Influence of Preoperative and Postoperative Pelvic Floor Muscle Training (PFMT) Compared with Postoperative PFMT on Urinary Incontinence After Radical Prostatectomy: A Randomized Controlled Trial

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Abstract

Background: The efficacy of preoperative pelvic floor muscle training (PFMT) for urinary incontinence (UI) after open radical prostatectomy (ORP) and robot-assisted laparoscopic radical prostatectomy (RARP) is still unclear.

Objective: To determine whether patients with additional preoperative PFMT regain urinary continence earlier than patients with only postoperative PFMT after ORP and RARP.

Design, setting, and participants: A randomized controlled trial enrolled 180 men who planned to undergo ORP/RARP.

Intervention: The experimental group (E, n = 91) started PFMT 3 wk before surgery and continued after surgery. The control group (C, n = 89) started PFMT after catheter removal.

Outcome measurements and statistical analysis: The primary end point was time to continence. Patients measured urine loss daily (24-h pad test) until total continence (three consecutive days of 0 g of urine loss) was achieved. Secondary end points were 1-h pad test, visual analog scale (VAS), International Prostate Symptom Score (IPSS), and quality of life (King's Health Questionnaire [KHQ]). Kaplan-Meier analysis and Cox regression with correction for two strata (age and type of surgery) compared time and continence. The Fisher exact test was applied for the 1-h pad test and VAS; the Mann-Whitney U test was applied for IPSS and KHQ.

Results and limitations: Patients with additional preoperative PFMT had no shorter duration of postoperative UI compared with patients with only postoperative PFMT (p = 0.878). Median time to continence was 30 and 31 d, and median amount of first-day incontinence was 108 g and 124 g for groups E and C, respectively. Cox regression did not indicate a significant difference between groups E and C (hazard ratio: 1.047 [0.768–1.425]). The 1-h pad test, VAS, and IPSS were comparable between both groups. However, “incontinence impact” (KHQ) was in favor of group E at 3 mo and 6 mo after surgery.

Conclusions: Three preoperative sessions of PFMT did not improve postoperative duration of incontinence.

Trial registration: Netherlands Trial Register No. NTR 1953.
1. Introduction

Urinary incontinence (UI) remains a common postoperative consequence after open radical prostatectomy (ORP) and robot-assisted laparoscopic radical prostatectomy (RARP) [1–4]. UI has a spontaneous recovery in most men, but it may take as long as 1–2 yr after radical prostatectomy (RP) [5]. Investigators have proved that continence can be achieved faster with pelvic floor muscle training (PFMT) [1,2,6]. Additionally, six studies attempted to investigate the effect of preoperative PFMT on the duration and severity of UI after RP [3,7–11]. Five of these studies found positive results of preoperative PFMT [3,7,8,10,11]. However, because of the multitude of existing bias, results must be interpreted with caution. Burgio et al. [3], Parekh et al. [8], and Tienforti et al. [11] altered both preoperative and postoperative treatment, which made defining the effect of preoperative PFMT impossible. Bales et al. [9] compared the effect of two different preoperative treatments, and Sueppel et al. [7] compared only one preoperative session with a control group who completed PFMT 6 wk after surgery and included only 16 patients. Follow-up was usually only 3 mo or 6 mo [3,9–11]. Finally, a wide range of continence criteria were used among studies, which made it difficult to compare results.

The aim of this study was to determine whether patients who performed PFMT before and after surgery regained urinary continence earlier than patients who performed PFMT only after catheter removal.

2. Methods

2.1. Patients

Inclusion criteria were men planning to undergo ORP or RARP in the University Hospitals Leuven who accepted ambulatory visits once a week until total continence was achieved and agreed to perform measurements preoperatively and at 1 mo, 3 mo, 6 mo, and 12 mo after surgery. Patients were excluded if they had cognitive problems, were non-Dutch speaking, simultaneously planned other pelvic surgery or a salvage procedure, had transport problems, had a lack of time, had psychosocial or other medical problems, did not want to participate, insisted on preoperative PFMT, were not approachable, or did not have enough time between diagnosis and date of planned surgery.

2.2. Procedure

Before surgery, patients were randomly assigned into the experimental group, which started PFMT 3 wk before RP and continued after surgery, or the control group, which started PFMT after catheter removal. Patients were recruited at the outpatient urology clinic. PFMT could start only 3 wk before surgery, because the waiting list for surgery was only 3 wk.

