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ORIGINAL ARTICLE

Does physiotherapist-guided pelvic floor muscle training increase the quality of life in patients after radical prostatectomy? A randomized clinical study

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Abstract

Objective. The aim of this study was to study the effect of postoperative physiotherapist-guided pelvic floor muscle training (PFMT) on health-related quality of life (HRQoL) parameters in patients treated with radical prostatectomy (RP). *Material and methods.* A prospective randomized controlled trial was conducted at St. Olavs Hospital, Trondheim University Hospital, Norway. Eighty-five men were randomized into two intervention groups (A and B). patients in group A ($n = 42$) were offered physiotherapist-guided PFMT (in groups or by DVD) once weekly throughout the first 12 months after RP, while those in group B ($n = 43$) trained on their own. HRQoL data were assessed using the University of California, Los Angeles Prostate Cancer Index (UCLA-PCI) and the Short Form-12 (SF-12) health survey. The physical component summary (PCS) and mental component summary (MCS) scores of the SF-12 plus the urinary, sexual and bowel function and bother of the UCLA-PCI make up the eight quality of life outcomes used in this study. Data were obtained preoperatively (baseline), 6 weeks, and 3, 6 and 12 months postoperatively. *Results.* Eighty patients completed at least one follow-up assessment, 38 in group A and 42 in group B, giving a dropout rate of 5.9%. The overall response rates were 96% at baseline, 83% at 6 weeks, 90% at 3 months, 88% at 6 months and 68% at 12 months. No statistically significant difference in HRQoL was found between groups A and B. *Conclusions.* Even though physiotherapist-guided training of the pelvic floor muscles after RP improved postoperative urinary incontinence significantly compared to those patients receiving standard care/training, this was not reflected in better outcome in HRQoL parameters.

Key Words: *health-related quality of life, pelvic floor muscle training, physiotherapy, radical prostatectomy*

Introduction

Prostate cancer is the most common type of cancer in Norwegian men [1]. Radical prostatectomy (RP) and radiotherapy are options with curative intent in patients with localized disease. The main side-effects of RP are urinary incontinence and erectile dysfunction, which can be severe and troublesome [2] and have been shown to affect the patients' quality of life [3]. There is increasing focus on the importance of the "trifecta" outcome values after localized prostate cancer therapy; these are disease control, potency and continence [4].

The reported prevalence of postoperative urinary incontinence varies depending on factors such as time after RP and use of different definitions of incontinence. Johansson et al. reported the results for quality of life for men in the Scandinavian Prostate Cancer Group Study Number 4 (SPCG-4) after a median follow-up of more than 12 years. The prevalence of urinary leakage was found to be 41% in the RP group, 11% in the watchful waiting group and 3% in the

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control group [5]. Rates of incontinence after RP obtained from self-reporting questionnaires are two to three times higher than those provided by physicians, and physicians underestimate the incidence of postoperative urinary incontinence by up to 75%. Physician ratings of patient symptoms do not correlate well with self-reported questionnaires on health-related quality of life (HRQoL) [6].

There are few published randomized controlled trials where training of pelvic floor muscles is used in the treatment of incontinence in men who have undergone RP. Van Kampen et al. found at 3 months' follow-up that 88% of men in the pelvic floor muscle training group were continent, compared to 56% in the control group. At 1 year follow-up, the prevalence of incontinence was 5% in the training group versus 19% in the control group [7]. Moore et al. [8] and Bales et al. [9] found no significant improvement in the training group compared with controls. However, it is difficult to compare the results of these studies because the severity of the incontinence and exercise protocols in the studies varied.

In 2009 the present authors presented data showing that patients receiving physiotherapist-guided pelvic floor muscle training following RP reduced urinary incontinence significantly compared with patients training on their own [10]. The aim of the present prospective randomized controlled trial was to study the effect of postoperative physiotherapist-guided pelvic floor muscle training on HRQoL parameters in the same study population, assessed with a validated questionnaire, the University of California, Los Angeles Prostate Cancer Index (UCLA-PCI) [11] with additional questions, the 12-item Short Form (SF-12) health survey [12].

