CONTRIBUTION OF EARLY INTENSIVE PROLONGED PELVIC FLOOR EXERCISES ON URINARY CONTINENCE RECOVERY AFTER BLADDER NECK-SPARING RADICAL PROSTATECTOMY: RESULTS OF A PROSPECTIVE CONTROLLED RANDOMIZED TRIAL

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Aims: In this prospective controlled randomized trial we assessed the effects of early, intensive, prolonged pelvic floor exercises (PFE) on urinary incontinence following bladder neck (BN) sparing RRP. Methods: A sample of 152 patients with localized prostate cancer underwent RRP with BN preservation. Out of this group we randomized 107 incontinent patients into 2 groups. We considered incontinent patients with 24 hr Pad test >2 g. The T group received instructions regarding an intensive program of PFE, from 7 days after catheter removal for as long as any degree of incontinence persisted, within a period of 1 year. The control (C) group did not receive instructions. The outcome was assessed using the 24 hr Pad test, a visual analogue scale (VAS) and a single question of QoL. Results at baseline and at 1, 3, 6, and 12 months were available for 54 and 40 patients, respectively. Results: The overall spontaneous continence rate after catheter removal was 23.6%. The proportion of men still continent was significantly higher in the C group than treatment (T) group at 1 (97.5% vs. 83.3%; \(P = 0.04\)), 3 (77.5% vs. 53.7%; \(P = 0.03\)), 6 (60% vs. 33.3%; \(P = 0.01\)), and 12 months (52.5% vs. 16.6%; \(P < 0.01\)). Similarly, the VAS and the response to the QoL question at 12 months significantly differed between the two groups (\(P = 0.01\) and \(P = 0.03\), respectively). Conclusions: Our study suggests that early intensive prolonged PFE can further increase the number of continent patients and this improvement persists in the first 12 months. The second 6 months following surgery are still useful to recovery. Neurourol. Urodynam. 26:985–989, 2007. © 2007 Wiley-Liss, Inc.

Key words: urinary incontinence; pelvic floor; prostate cancer; retropubic prostatectomy

INTRODUCTION

Urinary incontinence continues to be one of the most bothersome complications following retropubic radical prostatectomy (RRP) for localized prostate cancer, with reported incidence varying from 2% to 87% and it is an independent predictor of global QoL. Several factors contribute to this broad range such as patient selection and age, previous transurethral resection of the prostate or damage to the striated urethral sphincter, urologist experience, details of surgical technique (such as bladder neck (BN) preservation, apex preparation, control of the deep dorsal vein and sparing of the neurovascular bundles) and not least the definition of incontinence, the method used to measure it and the duration of follow up. The pathophysiology of incontinence is not completely clear, but in most cases it is caused by sphincteric injury with or without detrusor overactivity.

The anatomical relation between the urogenital diaphragm, prostate and urethral sphincter mechanism allows urinary control to be achieved even in the presence of injury to the distal sphincter mechanism. At our institution the standard technique of RRP preserves the circular fibers of the BN and the proximal sphincter located within. Several groups have investigated the effect on degree and duration of incontinence after RRP with pelvic floor reeducation, with discrepancies in the reported efficacy, because trials are often not randomized or controlled. However, in all these studies the BN had not been preserved and the “tennis racket” technique for bladder outlet closure was used. Therefore, we assessed in a prospective, randomized, controlled trial whether an early intensive prolonged treatment program of pelvic floor exercises (PFE) could improve the continence recovery after BN sparing RRP.

MATERIALS AND METHODS

One hundred fifty-two consecutive patients who underwent RRP for clinically localized cancer from May 2003 to January 2005 were included in the trial. The study was approved by the Medical Centre Institutional Review Board and all men provided informed consent. The RRP were carried out by the same surgeon, with careful dissection with scissors of the circular BN fibers in all patients, using a technique previously described. The catheter was removed after 2 weeks and urinary continence, objectively (24 hr Pad test) and subjectively (visual analogue scale—VAS) assessed after 7 days, was defined a leakage ≤2 g of urine on 24 hr and confirmed by the patient.

Only patients who could comply with the protocol and regularly attend hospital appointments were considered for the study. The inclusion criteria for the trial were: objectively confirmed urinary incontinence (>2 g of urine loss on 24 hr

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activities and circumstances associated with leakage. All the patients were asked to have a normal life, neither reducing the liquid assumption nor increasing the frequency of urinary loss. Residual incontinence was also assessed regarding the rate of residual incontinence.