Randomization was performed within each stratum by using permuted blocks (size = 4). Strata were age (<65 yr compared with ≥65 yr) and surgical technique (ORP compared with RARP), because these two factors are important risk factors for UI [12–16]. Allocation to the treatment groups was concealed. A computer program carried out the randomization. The sequence of randomization was determined by the patients’ presence at the outpatient urology clinic. Choice of surgical technique depended on tumor characteristics, choice of the patient, and medical history. Three experienced surgeons each specialized in ORP and/ or RARP and completed all operations blinded to randomization.

2.3. Interventions

The PFMT program consisted of exercises of the pelvic floor manually controlled by the therapist and supplied with electromyography (EMG) biofeedback. Every patient received individual treatment on an outpatient basis once a week. The experimental group started exercising 3 wk before RP. They received one session of 30 min of guided PFMT per week until surgery. Additionally, patients performed a home program of 60 contractions per day and were instructed on contracting the pelvic floor muscles while coughing and sitting down or getting up from a chair. The fourth day after surgery, with the urinary catheter in situ, patients were encouraged to restart PFMT. The control group started exercising the day of catheter removal. Postoperatively, all patients came to the hospital once a week to discuss their bladder diary and to perform an individual guided exercise session with digital or EMG biofeedback control. Further specific exercises were given, along with advice on how to use the pelvic floor muscles to prevent urine loss during particular functional activities indicated by the patient. In both groups, PFMT was continued as long as any degree of UI persisted.

All patients in the experimental group were preoperatively treated by the same therapist (who was different from the therapist who performed the postoperative treatments and different from the assessor). After catheter removal, all patients were treated by another therapist. Both therapists had several years of experience in the treatment of UI. Patients were controlled for adherence to the home exercises. When they performed the prescribed 60 contractions per day, they had to color three squares in their diary (each square equaled 20 contractions).

2.4. Assessments

After catheter withdrawal, urine loss per 24 h was recorded. Patients continued this record at home until continence was achieved. Continence was defined as three consecutive days of 0 g of urine loss on the 24-h pad test. Double-checking of the patients’ self-measurements was performed on a regular basis by weighing the pads they wore when they came to therapy. From time to time, patients had to collect all diapers over 24 h in a plastic bag and bring the bag to the hospital for a second measurement. No difference was made in analysis between types of incontinence (stress or urge).

All patients were prospectively assessed before RP and 1 mo, 3 mo, 6 mo, and 12 mo after RP in the physiotherapy department. Patients had to perform a 1-h pad test, fill in a visual analog scale (VAS) concerning their subjective feelings about UI, and complete the International Prostate Symptom Score (IPSS) [17], a questionnaire to assess voiding symptoms. Additionally, the King’s Health Questionnaire (KHQ), to evaluate the impact of UI on quality of life, was completed [18]. Strength and endurance were also measured. Preoperatively, all patients performed a 24-h pad test during 3 d. One blinded and well-trained assessor performed the measurements. Patients were explicitly asked not to mention their group allocation to the assessor. No urodynamic measurements were performed in the first postoperative year. Anticholinergic drugs were not prescribed in the initial postoperative period.

Primary outcome parameters were cumulative incidence of continence and time to continence (24-h pad test). Secondary outcomes were the point prevalence of continence, measured with the 1-h pad test and the VAS at 1 mo, 3 mo, 6 mo, and 12 mo after surgery. At the same time points, IPSS and KHQ were assessed.

2.5. Sample size and statistical analysis

Sample size was calculated to detect a difference between the control and treatment groups in time until continence based on a two-sided log-rank test (α = 0.05). An exponential distribution was assumed for the event times, yielding 60% and 40% of patients being continent after 6 mo in the treatment and control groups, respectively. Note that the scenario for
the difference after 6 mo was derived from Burgio et al. [3]. The assumed distribution and difference after 6 mo corresponded to a median time until continence of 4.5 mo and 8.1 mo in treatment and control groups, respectively. It also implied that 84% of the subjects (treatment group) and 64% of the subjects (control group) were continent after 1 yr, the time at which the comparison was made. In total, 166 subjects were needed to have 90% power to detect the assumed difference between both survival curves. With drop-outs taken into account, 180 patients had to be included. We compared patient characteristics between excluded and included patients to analyze whether both groups were comparable.

Data were analyzed according to the intention-to-treat principle. Kaplan-Meier analyses with the log-rank test were used to compare the time to continence between both groups. Drop-outs were censored at the moment of last follow-up. Afterward, a Cox regression was applied to compare the different groups concerning the time to continence with correction for the two strata. The Fisher exact test was used to compare objective and subjective point prevalence of urinary continence, defined as 0 or ≤1 g on the 1-h pad test and the VAS, measured at 1 mo, 3 mo, 6 mo, and 12 mo after surgery. For comparison of voiding symptom severity and quality of life at 1 mo, 3 mo, 6 mo, and 12 mo after surgery, the Mann-Whitney test was used because data were not normally distributed. All data were analyzed with SPSS 19.0.