Material and methods

Patients

Men diagnosed with clinically localized prostate cancer operated with open RP at St. Olavs Hospital, Trondheim, Norway, between September 2005 and December 2006 were invited to participate in this study and were followed postoperatively for 12 months. The regional committee for medical and health research ethics approved the study. The trial is registered under ClinicalTrials.gov Protocol Registration System, Account NCT00239824.

The primary outcome measure of this prospective randomized controlled trial was self-reported continence/incontinence at 3 months after surgery. Urinary incontinence was defined according to the International Continence Society guidelines, and urinary continence was defined as no need for wearing a pad (0 pads). These data have previously been reported by Overgård et al. [10].

The current study presents the result of the secondary outcome measures: patient-reported perception of urinary, sexual and bowel function, and bother at 6 weeks, 6 and 12 months postoperatively. Eighty-five men were included and randomized into two groups which consisted of intensive pelvic floor muscle training with (group A) or without (group B) postoperative follow-up training instructed by a physiotherapist once a week throughout 1 year. Clinical and demographic characteristics were obtained from medical records and included age, preoperative serum prostate-specific antigen (s-PSA), clinical T stage and Gleason score. The computerized randomization was conducted by the Unit for Applied Clinical Research at the Norwegian University of Technology and Science.

Surgical technique

All participants were operated on with open RP [13]. Two urologists without knowledge of the outcome of the randomization performed the operations. A nerve-sparing procedure was performed in men with Gleason score ≤ 6 and T1c disease. Patients with Gleason score ≥ 7, clinical T2c or preoperative s-PSA $>$ 10 ng/ml were usually not operated on with a nerve-sparing technique. The bladder mucosa was everted in all patients. The seminal vesicle apex and puboprostatic ligament were spared in almost all patients. The bladder neck was spared in patients with no palpable tumour in the prostate base.

Intervention

All participants were individually informed of the anatomy and function of the pelvic floor muscles and how to correctly contract the muscles. Feedback to patients on performance and training technique was provided by the physiotherapist. Correct pelvic floor muscle contraction was assessed (digital anal palpation) and muscle strength measured preoperatively and at 6 weeks, and 3, 6 and 12 months postoperatively. The training frequency was written into a training diary. Group A followed a pelvic floor muscle exercise course consisting of intensive pelvic floor muscle training guided by a physiotherapist for 45 min once a week, starting immediately after catheter removal and lasting as long as the patient used pads or chose to continue training. Patients were instructed to perform 3×10 contractions daily at home, in a supine, sitting or standing position. The physiotherapist encouraged the patients to contract the pelvic floor muscles as hard as possible and to hold for 6–8 s, and at the end of each contraction add three

Table I. Demographic and clinical characteristics.

	Treatment group	Control group
	(n = 38)	(n = 42)
Age (years), mean (range)	60 (48–68)	62 (49–72)
BMI, mean ± SD	26.35 ± 3.10	26.24 ± 2.79
Preoperative s-PSA, mean ± SD	9.23 ± 3.67	9.15 ± 3.80
Biopsy Gleason score, mean ± SD	6.83 ± 1.03	6.49 ± 0.71
Clinical tumour stage, n (%)		
T1C	11 (31)	17 (42)
T2	18 (50)	14 (34)
T3	7 (19)	10 (24)
Pathological stage, n (%)		
pT2a	3 (8)	1 (2)
pT2b	0	5 (12)
pT2c	28 (78)	26 (63)
pT3a	5 (14)	6 (15)
pT3b	0	3 (7)
Surgical margin apex, n (%)		
Negative apex	29 (81)	33 (81)
Positive apex	7 (19)	8 (20)
Prostate volume (ml), mean ± SD	35.8 (17.01)	34.75 (18.65)

BMI = body mass index; s-PSA = serum prostate-specific antigen.

or four fast contractions [14]. Oral and written instructions were given. Group A patients who were unable to participate in the weekly training sessions at the hospital owing to long travelling distance (n = 20) were given a DVD with instructions on the pelvic floor muscle training programme provided by the physiotherapist. Group B received oral and written descriptions from a nurse of the postoperative training programme that had been used for the last 5 years at the Department of Urology. These included encouragement to perform 3 × 10 pelvic floor muscle contractions daily.