The primary endpoints were the incontinence rates at 1, 3, 6, and 12 months following surgery. The secondary endpoints were the correlation between the subjective assessment of incontinence on the VAS, the objective one on 24 hr Pad test and the QoL, and the correlation of incontinence rate with nerve-sparing surgery and age.

Each patient in both groups received an individual evaluation in outpatient clinic at 1 week, 1, 3, 6, and 12 months after catheter removal. All patients underwent physical examination, including a neurological assessment, and had a complete history taken, including previous urological symptoms assessed by the International Prostate Symptom Score (IPSS score).

Patients in the treatment (T) group took part in a pelvic floor reeducation program for as long as any degree of incontinence persisted, within a 1 year period. The training program involved active PFE. Verbal feedback of the contraction was used to instruct the patients to correctly and selectively contract their pelvic muscles while relaxing the abdominal muscles. The strength of the pelvic-floor muscles was measured by digital anal control, using a score of 0–5 (0 = no contraction, 1 = flicker, 2 = weak contraction, 3 = good good contraction but without resistance, 4 = good contraction against slight resistance, 5 = good contraction against strong resistance). The patients not able to contract the pelvic floor muscles or with a weak contraction (score 0–2) were given ES against slight resistance, 5

The statistical significance of the differences in baseline characteristics between the two groups was assessed through Wilcoxon’s Rank Sum test for continuous and ordinal variables and through Fisher’s Exact test for categorical variables.

The statistical significance of differences in the study outcomes (Pad test and VAS scores at 1, 3, 6, and 12 months, and quality of life at 12 months) between the two groups was tested through Wilcoxon’s Rank Sum test.

Spearman’s coefficient was calculated to evaluate correlations among outcome variables.

The difference in the proportion of subjects in each group who were incontinent at each time was tested through Fisher’s Exact test. In addition, Kaplan–Meier analysis was used to compare the proportion of subjects in each group who were still incontinent at different times. The significance of the difference between the two curves was tested through the Log–rank test and Wilcoxon’s test. P-values < 0.05 were considered statistically significant.

Multivariable logistic regression was used to evaluate the association between incontinence at 12 months and experimental group, after adjusting for age, IPSS score, blood loss, baseline QoL, incontinence at 1 week measured with the 24 hr Pad test, tumor stage and nerve preservation. The association was expressed by the Odds Ratios (OR) and 95% confidence intervals (95%CI).

RESULTS

A total of 152 patients were evaluated for the study: 12 were excluded because they could not regularly attend clinic appointments and 33 were continent immediately (23.6%). Out of 107 men with eligibility criteria, 54 were randomized to treatment group and 53 patients acted as controls.

Thirteen patients in the C group were lost at follow up, 5 for social reasons and the others refusing further follow up. Patients were followed up for 1 year and no deaths were recorded (Fig. 1). Table I lists T and C groups characteristics, comparable in all clinical variables, and no statistically significant differences were found. The mean urinary leakage in the T group was higher, compared to the C group, but not significantly (P = 0.98). The degree of incontinence at the beginning was higher in the T group, as 14 patients had high volume loss (24 hr Pad test > 250 g), instead of 5 patients in the C group.

The difference between the T and C groups in the proportion of men remaining incontinent was significant at 1 (P = 0.04), 3 (P = 0.03), 6 (P = 0.01), and 12 months (P < 0.01) and the continence rate was higher and progressively increasing in the T group (Table II).

Kaplan–Meier curves, the Log–rank test, and the Wilcoxon’s test (Fig. 2) showed a statistically significant difference between two groups (P < 0.01). After 1 year 9 patients in the T group and 21 patients in the C group were still incontinent, 1 mild (2–9 g), 1 moderate (10–49 g), 7 severe (≥50 g) in the first group and 7 mild, 10 moderate, and 4 severe in the second group, respectively.
The comparison of results for the subjective assessment of incontinence with VAS ($P = 0.01$) and for the QoL ($P = 0.03$) between two groups shows a significant difference at 12 months.