The procedures of the study received ethical approval from the commission on medical ethics of the University Hospitals Leuven responsible for human/animal experimentation (ML5470).

### Results

Between September 2009 and July 2011, 275 patients with localized or locally advanced prostate cancer were scheduled for ORP or RARP in the University Hospitals Leuven. A total of 180 patients met the inclusion criteria (Fig. 1) and signed written informed consent. Patients who did not want to participate for several reasons (n = 81) were asked to report their date of continence.

Compared with nonparticipating (excluded) patients, included patients had less ORP and more RARP surgery (p = 0.001), more patients with an intermediate D’Amico risk group and fewer patients with a high D’Amico risk group (p < 0.001), and fewer patients with non–nerve-sparing surgery and more patients with bilateral nerve-sparing surgery (p = 0.001). Other characteristics, such as age and surgical margin status, were comparable between both groups (data not shown).

One hundred eighty patients were included; 91 patients were randomized to the intervention group and 89 patients to the control group. Ten patients were lost to follow-up. Figure 1 shows the flow of patients and reasons for drop-out. Patients were very strict toward their appointments with the physiotherapist and the performance of exercises.

### Table 1 – Characteristics of patients according to treatment group

<table>
<thead>
<tr>
<th></th>
<th>Experimental group, n = 91</th>
<th>Control group, n = 89</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yr, mean (SD) (range)</td>
<td>61.88 (5.90) (44–73)</td>
<td>62.04 (6.33) (41–76)</td>
</tr>
<tr>
<td>Type of surgery, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ORP</td>
<td>60 (66)</td>
<td>56 (63)</td>
</tr>
<tr>
<td>RARP</td>
<td>31 (34)</td>
<td>33 (37)</td>
</tr>
<tr>
<td>D’Amico risk group, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>13 (14)</td>
<td>9 (10)</td>
</tr>
<tr>
<td>2</td>
<td>45 (49)</td>
<td>48 (54)</td>
</tr>
<tr>
<td>3</td>
<td>32 (35)</td>
<td>32 (36)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Nerve sparing, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non–nerve sparing</td>
<td>13 (14)</td>
<td>11 (12)</td>
</tr>
<tr>
<td>Unilateral nerve sparing</td>
<td>22 (24)</td>
<td>22 (25)</td>
</tr>
<tr>
<td>Bilateral nerve sparing</td>
<td>56 (62)</td>
<td>56 (63)</td>
</tr>
<tr>
<td>Missing</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Surgical margin status, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>73 (80)</td>
<td>63 (71)</td>
</tr>
<tr>
<td>Positive/doubtful</td>
<td>17 (19)</td>
<td>26 (29)</td>
</tr>
<tr>
<td>Missing</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Preoperative continence status, no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continent</td>
<td>63 (69)</td>
<td>53 (59)</td>
</tr>
<tr>
<td>Incontinent</td>
<td>25 (28)</td>
<td>30 (34)</td>
</tr>
<tr>
<td>Missing</td>
<td>3 (3)</td>
<td>6 (7)</td>
</tr>
<tr>
<td>Body mass index, kg/m², no. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;25.0</td>
<td>30 (33)</td>
<td>24 (27)</td>
</tr>
<tr>
<td>25.1–30.0</td>
<td>51 (56)</td>
<td>48 (54)</td>
</tr>
<tr>
<td>&gt;30.0</td>
<td>10 (11)</td>
<td>17 (19)</td>
</tr>
</tbody>
</table>

SD = standard deviation; ORP = open radical prostatectomy; RARP = robot-assisted laparoscopic radical prostatectomy.

All characteristics of both groups were comparable (Table 1). Median time to continence was 30 and 31 d for the control group and the experimental group, respectively (p = 0.878). The median amount of first-day UI was 108 and 124 g for the experimental and control groups, respectively (p = 0.880).

#### 3.1. Primary outcomes

Figure 2 shows the Kaplan-Meier analyses for time to continence (24-h pad test). Time to continence was comparable between experimental and control groups during the first year after surgery (p = 0.878). Additionally, Cox regression with correction for the two strata (age and type of surgery) gave comparable results (p = 0.773; hazard ratio: 1.047 [0.768–1.425]) (Table 2).