Health-related quality of life outcomes

HRQoL outcomes were assessed at baseline and at 6 weeks, and 3, 6 and 12 months after RP using validated instruments: the UCLA-PCI [11] and SF-12 [12]. The UCLA-PCI is specific for assessing HRQoL in men with localized prostate cancer, while the SF-12 measures general mental and physical HRQoL outcomes. The UCLA-PCI was a validated Norwegian translation of UCLA-PCI with additional questions (SF-12). The UCLA-PCI covers urinary, sexual and bowel symptoms in two domains: function and bother. Gore et al. showed that bother measurement is important in understanding self-reported HRQoL after RP [15]. It is responsive to acute and chronic change in assessing HRQoL in men treated for prostate cancer [16]. SF-12 is a generic quality of life instrument which measures eight health domains and uses psychometrically based physical component summary (PCS) and mental component summary (MCS) scores. It is validated and covers the general HRQoL [12]. The PCS and MCS of the SF-12 plus the urinary, sexual and bowel function and bother of the UCLA-PCI make up the eight quality of life outcomes used in this study.

Statistical analyses

All data were entered into and analysed with PASW Statistics 18. From UCLA-PCI the six disease-specific domains, i.e. urinary, bowel and sexual function and bother, were determined according to a validated scoring manual. The data were given values from 0 to 100, with higher values reflecting good function and less bother. The function scores are sum scores out of four to eight questions. The bother scores reflect graded answers (no, very small, small, moderate and big problem) to one question about how much bother the function had caused the past 4 weeks. From SF-12, PCS and MCS scores were determined according to a validated scoring manual [17]. The scores are calibrated so that 50 is the average score and 10 the standard deviation, with high scores reflecting high quality of life. Generalized estimating equations (GEEs) with an exchangeable working correlation structure were used to analyse the data. Covariates were treatment, age, time of HRQoL assessment, and interaction between treatment and time. Analyses using the alternative approach of multilevel models were also carried out. The results were approximately the same, so a decision was made to use GEEs. A linear response model was used for the analysis of PCS, MCS, and urinary, bowel and sexual function. For urinary and sexual bother an ordinal logistic model response with five response categories was used. For the variable "bowel bother", the lowest response categories had been little used, so these were merged with the second highest category and analysed using a binary logistic response model. Furthermore, for this variable, the GEE estimating procedure did not converge owing to missing values. Hence, the "bowel bother" variable was analysed assuming that missing values represented "No bother". This represents 51 missing values out of 80 × 5 = 400 values. For the other variables analysed, missing values created no such problems in the GEE estimating procedure. Mean, odds ratio (ORs), 95% confidence intervals

Table II. Health-related quality of life functional outcomes by treatment with time (n = 80), from generalized estimating equation analysis.