At each time, there was a strong significant correlation between the subjective assessment of incontinence on the VAS and the objective 24 hr Pad test (Spearman correlation coefficient was $0.861$ at 1 week, $0.871$ at 1 month, $0.931$ at 3 months, $0.943$ at 6 months, and $0.904$ at 12 months, all with $P < 0.01$). Similarly, there was good correlation between the VAS and QoL at 12 months (correlation coefficient $= 0.686$, $P < 0.01$) and between Pad test and QoL at 12 months (correlation coefficient $= 0.725$, $P < 0.01$).

After adjusting for age, IPSS score, blood loss, baseline QoL, incontinence at 1 week, tumor stage and nerve preservation, the reduced likelihood of being still incontinent at 12 months was confirmed for subjects in the T group (OR $= 0.04$; 95%CI: $0.01–0.04$). A significantly increased likelihood of incontinence at 12 months, on the contrary, was associated with age (for each increasing year, OR $= 1.18$; 95%CI: $1.01–1.39$), blood loss (for each ml, OR $= 1.002$; 95%CI: $1.000–1.003$), and Pad test at 1 week (for each ml, OR $= 1.003$; 95%CI: $1.001–1.005$).

**DISCUSSION**

Several groups have investigated the effect on recovery of continence after RRP with conservative treatment, but the results are still controversial. It is unclear whether the theoretical basis of PFE, working well in women with stress incontinence, can be applied directly to men, because the normal male continence mechanism differs from that in the female, in spite of the surgical impairment. However, there are very few alternative options and PFE remain the mainstay of treatment for the incontinence after RRP. Most studies did not show any effect. In the Cochrane review by Hunter et al. the analysis of PFE alone was inconclusive, but Van Kampen et al. demonstrated beneficial effects of

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**TABLE I. Baseline Characteristics of the Treatment (T) and Control (C) Groups**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>T group (n = 54)</th>
<th>C group (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>66.8 (6.3 years)</td>
<td>67.9 (5.5 years)</td>
</tr>
<tr>
<td>Mean urine leakage per day (SD)</td>
<td>247 g (505 g)</td>
<td>97 g (138 g)</td>
</tr>
<tr>
<td>% Positive margins (neck)</td>
<td>0.6%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Preoperative IPSS</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>&lt;10</td>
<td>41 (76%)</td>
<td>25 (62.5%)</td>
</tr>
<tr>
<td>10–20</td>
<td>8 (14.8%)</td>
<td>12 (30%)</td>
</tr>
<tr>
<td>&gt;20</td>
<td>5 (9.2%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>Mean prostate specific antigen (PSA) (SD)</td>
<td>9.38 ng/ml (4.7 ng/ml)</td>
<td>10.6 ng/ml (4.2 ng/ml)</td>
</tr>
<tr>
<td>Pathological stage</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>pT2a</td>
<td>3 (5.5%)</td>
<td>6 (15.0%)</td>
</tr>
<tr>
<td>pT2b</td>
<td>4 (7.4%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>pT2c</td>
<td>25 (46.3%)</td>
<td>15 (37.5%)</td>
</tr>
<tr>
<td>pT2x</td>
<td>1 (1.9%)</td>
<td>3 (7.5%)</td>
</tr>
<tr>
<td>pT3a</td>
<td>15 (27.7%)</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>pT3b</td>
<td>4 (7.4%)</td>
<td>6 (15.0%)</td>
</tr>
<tr>
<td>pT4</td>
<td>2 (3.7%)</td>
<td>2 (5.0%)</td>
</tr>
<tr>
<td>Mean blood loss (SD)</td>
<td>1087 g (549 g)</td>
<td>993 g (508 g)</td>
</tr>
<tr>
<td>Nerve sparing</td>
<td>No</td>
<td>N (%)</td>
</tr>
<tr>
<td>Monolateral</td>
<td>13 (24.0%)</td>
<td>10 (25.0%)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>41 (76.0%)</td>
<td>30 (75.0%)</td>
</tr>
</tbody>
</table>

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postoperative PFE, since both the duration and degree of incontinence after RRP decreased.

Results of preoperative pelvic floor muscle training with biofeedback are still conflicting. An advantage of training before surgery is that patients learn how to control their muscles when they are pain-free and sensation is normal. In addition, they are prepared in advance to begin using the muscles immediately after catheter removal. It is not clear whether training would have been successful even without biofeedback and the optimal time frame in which to implement behavioral training remains to be determined.