Four patients in the control group and two patients in the experimental group remained incontinent 12 mo after surgery. Compared with controls, patients in the intervention

### Table 2 – Cox regression for time to urinary continence according to type of treatment

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SE</th>
<th>Wald</th>
<th>df</th>
<th>p value</th>
<th>HR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>0.046</td>
<td>0.158</td>
<td>0.083</td>
<td>1</td>
<td>0.773</td>
<td>1.047</td>
<td>0.768–1.425</td>
</tr>
<tr>
<td>Type of surgery</td>
<td>0.430</td>
<td>0.164</td>
<td>6.850</td>
<td>1</td>
<td>0.009</td>
<td>1.537</td>
<td>1.114–2.122</td>
</tr>
<tr>
<td>Age</td>
<td>-0.519</td>
<td>0.173</td>
<td>9.035</td>
<td>1</td>
<td>0.003</td>
<td>0.595</td>
<td>0.424–0.835</td>
</tr>
</tbody>
</table>

B = B coefficient; SE = standard error; df = degrees of freedom; HR = hazard ratio; CI = confidence interval.
group had comparable cumulative incidence rates for continence and average amount of urine loss (24-h pad test) at all time points (Table 3).

3.2. Secondary outcomes

The point prevalence of urinary continence, defined as 0 or ≤1 g on the 1-h pad test and the VAS, was comparable for both groups at 1 mo, 3 mo, 6 mo, and 12 mo after RP (Table 4). Voiding symptoms (IPSS) did not differ between the experimental and control groups at any time point. Only one aspect of the KHQ, incontinence impact, was in favor of the experimental group at 3 mo and 6 mo after surgery (p = 0.008 and p = 0.024, respectively).

Strength and endurance did not significantly differ between the two groups at any time point. However patients with stronger pelvic floor muscles needed less time to become continent (p = 0.015).

Of 180 patients, 23 (13%) received additional radiotherapy. For all patients except three, radiotherapy was started only after continence was achieved. In these three patients, mean urine loss at the start of radiotherapy was 7 g/d, 8 g/d, and 64 g/d, respectively.

Sixty-five percent of patients were completely continent during 3 d in the preoperative period. Thirty percent had a small amount of urine loss (range: 1–10 g/d). However, Kaplan-Meier analysis for time to continence indicated that patients without preoperative urine loss achieved continence...
significantly faster than preoperatively incontinent patients \((p = 0.01)\).

Duration of incontinence, based on the patient-reported date of continence, did not differ between included and excluded patients \((p = 0.121)\).

### 4. Discussion

Patients who performed PFMT before and after surgery had no shorter duration of postoperative UI than patients who performed PFMT only after catheter removal. Only six patients remained incontinent after 1 yr (range: 6–167 g/d). Four patients opted for a male sling procedure and were continent afterward. Two patients refused surgical treatment because of minimal incontinence rate (6 g/d; \(n = 1\)) or other comorbidities (130 g/d; \(n = 1\)). Secondary analyses revealed that the 1-h pad test and the VAS did not significantly differ between both groups. The median time to urinary continence and the median amount of first-day UI were approximately the same for both groups. Voiding symptoms were comparable between both groups. Quality of life concerning the impact of incontinence was in favor of the experimental group at 3 mo and 6 mo after surgery. Although both groups recovered continence to the same extent, we cannot explain why the experimental group had better quality-of-life scores. Preoperative urine loss had a significant effect on duration of postoperative UI.

Our study had several strengths. First, it was a prospective study offering the same postoperative treatment to both groups and only three sessions of preoperative PFMT to the experimental group. This characteristic makes comparison possible. All patients were followed for 12 mo and evaluated at regular time intervals. All patients measured urine loss daily during 24 h by weighing pads.
Patients in the control group were in general rather disappointed in not having had preoperative treatment. Three preoperative sessions of PFMT did not improve postoperative duration of incontinence.

5. Conclusions

Standard postoperative continence rehabilitation using a strict pelvic floor reeducation scheme could not be improved by adding three preoperative sessions of PFMT. The impact of incontinence on quality of life, however, was less in the experimental group.

Author contributions: Inge Geraerts had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Geraerts, Van Kampen, Van Poppel.

Acquisition of data: Geraerts, De Groef, Van Poppel, Joniau, Van Cleynenbreugel.

Analysis and interpretation of data: Geraerts, Van Kampen, De Groef.

Drafting of the manuscript: Geraerts, Van Kampen, De Groef.

Critical revision of the manuscript for important intellectual content: Van Kampen, Van Poppel, Devoogdt, Joniau, Van Cleynenbreugel.

Statistical analysis: Geraerts, De Groef.

Obtaining funding: Geraerts, Van Kampen, Devoogdt.

Administrative, technical, or material support: Geraerts, Van Kampen.

Supervision: Geraerts, Van Kampen, Van Poppel.

Other (specify): None.

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References