	Mean UCLA-PCI score			Mean SF-12 composite score	
	Urinary function	Bowel function	Sexual function	Physical[a]	Mental
Baseline					
Control	95.53 (90.41–98.65)	90.51 (87.25–93.77)	66.12 (59.93–72.32)	53.30 (15.92–54.69)	52.21 (48.87–55.55)
Training	96.67 (94.42–98.92)	90.44 (87.47–93.40)	64.78 (58.30–71.25)	53.41 (51.33–55.50)	50.04 (46.61–53.47)
6 weeks					
Control	50.94 (43.66–58.22)	89.71 (85.63–93.80)	16.41 (11.89–20.94)	48.21 (46.07–50.35)	53.51 (50.52–56.51)
Training	49.02 (41.42–56.63)	91.76 (88.71–94.81)	11.71 (7.87–15.55)	45.18 (41.99–48.38)	52.42 (49.05–55.79)
3 months					
Control	64.92 (57.44–72.39)	91.78 (87.97–95.60)	18.30 (13.30–23.29)	51.89 (50.04–53.73)	54.45 (51.76–57.14)
Training	69.98 (62.07–77.89)	96.04 (94.24–97.85)	17.97 (13.86–22.07)	51.42 (49.17–53.66)	53.20 (50.39–56.01)
6 months					
Control	77.93 (71.42–84.44)	91.92 (88.68–95.16)	21.68 (16.83–26.53)	53.44 (52.13–54.75)	54.23 (51.63–56.83)
Training	80.78 (73.42–88.13)	94.85 (92.55–97.15)	20.58 (14.90–26.26)	51.40 (49.03–53.76)	55.22 (52.53–57.90)
12 months					
Control	83.55 (76.98–9065)	92.41 (89.99–94.82)	25.26 (19.43–31.10)	53.54 (51.76–55.31)	54.47 (50.62–58.31)
Training	88.20 (82.67–93.74)	93.46 (90.26–96.66)	22.63 (16.02–29.24)	50.11 (46.77–53.45)	55.99 (53.43–58.55)

Data are shown as mean estimate (confidence interval).
[a]For the physical component summary score, 5 extreme observations were excluded from the analysis.
UCLA-PCI = University of California, Los Angeles Prostate Cancer Index; SF-12 = Short Form-12.

(CIs) and p values are reported where relevant. Two-sided p values under 0.05 were considered significant.

Results

Eighty-five patients were randomized into group A (n = 42) or group B (n = 43). Demographic and clinical characteristics were similar in the two groups (Table I). Eighty patients completed at least one follow-up assessment, 38 in group A and 42 in group B, giving a dropout rate of 5.9%. The overall response rates were 96% at baseline, 83% at 6 weeks, 90% at 3 months, 88% at 6 months and 68% at 12 months. One patient in group A was excluded owing to postponement of the operation. Four patients did not complete the trial, three in group A and one in group B. Two patients regretted inclusion, one quit for psychological reasons and one because of aggravation of leakage when performing pelvic floor muscle exercises.

There was a statistically significant decline in urinary function and increase in urinary bother after 6 weeks compared to baseline (Tables II and III, Figures 1 and 2). Thereafter, the scores gradually improved throughout the follow-up period, emerging somewhat below the baseline value after 12 months. Sexual function decreased and sexual bother increased considerably at 6 weeks. Sexual function showed a slight improvement in the follow-up period, while sexual bother remained high. Bowel function was high and bowel bother low at all time-points. The PCS score had a minor decline at 6 weeks, but merged with the baseline score at 3 months and remained at this level throughout the trial. The MCS remained at a consistently high score at all time-points (Tables II and III, Figures 1 and 2).

Table III. Health-related quality of life bother outcomes by treatment with time (n = 80).

	Urinary bother	Bowel bother	Sexual bother
Baseline: treatment (vs control)			
6 weeks: treatment (vs control)	5.02 (1.08–23.25)	0.91 (0.31–2.64)	0.76 (0.44–3.99)
3 months: treatment (vs control)	1.84 (0.41–8.34)	2.96 (0.78–11.27)	1.74 (0.20–1.63)
6 months: treatment (vs control)	1.40 (0.40–4.90)	2.52 (0.59–10.79)	1.54 (0.23–1.87)
12 months: treatment (vs control)	1.78 (0.30–10.78)	3.20 (0.83–12.34)	1.10 (0.30–2.80)

Data are shown as odds ratio (OR) estimate (95% confidence interval), where OR > 1 indicates positive effect of training. From generalized estimating equation analysis.

