Effect of pelvic-floor re-education on duration and degree of incontinence after radical prostatectomy: a randomised controlled trial

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Summary

Background Urinary incontinence is a common long-term complication after radical prostatectomy. Spontaneous recovery of normal urinary control after surgery can take 1–2 years. We aimed to investigate whether there was any beneficial effect of pelvic-floor re-education for patients with urinary incontinence as a result of radical prostatectomy.

Methods 102 consecutive incontinent patients who had had radical retropubic prostatectomy for clinically localised prostate cancer and who could comply with the ambulatory treatment schedule in our hospital were randomised, after catheter removal, into a treatment group (n=50) and a control group (n=52). Patients in the treatment group took part in a pelvic-floor re-education programme for as long as they were incontinent, and for a maximum of 1 year. The control group received placebo therapy. The primary endpoint was continence rate at 3 months. Incontinence was assessed objectively with the 1 h and 24 h pad tests and subjectively by the visual analogue scale. The groups were analysed on an intention-to-treat basis by ANOVA and χ^2 -test.

Findings In the treatment group continence was achieved after 3 months in 43 (88%) of 48 patients. In the control group, continence returned after 3 months in 29 (56%) of 52 patients. At 1 year, the difference in proportion between treatment and control group was 14% (95% CI 2–27). In the treatment group improvement in both duration (log-rank test, p=0·0001) and degree of incontinence (Wald test, p=0·0010) was significantly better than in the control group.

Interpretation Pelvic-floor re-education should be considered as a first-line option in curing incontinence after radical prostatectomy.

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Introduction

Localised prostate cancer can be cured by surgery or radiotherapy. Radical prostatectomy is commonly thought to be the most effective treatment.[1–4] Removal of the prostate and surrounding tissue can lead to leakage of urine, one of the most distressing sequelae of prostate surgery and a major cause of urinary incontinence in men.[4–7] In previous studies, the rate of incontinence after radical prostatectomy varied from 8% to 87% at 6 months and from 5%–44·5% 1 year after the operation.[1–17] Some investigators defined incontinence strictly to include all patients with any lack of control, whereas others reported only severe incontinence. Most studies used subjective assessments.[5,10,16] A few prospective studies that used an objective assessment, such as a 1 h[18] or 24 h pad test and urodynamic investigation,[9,16] provided more reliable information.

Postprostatectomy incontinence may be caused by bladder dysfunction or sphincter incompetence. Most patients present with sphincter insufficiency with or without detrusor instability.[7,9,11,17] Previous transurethral resection, age, operative technique, preservation of the neurovascular bundles, urodynamic measurements, and clinical and pathological stage of the tumour were found to be risk factors for incontinence after radical prostatectomy.[12,14,15,19,20]

The spontaneous recovery of urinary control may take up to 1 or 2 years after surgery. Pelvic-floor re-education is an effective non-invasive method of treating urinary incontinence in women.[21–25] Physiotherapy is not mentioned in most studies about incontinence after radical prostatectomy. In only a few studies were rehabilitation programmes initiated to treat incontinence after prostate surgery.[26–29] These studies suggested beneficial effects of re-education programmes, but the effect of spontaneous recovery was not taken into account.

We aimed to find out whether pelvic-floor re-education decreases the duration and degree of urinary incontinence after radical prostatectomy in a randomised controlled study.

Methods

Patients

From January, 1995, to June, 1996, all patients who had a radical retropubic prostatectomy for clinically localised prostate cancer at our hospital were screened. Patients were included if they were seen to be incontinent on day 15 after surgery after removal of the catheter, and if the patient could regularly attend hospital appointments. All patients included in the study gave written informed consent.

Procedures

The radical retropubic prostatectomies were done by two surgeons (HVP and LB). The same surgical approach was used for all patients—a classic retropubic retrograde radical prostatectomy maintaining the pelvic-floor structures.[30]

To obtain balanced groups, factors that could be used to predict the rate of postoperative incontinence were identified. This prediction allowed the classification of patients according to the most relevant prognostic factors. In a previous study, patients who had had a transurethral resection of the prostate had an increased risk of incontinence.[19] Furthermore, men who lose a substantial volume of urine on day 1 after catheter removal remain incontinent for longer. Therefore, prior transurethral resection of the prostate and urine loss on day 1 after catheter removal were included in the stratification.

