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Abstract

Background

Despite improvements in surgical techniques, urinary incontinence (UI) is not uncommon after radical prostatectomy (RP), and it may dramatically worsen quality of life (QoL).

Objective

To determine the benefit of starting pelvic floor muscle exercise (PFME) 30 d before RP and of continuing PFME postoperatively for early recovery of continence.

Design, setting, and participants

A randomised, prospective study was designed. Men with localised prostate cancer (PCa) who underwent an open radical retropubic prostatectomy (RRP) at our department of urology were included.

Intervention

Patients were randomised to start PFME preoperatively and continue postoperatively (active group: A) or to start PFME postoperatively alone (control group: B).

Measurements

The primary outcome measure was self-reported continence after surgery. Secondary outcome measures were assessed by degree of UI based on a 24-h pad test and QoL instruments (International Continence Society [ICS] male short form [SF]).

Results and limitations

Of 143 men evaluated for the study, 118 were randomised either to start PFME preoperatively and continue postoperatively (group A; $n = 59$) or to start postoperative PFME (group B; $n = 59$). After 1 mo, 44.1% (26 of 59) of patients were continent in group A, while 20.3% (12 of 59) were continent in group B ($p = 0.018$). At 3 mo, 59.3% (35 of 59) and 37.3% (22 of 59) patients were continent in group A and group B, respectively ($p = 0.028$). The ICS male SF mean score showed better results in group A than in group B patients at both 1 mo (14.6 vs 18.3) and 3 mo (8.1 vs 12.2) after RP ($p = 0.002$). In age-adjusted logistic regression analyses, patients who performed preoperative PFME had a 0.41-fold lower risk of being incontinent 1 mo after RP and a 0.38-fold lower risk of being incontinent 3 mo after RP ($p \leq 0.001$).

Conclusions

Preoperative PFME may improve early continence and QoL outcomes after RP. Further studies are needed to corroborate our results.

1. Introduction

Despite improvements in surgical techniques, which allow a detailed dissection and a watertight vesical–urethral anastomosis, urinary incontinence (UI) is not uncommon after radical prostatectomy (RP) [1]. The real incidence remains unknown, as it depends on the definition key, the time of observation, and the caregivers involved in the follow-up. In previous studies, the rate of early UI (3–6 mo) varied from 0.8% to 87% and from 5% to 44.5% 1 yr after RP [2], [3]. Several predictors have been investigated, such as age, prostate volume, disease stage, body weight, comorbidities, history of previous lower urinary tract dysfunctions, surgical techniques, and urine loss ratio, but unfortunately, they rarely reached a high level of evidence [3], [4]. UI after RP has been considered the result of urethral sphincter deficiency or injury or of bladder dysfunctions such as detrusor overactivity, impaired bladder filling sensation, and low bladder compliance [5]. More recently, according to newly evolving understanding, the concept of a sphincteric laxity resulting from a postoperative intrinsic sphincter deficiency has been suggested as the cause of a disturbance of the male integral system [6]. UI is a particularly upsetting problem after RP, and it may dramatically worsen the quality of life (QoL) of a patient who has been successfully cured of prostate cancer (PCa) [7]. Many therapeutic strategies have been adopted, ranging from conservative therapy, behavioural interventions, pelvic floor muscle exercise (PFME), pharmacotherapy, penile clamp, pad use, bulking agents, artificial urinary sphincter, and the recently introduced polypropylene mesh using a transobturator approach [3].

As postoperative behavioural interventions and PFME are effective for decreasing UI following prostate surgery [8], [9], we hypothesised that PFME may be more effective if practiced preoperatively. As the UI rate and intensity are not predictable preoperatively, it may make sense to start muscle training preoperatively, so that patients can gain motor skills before surgery and be more prepared to exercise and use the pelvic floor muscles immediately after catheter removal. The aim of the current study is to determine the benefit of PFME started preoperatively and continued postoperatively for early recovery of continence after RP.

2. Materials and methods

Patients aged between 46 yr and 68 yr with clinically localised PCa (cT1-cT2a-b) who were candidates for an open nerve-sparing RP and who were treated between September 2007 and May 2008 at our urban tertiary university department of urology were evaluated. The study was approved by the university institutional review board. To be eligible, participants had to accept ambulatory visits, and they had to be continent preoperatively. Patients were enrolled in the study at least 4 wk prior to surgery, and they were provided written informed consent. Patients were excluded if they reported UI, underwent prior pelvic organ surgeries, had central or peripheral neurologic diseases and defects in walking, had metabolic diseases, or had impaired mental status (score <30 on the Mini-Mental State Examination [MMSE], Folstein version).

