve EF in men with ED caused by conditions other than postprostatectomy.^{23,24} It is unknown whether pelvic-floor biofeedback training (PFBT) can improve EF

following RP, which would be a great benefit especially considering that it may also improve urinary incontinence.

MATERIALS AND METHODS

Population

After Institutional Review Board approval, we performed a prospective, randomized, controlled trial comparing early postoperative biofeedback PFBT to usual care. Between July 2006 and September 2007, 122 consecutive patients who underwent standard radical retropubic prostatectomy at our institution for clinically localized prostate cancer were screened for this study. Patients were included if they could regularly attend an ambulatory schedule. Exclusion criteria were prior urethral, bladder or prostate surgery, pelvic radiotherapy, neurological disease with possible impact on potency, ED or any medical condition that could limit the training program. ED was defined as a total International Index of Erectile Function-5 (IIEF-5) score of ≤ 20 .^{25–27}

Of the 122 patients screened for this study, 52 fulfilled the eligibility criteria of the trial. They were randomized into a control group ($n = 26$) and a treatment group ($n = 26$) according to a randomization list. All patients signed an informed consent before randomization. The exclusion causes for the screened patients are depicted on Figure 1. Of the eligible patients, 19 were excluded before any treatment session or follow-up evaluation, including 9 patients in the treatment group and 10 in the control group. Reasons for these early dropouts were failure to return for the first evaluation (8 patients), urethral stricture requiring dilation and prolonged use of an indwelling catheter (5 patients), persistent urinary tract infection (3 patients), deep vein thrombosis (1 patient) or early need for adjuvant radiotherapy (2 patients). None of the dropouts in our study were actually ever included in the study, since they occurred before the first month evaluation and no patients assigned for the treatment group started the PFBT. After the first evaluation, there were no new dropouts. All patients were followed up to the 12 months evaluation (Figure 1).

Treatment

After catheter removal at postoperative day 15, patients in the treatment group received PFBT once a week for 12 weeks. Each session lasted 30 min and was performed by the same physiotherapist. For PFBT, an

electromyographic apparatus (Miotec, Porto Alegre, Rio Grande do Sul, Brazil) was used. A surface electrode (3M, Sumare, Brazil) was inserted into the anus and the reference electrode was placed on the left lateral malleolus. In the right lateral decubitus position, patients practiced 3 series of 10 rapid contractions while viewing a computer monitor to improve the phasic musculature component. Then patients practiced 3 sustained contractions of 5, 7 or 10 s depending on ability to maintain the contraction of pelvic-floor muscle tonic component. Subjects were then placed in the supine position, with hips flexed to approximately 60° , to practice 10 contractions during prolonged expiration, avoiding the Valsalva maneuver. Verbal and written instructions were used to conduct daily home exercises while lying, sitting and standing. Patients were not allowed to receive drug treatment for ED throughout the study duration.

Outcome assessments

The assessment of both groups was identical at all times and was performed by the same investigator during office evaluation. It included baseline as well postoperative evaluations 1, 3, 6 and 12 months after catheter removal. EF was evaluated with the IIEF-5.²⁸ Patients were considered potent when they had a total IIEF-5 score of > 20 .^{25–27} Continence was defined as the use of no pads per day. The association of continence and recovery of potency was evaluated.

Statistical analysis

Data were expressed as means \pm s.d. or absolute values and fractions. The Student's *t*-test was used to compare continuous variables while categorical variables were compared using the χ^2 or Fisher's exact test. Comparison of continuous variables between groups was performed using one-way analysis of variance, with the Bonferroni *post hoc* test to compare individual pairings of groups. Estimates of survival curves were calculated using the Kaplan–Meier method and compared by using the log-rank test. All tests were two-sided with $P < 0.05$ considered statistically significant and were performed using GraphPad Prism version 5.02 for Windows (GraphPad Software, San Diego, CA, USA). Our initial estimate for the study was to include 30 patients in each group in order to have a power of 80% to detect a 30% increase in the treatment group rate with a significance level of 0.05.