Patients were placed in one of six subgroups according to amount of initial urine loss (three categories: ⩽50 g, 51–249 g, and ⩾250 g), and if they had had a transurethral resection. On day 1 after catheter removal the patients in these six subgroups were randomly assigned by an independent person into the treatment group or the control group. Random permuted blocks were used to generate the randomisation list. Sealed envelopes were chosen to allocate the patients to either the control group or treatment group.

Patients in the treatment group took part in a pelvic-floor re-education programme for as long as any degree of incontinence persisted, with a time limit of 1 year. Each patient received individual treatment in an outpatient clinic once a week. During the first treatment session the anatomy and function of the pelvic floor and bladder were explained. The training programme involved active pelvic-floor muscle exercises and biofeedback. However, some of the patients initially could not actively contract their pelvic-floor muscles or the contraction was very weak. The strength of the pelvic-floor muscles was measured by digital anal control. A score of 0–5 was given (0=no contraction, 1=flicker, 2=weak contraction, 3=good contraction but without resistance, 4=good contraction against slight resistance, 5=good contraction against strong resistance). Seven of 50 patients were not able to contract the pelvic-floor muscles or had only a weak contraction (score 0–2). Those patients were given electrical stimulation with an anal probe to teach them how to contract the muscles. When the patients were able to do the appropriate pelvic-floor muscle activity, they were told to do 90 contractions per day at home in any of three positions—supine, sitting, or standing. Patients were also told how to integrate contractions into daily activities.

Patients in the control group also attended the outpatient clinic once a week. They were told about the origin of incontinence after radical prostatectomy and received placebo electrotherapy that could not affect the pelvic-floor muscle function. The placebo electrotherapy (a false interferential current) was given via four skin electrodes, two placed on the abdomen and two on the adductor muscles of the thighs.

The patients in both groups were treated by the same therapist (MVK) until they became continent, within a period of 1 year. Continence was defined as a loss of no more than 2 g urine on both the 24 h and 1 h pad test, and when the patients could indicate that they had not been incontinent during the previous 3 days.

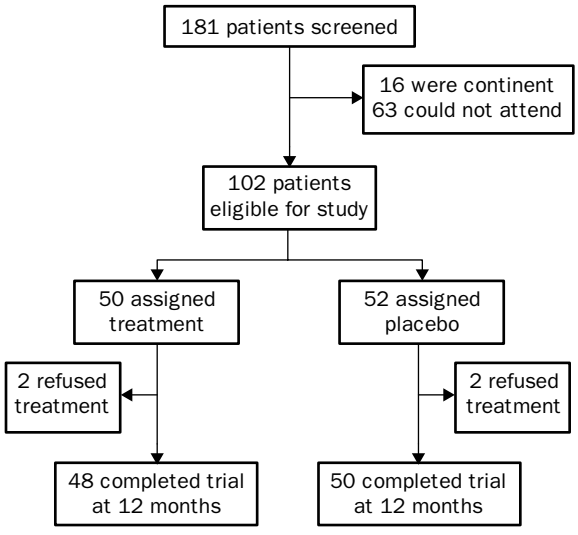


Figure 1: **Trial profile**

Characteristics	Treatment	Control group
Mean (SD) age (years)	64·36 (0·81)	66·58 (0·80)
Mean (SD) urine loss day 1 (g)*	5·30 (0·19)	5·48 (0·18)
Previous transurethral resection	2 (4%)	5 (10%)
Preoperative micturition†		
<10	37 (74%)	41 (81%)
10–20	9 (18%)	9 (17%)
>20	4 (8%)	2 (2%)
Clinical tumour stage		
T1	19 (38%)	19 (36%)
T2a	13 (26%)	11 (21%)
T2b	5 (10%)	4 (8%)
T2c	4 (8%)	5 (10%)
T3	9 (18%)	13 (25%)
Pathological tumour		
pT2a	7 (14%)	6 (11%)
pT2b	2 (4%)	1 (2%)
pT2c	12 (24%)	14 (27%)
pT3	29 (58%)	31 (60%)
Nerve-sparing operation		
One bundle	9 (18%)	3 (6%)
Two bundles	0	2 (4%)

*Log transformed. †International Prostate Symptom Score.