The preoperative clinical evaluation consisted of medical history, neurologic and physiologic screening (MMSE), and physical examination (height, weight, and specific urologic examination). Urodynamic testing consisted of a pressure flow study. Terminology complied with International

Continence Society (ICS) standards [10]. A 3-d bladder diary and ICS male short form (SF) questionnaire were completed before starting the study. It is noteworthy that a lower ICS score denotes better continence outcomes. Patients completed a Patient's Global Impression of Improvement (PGI-I) questionnaire after the PFME course. Self-reported continence and bladder diaries were used to define continence status prior to surgery.

Patients with localised PCa were randomised to start PFME preoperatively and continue postoperatively (active group: A) or to start PFME postoperatively (control group: B). All RPs were performed by a single experienced surgeon (GG) according to a standard and reproducible technique.

Participants in this randomised controlled trial were allocated to comparison groups based on random process. A restricted randomisation procedure was adopted to control the probability of obtaining an allocation sequence with an undesirable sample size imbalance in the two groups. Permuted block randomisation was used, with a block size of every 10 consecutively enrolled participants. Individuals were randomised by a computer-generated list that was centrally maintained. Each block of 10 patients was given to a person who acted as the randomisation authority in sequentially numbered, sealed, opaque envelopes. This individual—a resident not involved in the care of the trial patients—was responsible for allocation.

None of the participants was blinded to treatment assignment, but the surgeon who performed the procedures was blinded to randomisation allocation throughout the duration of the study. Only the statistician and the data monitoring committee saw unblinded data, but none had any contact with study participants.

Thirty days before the surgery, all patients in the active group started the PFME course, which consisted of intensive pelvic floor muscle training guided by a single physiotherapist twice per week for 30 min (and for 30 min daily at home). Then, 48 h after catheter removal, patients attended the PFME course twice per week for 1 mo and continued PFME until complete continence was achieved at home. Patients were instructed to perform PFME and provided feedback regarding endurances and contraction quality, breathing coordination, typifying muscle contraction as tonic, and modifying incorrect physical attitudes. The physiotherapist encouraged the patients to contract the pelvic floor muscles alternating maximal and submaximal contractions.

Our technique is not similar to what has been reported in the literature [11], [12] because we mainly focus on the tonic fibres of the superficial perineal musculature. Correct pelvic floor muscle contraction and muscle strength were assessed by subscrotal digital assessment. Visual feedback plus verbal instruction and reinforcement were used to teach patients how to control the pelvic floor muscles while keeping the abdominal muscles relaxed. Furthermore, the observation of cranial movements of the perineum and scrotum were used to assess the patients' ability to correctly perform pelvic floor muscle contraction. Postoperatively, patients in the control group (group B) performed the same PFME as patients in the active group (group A).

The primary outcome measure was self-reported continence at 1 and 3 mo after surgery. Continence (completely dry patient) was defined as the sum of no urinary leakage reported by the patient in his bladder diary and a negative stress test. Secondary outcome measures were assessed by the degree of UI based on a 24-h pad test and QoL instruments (ICS male SF). Satisfaction for preoperative PFME was evaluated with PGI-I questionnaires in group A patients only.

Using the two-sided test to differentiate between proportions, this study had an ability of 80% to detect a difference of 24% in the proportion of patients remaining incontinent at 1–3 mo, assuming

a total sample size of 118 patients and a type 1 error rate of 0.05. Because we investigated the early postprostatectomy continence, interim analyses were not performed during the trial.

Patient characteristics are described in terms of mean and standard deviation (SD) or range for continuous variables. The χ^2 statistic was used for categorical variables, and the *t* test was used for continuous variables. Finally, after testing for proportionality of odds across response categories, ordered logistic regression models were used to evaluate the effect of PFME at 1 and 3 mo after RP on the probability to be continent. The logistic regression model was adjusted for patient age. The Consolidated Standards of Reporting Trials (CONSORT) checklist and its indications were strictly followed in writing the manuscript [13].