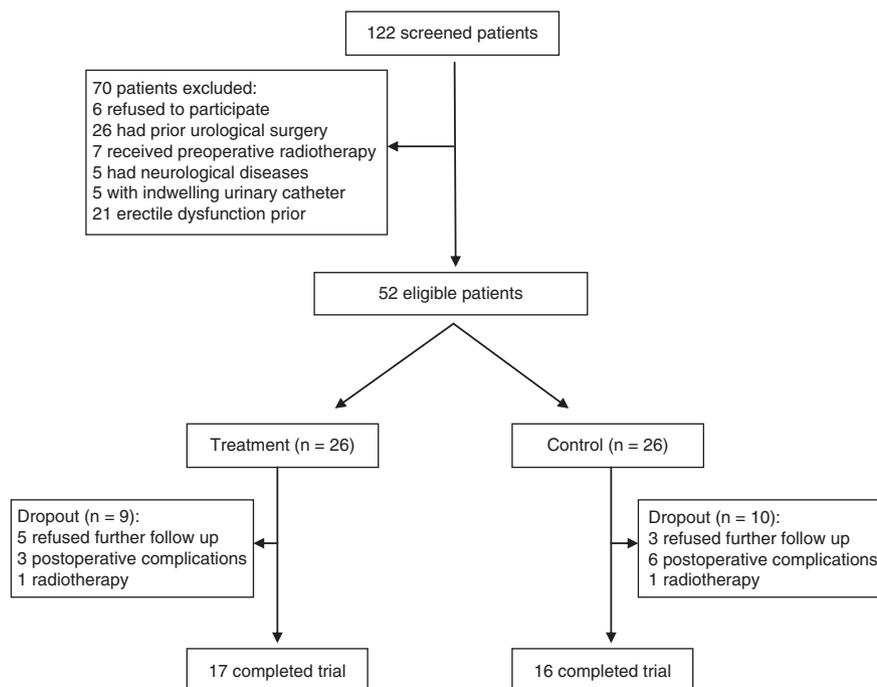


Figure 1. Study flow chart.

RESULTS

Preoperative assessment did not show differences in EF, age, body mass index, prevalence of diabetes or pelvic-floor muscle strength between the groups (Table 1).

Similarly, the rate of neurovascular bundle preservation was similar for patients in the treatment (64.7%) and control (68.8%) groups ($P = 0.99$).

Baseline and postoperative IIEF scores for both groups are presented in Figure 2. There was a dramatic reduction in IIEF-5 scores after surgery in both groups and a progressive increase was observed over time, which was higher in the treatment group. The time to recover potency was significantly lower in the treatment group (hazard ratio = 4.14; 95% confidence interval (CI): 1.12–15.28; $P = 0.032$). At 12 months postoperatively, 47.1% (8/17) of the subjects in the treated group were considered potent, as opposed to 12.5% (2/16) in the control group. The absolute risk reduction for impotence was 34.6% (95% CI: 3.8–64%). The number of patients needed to treat to obtain one more potent subject was 3 (95% CI: 1.5–17.2) (Figure 3).

An association was observed between the recovery of potency and urinary continence both in the treatment group as in controls. A total of 10 patients were potent after 12 months. All but one of these patients was also continent. Of the impotent patients, only 11 (50.0%) were continent (relative risk (RR) = 5.40; 95% CI: 0.77–37.52; $P = 0.04$).

DISCUSSION

The early rehabilitation of EF has been proposed to promote the spontaneous recovery of the erection after RP. In this regard, the use of PDEi-5 has been used with positive results.^{10,15–17,29}

	Treatment group	Control group	P-value
Mean \pm s.d. age	62.4 \pm 6.4	64.0 \pm 8.0	0.517
No. diabetes (%)	3 (17.6)	2 (12.5)	0.989
Mean \pm s.d. body mass index	26.05 \pm 2.7	28.1 \pm 3.7	0.183
Median IIEF-5	24 (21–25)	23.5 (21–25)	0.571
Median PFMS (IQR)	3 (3–5)	4 (3–5)	0.226
Neurovascular bundle preservation (%)	64.7	68.8	0.987
<i>Clinical tumor stage</i>			
No. Pt 2 (%)	13 (76.5)	12 (75.0)	1.000
No. Pt 3 (%)	4 (23.5)	4 (25.0)	

Abbreviations: IIEF-5, International Index of Erectile Function-5; IQR, interquartile range; PFMS, pelvic-floor muscle strength.