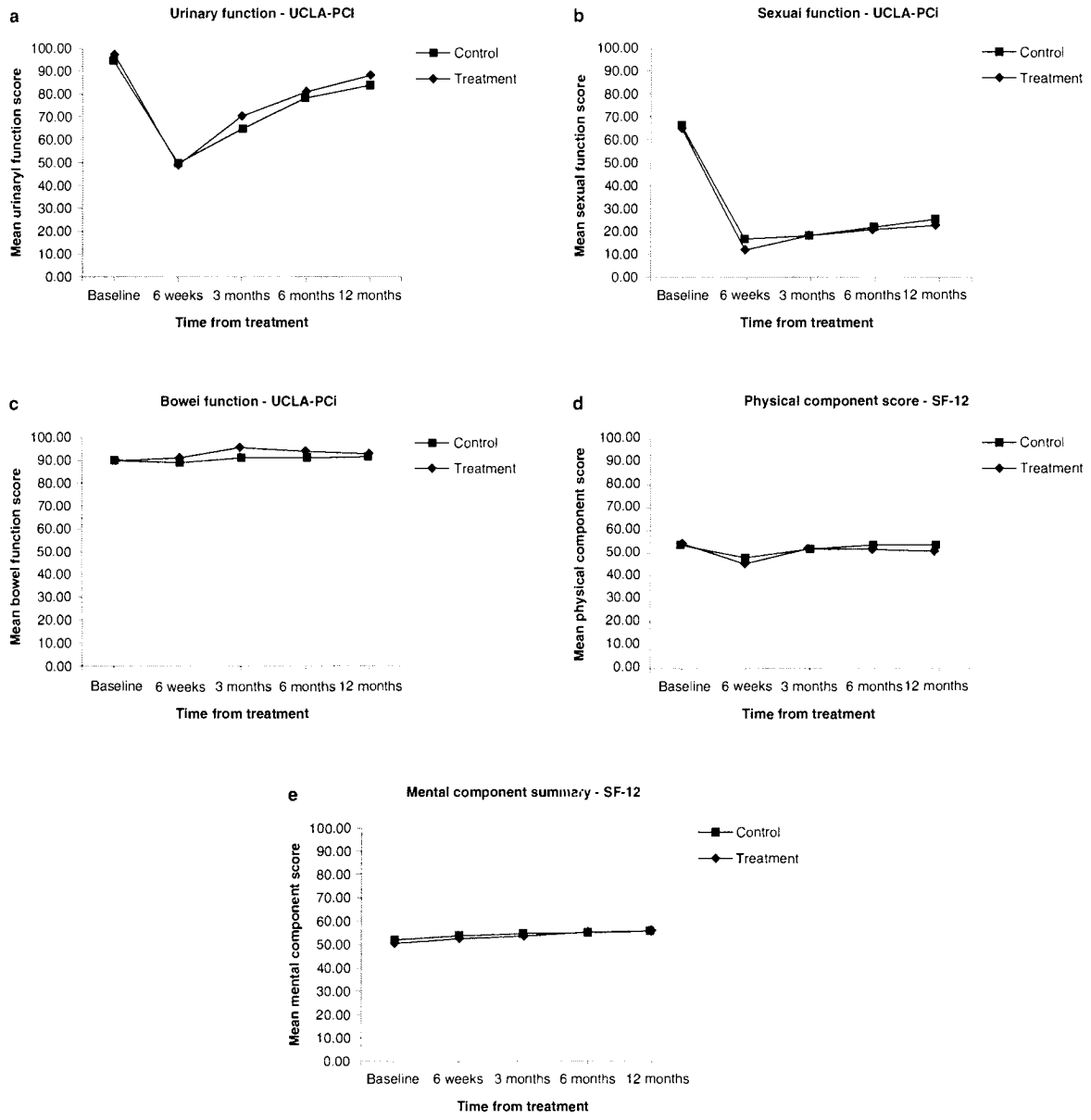

Figure 1. Mean University of California, Los Angeles Prostate Cancer Index (UCLA-PCI) scores: (a) urinary function; (b) sexual function; (c) bowel function; and Short Form-12 (SF-12) scores: (d) mental component summary; (e) physical component summary.