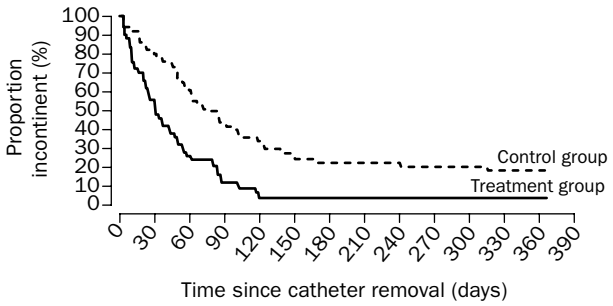
Table 1: **Baseline characteristics**

The 24 h pad test was done every day from the time of catheter withdrawal until the patient became continent. On day 1 after catheter removal a nurse weighed every pad, wet and dry, and calculated urine loss in 24 h. At home, the patient weighed the pads (on a scale with an accuracy of one gram) and noted the amount of urine loss. When a loss of less than 2 g was achieved, a 1 h pad test was done in hospital as an additional assessment to confirm that the patient was continent. The 1 h pad test was repeated for all patients 1 year after radical prostatectomy. Continence was also assessed subjectively preoperatively and at 1, 6, and 12 months with a visual analogue scale (0=completely dry, 10=completely incontinent). All patients were asked to fill in voiding volume charts to detect prevention of urine leakage by increasing the frequency of urination. Patients were encouraged to have a bladder capacity to enable them to reach voiding volumes above 150 mL. Patients noted which activities or circumstances provoked urine leakage. All the assessments were done and data collected by a therapist who was not involved with the study.

Statistical analysis

Analysis was done in the Department of Public Health and Biostatistical Centre of the University of Leuven. Factors predisposing to incontinence in the treatment group and the control group were compared by ANOVA or exact χ^2-test. Risk factors were age, urine loss on day 1 after catheter removal, previous transurethral resection, preoperative micturition (assessed by the International Prostate Symptom Score[31]), nerve sparing operation, and the clinical and pathological stage of the tumour. In a primary analysis, continence rates for patients in the treatment group were compared with those of the control group. The difference in the proportion of patients in the treatment and control groups who were continent at 3 months were tested with Fisher's exact test. Also, the duration of incontinence tested by the 24 h pad test was found for treatment and control group and analysed by the Kaplan-Meier method. The log-rank test was used to assess the significance of the difference in duration of incontinence between the two groups. The degree of incontinence was analysed by calculating the area under the curve of the daily urine loss. A logarithmic transformation of this measurement was used. Groups were then compared by the Wald test.

The Cochran-Mantel-Haenszel test was used to compare the visual analogue-scale results from control and treatment groups.



Number still incontinent

Treatment	50	25	13	5	2	2	2	2	2	2	2	2	2
Control	52	42	32	23	18	14	12	12	12	11	11	9	9

Figure 2: **Incontinent patients in control and treatment groups after radical prostatectomy in function of time**

We calculated that a sample size of 92 patients would enable the detection of a decrease from 100% to 50% in the incontinence rate for the treatment group and a decrease from 100% to 75% for the control group, with a power of 90% at p=0·05 after 3 months.

Results

181 patients who had had a radical retropubic prostatectomy for clinically localised prostate cancer were screened (figure 1). 16 patients were excluded because they were continent and did not need any further treatment and 63 patients with incontinence were excluded since they were not able to come regularly to the hospital, mostly because of the distance or problems of access. They were referred to private community physiotherapists who specialised in pelvic-floor re-education. 102 patients were included in the study. The mean age of the patients was 65 years (range 52–76). 50 patients were randomly allocated to the treatment group and 52 to the control group. The treatment and control groups were similar in terms of baseline characteristics (table 1).

Two patients in the treatment group refused further follow-up; one patient had newly regained continence but stopped treatment after 2 months because of transport problems to the hospital and the other was still incontinent but stopped after 2 months because of psychiatric problems. In the control group two patients refused further follow-up for social reasons; one patient was already continent but underwent a cystectomy for bladder carcinoma within the first postoperative year. Patients were followed up for 1 year. In practice, it was impossible for all patients to come every week during the entire treatment period. Occasionally patients came only once a fortnight for reasons as sickness, holiday, or social events. No patient died during the follow-up period.