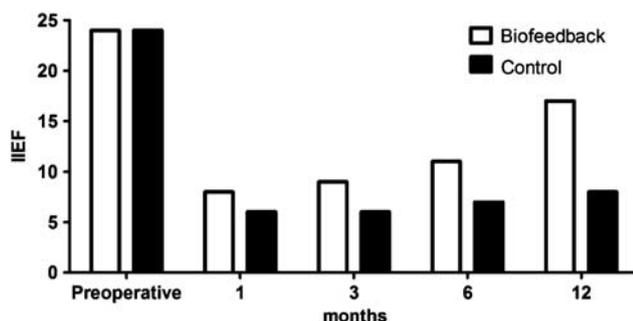


Figure 2. Temporal evolution of International Index of Erectile Function-5 (IIEF-5) scores after radical prostatectomy.

Although pelvic-floor exercises have been successfully used for the treatment of postprostatectomy urinary incontinence, its impact on the recovery of EF had never been evaluated before.^{21,22}

Few studies have evaluated the effects of pelvic-floor exercises in the EF.^{23,24,30,31} Although they suggest an improvement of EF with pelvic-floor exercises, they are methodologically inadequate. Patients included in those studies had various causes of ED and underwent different intervention methods. In addition, they were evaluated with nonvalidated outcome measures. In the only prospective, randomized and controlled trial available, an improvement in the EF was observed in the group that practiced pelvic-floor exercises. This study, however, did not include patients with postprostatectomy ED.²³

In this study, we tested the effectiveness of PFBT for improving EF 12 months following radical retropubic prostatectomy. We have shown that patients in the treatment group had superior results in terms of duration and severity of ED when compared with controls. Baseline parameters that have been associated with poor recovery of EF such as age, obesity, diabetes, and EF were comparable between patients in the biofeedback and control groups. Owing to limitations of our sample size, we were not able to evaluate the impact of these parameters on the recovery of potency. The importance of neurovascular bundle preservation for recovery of potency is well recognized.^{32,33} Our neurovascular bundle preservation rate was close to 70%, which is in accordance with many contemporary reported series that have reported rates of 53 to 80%.^{32–34} In this study, the rates of nerve preservation were similar in both groups, indicating that it did not have an impact on the postoperative differences observed between them.

The association of potency and urinary continence recovery was an important finding in our study. Despite the fact that these are two common complications of RP, few studies have evaluated the association between continence and EF recovery. In a retrospective study using mailed questionnaires, Kao *et al.*³⁵ have shown that men with urinary incontinence tended to have a higher chance of being impotent. Similarly, it has been reported that neurovascular bundle preservation during prostatectomy might not only be important for postoperative EF, but also help in the recovery of urinary continence.³⁶ This hypothesis, however, has not been confirmed in other studies.^{37,38}

It is well known that urinary incontinence is the most devastating complication after RP.³⁹ It is clear that continent patients are more interested in resuming sexual function than incontinent ones, who have been shown to have lower sexual function satisfaction.³⁵ They may be distressed by their condition as well as embarrassed to try to engage in sexual activities. Although we do believe that this may be an important factor to explain the finding of better EF in patients that were continent in

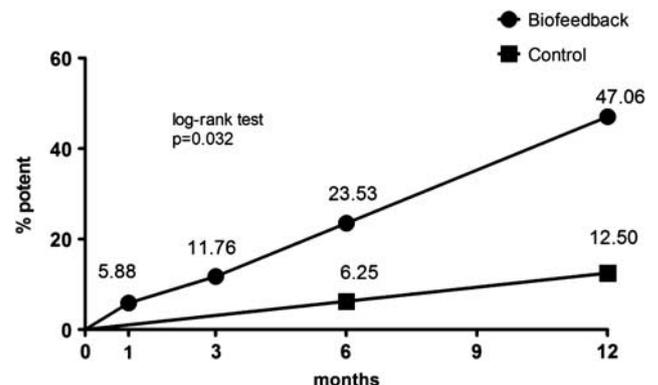


Figure 3. Cumulative percentage of potent patients after radical prostatectomy.