3. Results

A total of 143 men were evaluated for the study, and 118 were randomised either to PFME started preoperatively and continued postoperatively (group A: $n = 59$) or to postoperative PFME alone (group B: $n = 59$). Fig. 1 shows the flow diagram. Table 1 lists the demographic, clinical, and treatment characteristics of group A and group B patients, respectively. Of the 143 eligible patients, 25 were excluded because the RP was performed earlier than planned ($n = 8$) or postponed ($n = 4$), patients were unable to attend preoperative PFME ($n = 7$), or the patient did not agree to participate ($n = 6$). All patients randomised to both groups completed the follow-up.

The median age was 60.5 yr (range: 48–68) in group A and 57.5 yr (range: 46–67) in group B ($p < 0.001$). Immediately after catheter removal, 35 patients were continent: 21 (35.6%) patients in group A and 14 (23.7%) patients in group B ($p = 0.037$).

After 1 mo, 44.1% of the patients (26 of 59) were continent in group A, while 20.3% of the patients (12 of 59) were continent in group B (primary outcome); this difference was statistically significant ($p = 0.018$). This important difference was maintained after 3 mo: 59.3% of the patients (35 of 59) were continent in group A, while 37.3% of the patients (22 of 59) were continent in group B ($p = 0.028$).

At 1 mo, the mean ICS male SF score was 14.6 in group A versus 18.3 in group B; this difference was statistically significant ($p = 0.002$). The difference remained statistically significant after 3 mo (8.1 vs 12.2; $p = 0.002$). When considering the patients who were dry after 2 mo, the mean ICS male SF score was not statistically significantly different between groups A and B (9.7 vs 8.7; $p = 0.202$). However, at 3 mo, the difference became statistically significant (3.8 vs 5.5; $p < 0.001$). When focusing on patients who reported occasional incontinence, a statistically significantly different ICS male SF score was found at 1 mo (14.5 vs 16.2; $p = 0.006$). This difference persisted 3 mo after RP (8.5 vs 10.5; $p = 0.014$). When considering patients who were incontinent, the mean ICS male SF score was statistically significantly different at 1 mo (21.9 vs 25.9; $p \leq 0.001$). However, no statistically significant difference was observed at 3 mo (22.2 vs 22.3; $p = 0.886$). Additionally, 75% of patients in the active group (group A) reported extreme satisfaction for preoperative PFME by PGI-I.

In group A, 15 patients (25.4%) had a 24-h pad test weigh >150 g versus 20 patients (33.9%) after 1 mo; this difference was statistically significant ($p = 0.040$). After 3 mo, 10 patients (16.9%) had a 24-h pad test weigh >150 g in group A versus 19 patients (32.2%) in group B ($p = 0.033$).

In ordered logistic regression analyses, no interaction was observed between preoperative PFME and age. Patients who performed preoperative PFME had a 0.41-fold lower risk of being incontinent 1 mo after RP (95% confidence interval [CI], 0.20–0.85; $p = 0.001$) and a 0.38-fold lower risk of

being incontinent 3 mo after RP (95% CI, 0.18–0.79; $p < 0.001$; Table 2). Conversely, age was not an independent predictor of continence outcomes.

4. Discussion

The results of this study show that 30-d preoperative PFME training can decrease the duration and severity of incontinence following nerve-sparing open RP at 1 and 3 mo. At 1- and 3-mo follow-up, the self-reported continence status (pad test) was higher in group A (preoperative PFME) than group B (no preoperative PFME). Additionally, QoL indices were higher in group A patients.

A previous study of PFME with biofeedback prior to surgery compared continence outcomes at 6 wk and 12 mo [14]. Findings were promising on several measures, but the small sample size (eight patients per group) precluded statistical comparisons of the outcomes. Bales et al showed no benefit using a preoperative PFME that was started 2–4 wk before surgery [15]. Burgio et al tested the effectiveness of preoperative biofeedback-assisted behavioural training for decreasing the duration and severity of UI and improving QoL 6 mo after RP [16]. Their prospective, randomised, controlled trial showed that preoperative behavioural training significantly decreased time to continence and the proportion of patients with severe/continual leakage at the 6-mo end point (5.9% vs 19.6%). Additionally, the authors reported statistically significant differences between the groups (preoperative training vs no training) for self-reported urine loss with coughing (22.0% vs 51.1%), sneezing (26.0% vs 48.9%), and getting up from lying down (14.0% vs 31.9%). No differences were found on return to work and usual activities or QoL measures.