When analysing the UCLA-PCI and SF-12 parameters over time, all showed a statistically significant effect of time apart from MCS and bowel function (Table IV). PCS, urinary and sexual function scores improved with time, and urinary, bowel and sexual bother decreased with time.

The UCLA-PCI and SF-12 parameters did not show any statistically significant effect of age, except for the sexual function and urinary bother (Table IV). The sexual function score was reduced by 0.872 for each year ($p < 0.001$). There was a decrease in urinary bother with age, with OR 1.20 (1.05–1.37) and $p = 0.008$. The values for urinary function score showed a tendency towards reduction, by 0.575 for each year ($p = 0.078$).

When analysing the interaction between treatment and time, adjusted for age, no significant differences were found between the two intervention groups in any of the HRQoL values. This result was not altered in a secondary analysis, which excluded the DVD

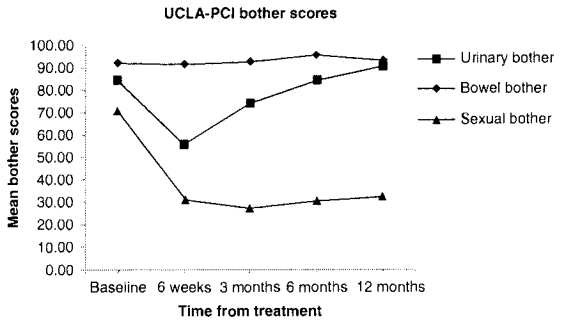

Figure 2. Mean University of California, Los Angeles Prostate Cancer Index (UCLA-PCI) bother scores based on descriptive statistics.

group and compared the 18 patients with a personal physiotherapist instructions with the control group. However, the PCS score showed a significant difference between the two groups before correction for outliers ($p = 0.022$).

Discussion

The incidence of urinary continence (defined as "no pads") at 12 months after RP in the study population was 92% in treatment group A (receiving postoperative physiotherapist-guided training of the pelvic floor muscles) and 72% in treatment group B (pelvic floor muscle training on their own), as reported by Overgård et al. [10]. The incidence of pad use at 6 weeks, and 3, 6 and 12 months postoperatively reported by Overgård, corresponds with the information given in the patient-reported questionnaires at the same time-points in the present report. The definition of incontinence used in this study was "no pads", which is a very strict definition. Despite the significant difference in continence status at 12 months postoperative follow-up between groups A and B, this finding was, surprisingly, not reflected in HRQoL (patient-reported urinary, sexual and bowel). However, the fact that only 18 of 36 patients were able to participate in the group training sessions might have caused an underestimation of the value of regular in-person contact with the physiotherapist throughout the treatment period.

In this study, urinary function declined and urinary bother increased at 6 weeks compared to baseline, then gradually improved throughout the follow-up period to end up somewhat below the baseline at 12 months, in accordance with the findings of Rice et al. [18]. Urinary bother was affected by age whereas urinary function was not. Younger men seemed to associate reduced urinary function with more bother than older men, and older men seemed more prone to accept reduced urinary function.

The patients in this study experienced good bowel function and little bowel bother at all times, as shown by others [18,19]. Altered bowel function and bowel bother are primarily associated with radiation [20]. Bowel bother showed an effect with time, even though bowel function did not. Some patients may relate some of the urinary and sexual bother to bowel bother.