We found that the postoperative PFE was significantly more effective than no treatment in decreasing the rate of incontinence with extended follow up. The difference between the two groups in incontinent patients was 14.2% after the first month and it progressively increased to 35.9% at 12 months, reaching a statistically significant difference, while Van Kampen et al. reported that the percentage of patients remaining incontinent was high in the first months and decreased to 14.4% at 1 year. Unlike other studies that reached the highest efficacy in the first months, in our experience PFE increase their effect with time. Our impression is that the benefits can carry on after 12 months.

We documented an elevated number of immediately continent patients after catheter removal (23.6%) compared with those described in the literature (8.8% Van Kampen). A possible explanation might be that increasing the immediate continence rate selects the most "difficult" incontinent patients, where physiotherapy needs more time to be successful and we achieved the best results at 12 months.

Retrospectively performing the stratification by the initial urine loss before the randomization would have been more correct. Moreover, using the cut-off of 50 g, the lower initial urine loss was significantly correlated with the continence in C group ($P = 0.01$) and in the T group ($P = 0.02$). Furthermore, in our experience, rehabilitation seems to be more effective

<table>
<thead>
<tr>
<th>Time since catheter removal (months)</th>
<th>Proportion of patients still incontinent</th>
<th>Difference in proportion (%)</th>
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<tbody>
<tr>
<td></td>
<td>T group (n = 54) (%)</td>
<td>C group (n = 40) (%)</td>
</tr>
<tr>
<td>1 month</td>
<td>83.3</td>
<td>97.5</td>
</tr>
<tr>
<td>3 months</td>
<td>53.7</td>
<td>77.5</td>
</tr>
<tr>
<td>6 months</td>
<td>33.3</td>
<td>60</td>
</tr>
<tr>
<td>12 months</td>
<td>16.6</td>
<td>52.5</td>
</tr>
</tbody>
</table>
on mild and moderate incontinence. For that reason, the majority (7/9 – 77.7%) of patients still incontinent in the T group have severe leakages rather than 4/21 = 19% in the C group.

Although the degree of initial incontinence was always slightly higher in the T group, the reduction in terms of 24 hr Pad test shows the significant improvement given by PFE. This fact strengthens our hypothesis. In both groups, older age significantly increases the possibility to be incontinent and this fact could be not related to worse learning in elderly people, but to their reduced tissue tone. Even if not all authors agree, the majority claim that the age at surgery has statistically significant effect on urinary control. There was not a significant correlation between bilateral neurovascular preservation and recovery of continence. Eastham et al. reported that resection of one or both bundles substantially decreases the continence rate, but this factor continues to be widely debated.

We chose the 24 hr Pad test because it is a useful way to quantify incontinence, superior than Pad per day usage, which is an unreliable measure of incontinence only measuring 38% of the variation of urinary incontinence volume and than 1 hr Pad test which is not so sensitive in the detection of slight leakages. The majority of incontinent patients complained of urine leakage during the second half of the day, commonly moving into sitting or standing. Therefore, the relatively short time of 1 hr can affect the reliability of the short Pad test. A subjective method to assess incontinence is a VAS, although it is not one of the validated questionnaires for incontinence now achieving the highest level of scientific rigor. However, our results showed a very good degree of correlation between the VAS and the 24 hr Pad test at 12 months. As far as we are concerned, VAS is a good subjective evaluation instrument for incontinence, easy to use and to understand, not too strict for the assessment of incontinence.

One weakness of the present study is the lack of one extended QoL questionnaire. Actually, we had considered several tests but finally we preferred only to use one item, part of the IPSS test, “If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?” direct and simple.

The significant correlation between QoL and Pad test might be explained with the fact that, initially, the presence of incontinence per se affects QoL, while with time a persistence of leakage, even if lower, would continue to deteriorate the QoL.

BN preservation has shown to offer an earlier return to continence compared with BN excision by some authors, while others reported that preservation of the BN does not have an impact on speed of restoration of urinary control. As pointed out by many authors, the preservation of the BN does not impair cancer control. The likelihood of a solitary positive BN margin in any patient is low in our (0.6%) and in other experiences (0.5%). This approach benefits patients by providing a more precise dissection of the BN circular muscle fibers, and could be even helpful for patients who have undergone a pervious transurethral resection of the prostate. The logic is that the remaining continence structures are better preserved with this kind of dissection.

**REFERENCES**