Other investigators examined the effects of PFME soon after surgery with contrasting results. In one trial, patients who were incontinent 15 d after RP received weekly pelvic floor reeducation for up to a year or placebo therapy [2]. The treatment group showed advantages in the duration and degree of incontinence. Other studies have not shown a benefit for PFME started 3, 6, or 8 wk after surgery [17], [18], [19]. In some cases, there was evidence of a training effect, but sample sizes suggest that these studies were underpowered. More recently, Filocamo et al reported a randomised study of 300 consecutive patients who underwent RP for clinical stage T1 or T2 PCa. The treatment group received an early postoperative pelvic floor rehabilitation programme [8]. In the treatment arm, the proportion of continent patients was 19% (29 patients) and 94.6% (146 patients) after 1 and 6 mo, respectively, versus 8% (12 patients) and 65% (97 patients) in the control arm. At 1-yr follow-up, 93.3% of the total population achieved complete continence.

Overgard et al investigated the effects of PFME in a randomised controlled trial [9]. No statistically significant difference in continence status was observed at 3 mo between the active (46% of continent patients) and control group (43%; $p = 0.73$). In the active group, 97% reported no or only mild problems with urinary function compared to 78% in the control group ($p = 0.010$). After 6 mo, there was a clinically relevant difference in continence status between the active group (79% continent patients) and the control group (58% continent patients; $p = 0.061$). Twelve months after RP, the difference became clinically and statistically significant: 92% of patients in the active group were continent relative to 72% of patients in the control group ($p = 0.028$). The study concluded that continence rates were similar 3 mo after RP in patients performing intensive PFME with or without follow-up instructions by a physiotherapist. However, in the period up to 1 yr, the group receiving physiotherapist-guided training showed a significantly lower UI rate than patients training on their own.

Our results seem to support the suggestion that preoperative action may improve early continence after RP, although it may not change the late outcome. In this study, for the first time, the QoL changes were studied performing a three-group stratification: completely dry, occasional

incontinence, and incontinence. We found that preoperative PFME may improve the QoL, as showed by ICS male SF questionnaire results.

A limitation of the current study is that mean age was statistically significantly different between the two groups. However, in age-adjusted analyses, preoperative PFME still resulted as an independent predictor of continence after RP. It is also possible that the improved continence in the active group (group A) was the result of members of this group being more motivated than the patients in the control group (group B). However, it is noteworthy that, using a motivation scale ranging from 1 to 10, the average score was 8 in both patient groups.

5. Conclusions

The use of preoperative PFME may improve early continence and QoL outcomes after RP. Further studies are mandatory in order to confirm and implement our data in clinical practice.

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Table 1. Descriptive characteristics of the study population

	Group A	**Group B**
No. of patients	59	59
Mean age, yr (range)	60.5 (48–68)	57.5 (46–67)*
BMI	<27	<27
PSA, mean ± SD	5.6 ± 3.9	5.8 ± 3.8
Clinical stage		
T1c	16	14
T2a	24	23
T2b	19	22
Gleason score		
<6	21	19
6–7	34	30

	Group A	Group B
>7	4	10
Pathologic stage		
T2a	10	2
T2b	3	8
T2c	34	42
T3a	10	6
T3b	2	1
Mean ICS male SF questionnaire score		
At 1 mo	14.6 ± 5.7	18.3 ± 5.9*
At 3 mo	8.1 ± 7.6	12.2 ± 7.5*
Continence recovery, %		
At 1 mo	44.1%	20.3%*
At 3 mo	59.3%	37.3%*
Nerve-sparing procedure	59	59

BMI = body mass index; PSA = prostate-specific antigen; SD = standard deviation; ICS = International Continence Society; SF = short form.

* $p < 0.05$.

Table 2. Logistic regression models predicting the probability of being continent at 1 mo and 3 mo after radical prostatectomy

Predictors	1 mo after RP	3 mo after RP
	***p* value OR (95% CI)**	***p* value OR (95% CI)**
Preoperative PFME	$p = 0.016$	$p = 0.010$
No (referent)	1.00	1.00
Yes	0.41 (0.20–0.84)	0.38 (0.18–0.79)
Age	$p = 0.127$	$p = 0.359$
Continuously coded	1.05 (0.99–1.11)	1.03 (0.97–1.10)

RP = radical prostatectomy; OR = odds ratio; CI = confidence interval; PFME = pelvic floor muscle exercise.

Fig. 1. The CONSORT flow diagram. PFME = pelvic floor muscle exercise.