Sexual function was found to be low and the sexual bother was high from 6 weeks and throughout the study, which is consistent with other studies [18,21]. It is reasonable to anticipate that an increased number of nerve-sparing operations would have improved postoperative erectile function [22]. Sexual function was reduced with age, as reported by Hollenbeck et al. [22]. However, both PCS and MCS showed high scores, with only a minor drop in PCS at 6 weeks, as shown previously [18,23]. Bergman et al. reported that urinary and sexual dysfunction strongly influence the total general HRQoL for men [16]. The present study showed a good subjective general HRQoL despite reduced urinary and sexual function, which is consistent with previous studies [24,25]. The explanation may be that patients in the early follow-up focus on survival, but thereafter HRQoL becomes an important issue as patients remain disease free [3]. Most of the patients have non-measurable PSA levels after RP and urinary function improves with time, as reflected in the stable high scores in PCS and MCS. Several factors may alter the HRQoL in the men in this study population (age range 48–72 years). Patient partnership status has implications for HRQoL after RP. Litwin et al. reported that age, ethnicity and

Table IV. Results from generalized estimating equation analysis: p-values.

	p Value			
	Treatment	Time	Age	Time × Treatment interaction
SF-12				
PCS[a]	0.512	< 0.001	0.145	0.177
MCS	0.809	0.657	0.955	0.399
UCLA-PCI				
Urinary function	03.479	< 0.001	0.078	0.414
Urinary bother	0.695	< 0.001	0.008	0.306
Bowel function	0.186	0.619	0.366	0.467
Bowel bother	0.223	< 0.001	0.119	0.123
Sexual function	0.639	< 0.001	< 0.001	0.639
Sexual bother	0.822	< 0.001	0.862	0.210

[a]For PCS, 5 extreme observations were excluded from the analysis. SF-12 = Short Form-12; PCS = physical component summary; mental component summary; UCLA-PCI = University of California, Los Angeles Prostate Cancer Index.

comorbidity did not have an impact on urinary function or bother, but being married was an advantage [26]. However, Arredondo et al. found that comorbidity reduced HRQoL both before and after RP [27]. These aspects of HRQoL were not examined in the present study.

When analysing the interaction between treatment and time, adjusted for age, no significant differences between the two intervention groups were found on any of the HRQoL parameters. However, there was a tendency towards increased PCS, MCS and urinary function, as well as reduced urinary bother for the treatment group compared with the standard care group.

There are several limitations to consider in this study. The lowest response rate was 68%, and occurred at 12 months. It is not unlikely that those who did not respond were more likely to have fewer problems than the responders, but this should not affect the comparison between the treatment groups.

The number of participants was low (n = 85) compared to other studies, which may lead to a type II error. There may have been a too small difference in adherence to the training protocol between the two intervention groups. Both groups learned how to correctly contract the pelvic floor muscles and how to perform the pelvic floor muscle training, and received a training programme. In addition, the treatment group was offered a place on a physiotherapist-led pelvic floor training course once a week. Only 18 out of 38 patients were able to attend the training course at the hospital, owing to the long distance to the hospital. The remaining 20 men in the treatment group exercised at home following a DVD where a physiotherapist gave instructions. Thus, the value of regular in-person contact with the physiotherapist and other patients throughout the treatment period might have been underestimated. The findings were not altered in a secondary analysis, which excluded the DVD group and compared the 18 patients with a personal physiotherapist instructions to the control group. However, the low numbers in the new analysis must be taken into account. Overgård found that weekly training with a physiotherapist or DVD enhanced the training rate compared to group training on their own, and this was probably the most important factor in increased clinically urinary continence [10]. The participants were followed for 1 year after RP, which could too short a period to detect any changes in HRQoL [3]. Moreover, the reduction in urinary incontinence in the treatment group compared to the control group may have been too small for discrimination by the HRQoL instruments used in this study [28]. However, the prospective randomized controlled design in the present study adds strength to the reliability of the findings.

The costs of physiotherapist-guided training have to be compared to the high costs of consumption of incontinence pads each day for many years. In addition, the clinically meaningful reduction in post-RP urinary incontinence should be stressed.

In conclusion, this study showed no statistically significant differences between the intervention groups in either disease-specific (UCLA-PCI) or general (SF-12) HRQoL parameters. Even though physiotherapist-guided training of the pelvic floor muscles after RP has been shown to reduce the incidence of postoperative urinary incontinence significantly compared to those patients receiving standard care, this was not reflected in better outcome in HRQoL parameters.

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