The primary endpoint was the incontinence rate at 3 months. There was a significant difference between the treatment and control groups (Fisher's exact test, p=0·001) in the proportion of patients who were continent at 3 months (43 [88%] of 48 *vs* 29 [56%] of 52; group difference in proportion 32%; table 2). The duration of incontinence was significantly shorter in the treatment group than in the control group (log-rank test p=0·0001, figure 2).

Time since catheter removal (months)	Number of patients still incontinent		Difference in proportion (95% CI)
	Treatment group (n=50)	Control group (n=52)	
1	25 (50%)	42 (81%)	31% (13–48)
2	13 (26%)	32 (61%)	35% (18–54)
3	5 (12%)	23 (44%)	32% (16–49)
4	2 (5%)	18 (35%)	30% (15–44)
5	2 (5%)	14 (25%)	20% (7–34)
6	2 (5%)	12 (23%)	18% (5–31)
12	2 (5%)	9 (19%)	14% (2–27)

Table 2: **Differences in proportions of incontinent patients between the treatment and the control group**

Time since catheter removal	Urine loss on 24 h pad test (g)	
	Treatment group	Control group
1 day	416	440
1 week	206	330
1 month	88	166
2 months	30	82
3 months	13	26
4 months	8	13
5 months	9	6
6 months	5	3
12 months	8	3

Table 3: **Average loss of urine per 24 h**

The proportions of patients who remained incontinent and the differences between the groups are given in table 2.

After 1 year two patients in the treatment group and nine patients in the control group were incontinent. The degree of incontinence was significantly lower in patients in the treatment group (Wald test p=0·0010; table 3). The average urine loss in the treatment group between 5 months and 12 months was higher than in the control group as one patient had a very high loss (374 g).

An additional test for assessment of incontinence, the 1 h pad test, done when the patient achieved less than 2 g urine loss on the 24 h pad test. No patient had more than 2 g urine loss on the 1 h pad test at that time. The results were also assessed by a visual analogue scale both preoperatively and at 1, 6, and 12 months (table 4). Comparison of results shows a significant result for the treatment group. 1 month after catheter removal (Cochran-Mantel-Haenszel test but not at the other times, p=0·006).

There was significant agreement between subjective assessment of incontinence on the visual analogue scale and the objective 24 h pad test only 1 month after the operation (Spearman coefficient=0·846; p=0·0001). 12 months after the operation, all patients who had a score of 1 on the visual analogue scale lost less than 2 g urine in 24 h. For all patients, moving into standing or squatting, walking long distances, and intake of alcohol were the activities commonly associated with urinary incontinence. Most patients complained of urine leakage during the second half of the day.

The average number of treatment sessions of physiotherapy in the treatment group was eight (range one to 50) and in the control group it was 16 (two to 47).

Score	Proportion of patients with VAS score (%)							
	Preoperatively		1 month		6 months		12 months	
	T	C	T	C	T	C	T	C
0	78	90	30	15	57	52	52	42
1	10	8	18	8	33	31	36	28
2	8	2	16	15	4	9	8	18
3	4	0	8	13	2	4	2	6
4	0	0	6	10	0	2	2	0
5	0	0	14	13	2	0	0	2
6	0	0	0	2	0	0	0	2
7	0	0	0	4	2	0	0	2
8	0	0	6	10	0	2	0	0
9	0	0	0	2	0	0	0	0
10	0	0	2	8	0	0	0	0

VAS=visual analogue scale; T=treatment group; C=control group.

Table 4: **Scores on the visual analogue scale preoperatively, and at 1, 6, and 12 months**

Discussion

We found that pelvic-floor re-education was significantly more effective than placebo treatment in decreasing both the duration and degree of incontinence after radical prostatectomy. Differences between the two groups in the percentage of incontinent patients remaining were highest in the first 4 months and decreased from 31% at 1 month to 14·4% at 1 year. This study shows that therapy should start as soon as possible after the operation. 1 year after radical prostatectomy, severe incontinence is rare. Only two patients, one in the treatment group and one in the control group had urine loss of more than 100 g per day after 1 year. In other studies[21–25] positive results were reported when physiotherapy was started at different times after the operation, however, spontaneous recovery was not taken into account.