our series, it cannot be ruled out that PFBT has a direct effect in the EF. Evidences for that include the fact that we used the IIEF-5 to evaluate our patients, which measures different aspects of the EF. Higher scores indicate that penile erection is better, not other aspects of sexual function. In addition, it has been suggested that pelvic-floor exercises may promote better perfusion of the corpora cavernosa, preventing erectile tissue hypoxia and decreasing the fibrosis process.⁴⁰ Another mechanism could be a direct effect of the pelvic-floor muscles in the mechanics of the penile erection. Some studies have shown increased ischiocavernosus and bulbocavernosus muscle activity during penile erection.^{41,42} It is known that these muscles have a role in the initiation and maintenance of human penile erection.⁴³ It is also known that the contraction of the ischiocavernosus muscle induces a more rigid erection because of the compression of the congested cavernous bodies and consequent increase in the intracavernous pressure.⁴³ Finally, another hypothesis is that pelvic muscle contractions might induce the production of neurotrophic factors. It has been shown that growth factors like brain-derived neurotrophic factor, vascular endothelial growth factor and growth differentiation factor-5 are important for the recovery of EF in animals subjected to cavernous nerve injury.^{44–46} Moreover, experimental studies have demonstrated that contraction of skeletal muscle can induce the release of neurotrophic factors. Matthews *et al.*⁴⁷ have shown in an animal model that muscle contraction induces an increase in brain-derived neurotrophic factor in muscle cells, which has an important role in regulating neuronal growth.

We used a simple treatment schedule of only one weekly biofeedback session and a maximum duration of 12 weeks. It is possible that a more intense and/or longer exercise regimen could afford better results, but it might not be very practical and patients might drop out the training program. Patients in the control group received only verbal instructions by the urologist on how to perform pelvic exercises. We decided not to offer any additional instruction or exercise schedule other than the usual patient care for the control patients because this is the usual care in our practice and probably in most clinical settings worldwide.

We acknowledge that the fact that we evaluated our patients for only 12 months after RP is a concern. It is known that the recovery of EF may continue beyond that time. However, we did not find interventional, prospective, randomized studies that evaluated patients for longer than 12 months.^{10,11,18–20,29} In addition, the spontaneous potency rates 24 months after RP are not substantially increased in comparison with 12 months. In a series by Penson *et al.*,⁴⁸ potency rates after 12 and 24 months were 17% and 22%, respectively, while Stanfortd *et al.*² obtained 14.7% and 18.5%, respectively. These data indicate that although EF may improve after 12 months, most patients are already potent at that moment. Moreover, it would be difficult for ethical and control reasons to keep patients off PDEi-5 beyond 12 months postoperatively.

The fact that the use of PDEi-5 was not allowed throughout the duration of the study is an important aspect, because it rules out the possibility of possible contamination of the results. As our center serves a community of poor patients that rely on the drugs that are supplied by the public health system it was not difficult to control for that. In addition, patients were specifically questioned about the use of PDEi-5 at every evaluation. In our practice, we offer on demand PDEi-5 for patients complaining of ED postoperatively. We do not offer a rehabilitation program based on the regular use of PDEi-5. As all patients agreed to participate in this trial after full disclosure, we felt comfortable to keep them off PDEi-5 throughout the study duration.

The timing of penile rehabilitation after nerve-sparing RP appears to affect the recovery of EF. In a recent study, Mulhall⁴⁹ demonstrated that delaying the start of penile rehabilitation after RP is associated with poorer outcomes for EF.

In our study, PFBT was initiated as soon as the urinary catheter was removed, which seems to be desirable for improvement of potency.

In summary, our results indicate that the early institution of pelvic-floor exercises may improve the recovery of EF in patients submitted to RP. As PFBT is a safe treatment modality that may improve the recovery of urinary continence and also help in the recovery of EF, it should be considered for all men undergoing RP. Certainly larger experiences are required to adequately evaluate and validate this issue.

CONCLUSION

Early PFBT appears to have a significant impact on the recovery of EF after RP. Urinary continence status was a good indicator of EF recovery, with continent patients having higher chance of being potent than incontinent patients.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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