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EFFECT OF PREOPERATIVE PELVIC FLOOR MUSCLE THERAPY WITH BIOFEEDBACK VERSUS STANDARD CARE ON STRESS URINARY INCONTINENCE AND QUALITY OF LIFE IN MEN UNDERGOING LAPAROSCOPIC RADICAL PROSTATECTOMY

Hypothesis / aims of study

Laparoscopic Radical prostatectomy (LARP) is one of the treatments of organ confined prostate cancer. Stress urinary incontinence (SUI) could be a consequence of this treatment. SUI is the complaint of involuntary loss of urine on effort or physical exertion.

Dysfunction of the bladder neck as well as intra operative damage of the nerves and sphincter may play a causative role. In this regard, damage of the urethral sphincter can result both from direct damage to the muscle or the neurovascular bundles. When achieving continence the pelvic floor could play a major role. Whether pelvic floor muscle therapy (PFMT) given prior to the RP could decrease the incidence of SUI after this procedure, is a matter of debate in literature at present. The aims of this study were to investigate the effectiveness of preoperative PFMT with biofeedback on SUI and Quality of Life (QoL) in men planned to undergo a LARP.

Study design, materials and methods

Patients scheduled to undergo a LRP are randomized into a group that will receive preoperative PFMT (inclusive biofeedback) or into a control group. Exclusion criteria were neurological disorders, a medical history with invasive perineal and/or rectal surgery and preoperatively existing SUI.

Validated questionnaires, the Pelvic Floor Inventories (PeLFIs), the King's Health Questionnaire (KHQ), the International Prostate Symptom Score (IPSS), a voiding dairy, a 24h pad test and examination of the pelvic floor are used to determine the effect of preoperative PFMT on SUI and QoL. Patients assigned to the intervention group received four 30-minutes sessions of PFMT in which they receive toilet behaviour instructions and biofeedback assisted behavioural training using a standardized protocol.

Six weeks, three months, six months, nine months and one year postoperatively both groups are requested to fill in the KHQ, IPSS and the 24h voiding diary again and to conduct a 24h pad test. In addition, the PeLFIs is administered one year postoperatively and the examination of the pelvic floor is repeated. Continence has been defined as completely dry. With a sample size of 124 patients in each group (248 in total), a power of 90% can be achieved in order to be able to detect a difference of 20% between both groups regarding patients being incontinent. An interim analysis was planned after inclusion of 120 patients.

Results

Of 121 patients the results have been analysed one year postoperatively. The mean age was 63.7 years (range 51-75 years), the mean Body Mass Index (BMI) was 27.4 (range 21.1-37.0), the mean prostate specific antigen was 10.9 µg/l and almost 90% of the patients had a T-stadium of T1 or T2. In the KHQ, IPSS and pad tests the score changed significantly over time (p=0.0001). During the study, a total of 18 patients were excluded from follow-up. There were no significant differences between the Intervention group and the control group in the incidence of SUI and QoL for the KHQ, IPSS and pad tests (p= > 0.05).

Continence was achieved in the total group in 20,8, % of the patients at 6 weeks, 43,6 % at 3 months, 61,4,5% at 6 months, 72,3 % at nine months and 77,2, % at one year. In total 22,8 % of the patients were still incontinent one year post operatively.

After one year follow up patients with the age ≤ 60 (N=17), 21, 7 % was still incontinent, age of 61- 70 years (N=74) 58,7 % was still incontinent and patients of ≥ 70 years (n=17) 77,8 % was still incontinent with our strict definition of no loss of urine at all.

One year postoperatively in the KHQ ,the domain severe measures showed that patients had significantly more complaints within this domain comparable to both groups pre-operatively (p= 0000.1)

In the domain micturition of the PeLFIs, which is an administered questionnaire and the question "When does urine leakage occur?" there was even a higher percentage of incontinence (40%) in relation to the self-administered questionnaires (22,8%).

Interpretation of results

Our sample size calculation was based on the assumption that men in the treatment group would do better than men in the control group. Interim analysis after 122 patients one year postoperatively showed that within the available data, we did not find an advantage for the men in the treatment group. The results in the interim analyses showed that it was not to be expected that including more patients in this study, there would be a significant change in the benefit in favour of the group with pelvic floor physiotherapy.

Concluding message

Preoperative PFMT is not effective in the prevention of SUI and QoL after a LARP. Other confounders play a major role in achieving continence after LARP.

Status on T5 * pre-operative Pelvic Floor Physiotherapy Cross tabulation

	pre-operative pelvic floor physiotherapy	Total

			yes	no	
Status on T5	not continent	Count	20	9	29
		% within pre-operative pelvic floor physiotherapy	34,5%	20,0%	28,2%
	continent	Count	38	36	74
		% within pre-operative pelvic floor physiotherapy	65,5%	80,0%	71,8%
Total		Count	58	45	103
		% within pre-operative pelvic floor physiotherapy	100,0%	100,0%	100,0%

Table: Continence after one year with and without pelvic floor physiotherapy

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