Postprostatectomy incontinence can be caused by bladder dysfunction or by sphincter incompetence. One function of the pelvic-floor muscles is to close the urethra and to reduce loss of urine. After radical prostatectomy, stress incontinence is common because of sphincter incompetence.[7,9,11,17] In our study, urine leakage occurred mostly during exertion. Urine leakage also occurred after the patient had consumed alcohol. Fatigue of the striated muscles of the pelvic floor led to increased loss of urine during the second half of the day. The active pelvic-floor exercises helped to avoid urine loss not only by improved muscle strength but also by improved endurance. In our study, patients did not usually have urine loss when coughing, because reflex contraction of the periurethral skeletal musculature increases the closing pressure of the urethra. When this compensatory mechanism is working efficiently, the patient will be continent when coughing. However, when the patient is relaxed, standing up or walking, this compensation is insufficient and he will lose urine. Another function of the pelvic-floor muscles is the capacity to inhibit bladder contraction in cases of detrusor instability to avoid urge incontinence.[23] Pelvic-floor re-education has proved to be effective in women with sphincter insufficiency and detrusor instability.[21–25]

Full urodynamic investigation with cystometry should perhaps have been done on all incontinent patients after radical prostatectomy to define the cause of incontinence.[7,13] However, previous reports have shown conflicting results on the frequency of the causes. In two studies, urodynamic investigations showed bladder dysfunction to be the cause of incontinence in small proportions of patients (3–4%).[9,12] By contrast, Leach and colleagues[13] found 40% of patients had stress incontinence alone and 60% had a major component of bladder dysfunction. Ficazzo and colleagues[17] compared urodynamic findings and subjective symptoms of stress and urge incontinence in a large population of incontinent men after radical prostatectomy, and found that the symptoms of stress incontinence accurately predicted sphincter insufficiency while symptoms of urge incontinence were not as reliable in predicting detrusor instability.

Urodynamic investigations are generally done on patients before and after radical prostatectomy to obtain more information about factors that affect incontinence.[11–13,15,17] This was not the purpose of our study. Surgical treatment for men with postprostatectomy incontinence is generally not considered for at least 12 months after the operation.[7] Therefore, our urologists made urodynamic assessments only for those patients who were incontinent 1 year after surgery. In our study only two patients were referred 1 year after operation for urodynamic investigation to decide on surgical treatment.

One patient in the treatment group had continuous leakage, caused by detrusor instability, during the year after the operation. This was diagnosed after urodynamic investigation. This patient lost 560 g urine the first day after catheter removal and was still losing about 375 g per day at 1 year. Physiotherapy was not effective because of total incontinence.

The 24 h pad test is a useful way to quantify incontinence.[32] The 1 h pad test tends to underestimate the severity of incontinence and is not as sensitive as the 24 h test for the detection of slight incontinence.[16] The time that the 1 h test is done can affect the reproducibility and reliability of a short test. Many patients have no urine loss in the morning even though they are incontinent the rest of the day. Donnellan and colleagues[16] compared the assessment of incontinence after a radical prostectomy by a 1 h pad test and a questionnaire. They reported that the rate of mild incontinence was higher with the questionnaire than the pad test; however, the pad test identified more patients with moderate and severe incontinence. A third method to assess incontinence is a visual analogue scale. In our study there was a high degree of correlation between the visual analogue scale and the 24 h pad test at 1 month but not at 6 months or 12 months. All patients who scored 1 on the visual analogue scale overestimate the rates of incontinence, because a score of zero was classified as completely continent. This result shows that the visual analogue scale is too strict for the assessment of incontinence. Only 47% of patients scored 0 at 1 year after the operation. The fact that many patients scored 1 or 2 was because of slight leakage or dribbling less than 2 g per day and, as a result, classed as continent. Most patients felt continent at that time. The number of physiotherapy sessions in the treated group was low on average, therefore the cost of treatment is not high.

Since there are no side-effects or risks from therapy we advise that physiotherapy should be offered to all patients with incontinence from day 1 after catheter removal. Treatment is most effective during the first 4 months after surgical intervention.

Contributors

M Van Kampen, designed the study, analysed and interpreted the data, drafted the article, and organised the project. W De Weerdt and H Van Poppel designed the study, analysed and interpretated the data, critically revised the article, contributed to the final approval of the article and collected the perioperative data. D De Ridder designed the study, revised critically the article and contributed to the final version. H Feys designed the study, revised critically the article, collected, analysed, and interpreted data, and contributed to the final approval of the article. L Baert designed the study, revised critically the article, contributed to the final approval of the article, and collected perioperative data.

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