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DOES PELVIC FLOOR MUSCLE TRAINING WITH FOLLOW UP INSTRUCTIONS BY A PHYSIOTHERAPIST REDUCE URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY? - A RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

Radical prostatectomy (RP) is often followed by urinary incontinence, which is a significant problem and may lead to reduced quality of life. A newly updated Cochrane-review [1] concluded that there still is a need for more studies to document the effect of conservative treatment for post prostatectomy urinary incontinence. The aims of this randomised controlled trial were to assess the effects of intensive and frequent pelvic floor muscle training with or without follow up instructions by a physiotherapist, on continence status, perceived problems with urinary function and pelvic floor muscle strength after RP.

Study design, materials and methods

We conducted a two-armed randomised controlled trial between September 2005 and December 2007. All men with clinically localised prostate cancer operated with open RP were invited until 85 men were included due to power calculation (80% power ($\alpha=5\%$) to detect a 30% difference in self-reported urinary incontinence).

The operations were performed by two urologists without any knowledge to the outcome of the randomization procedure. A nerve-sparing RP was usually performed in patients with low grade (Gleason score ≤ 6) and low stage (T1c) disease. Patients with Gleason score $\geq 7B$, cancer in bilateral biopsies or preoperative s-PSA > 10 ng/ml was usually considered as non-candidates for nerve-sparing operation. The bladder neck was preserved, unless there was a palpable tumour at the base of the prostate. In nearly all patients the apex of the seminal vesicles and the puboprostatic ligaments were preserved. Eversion of the bladder mucosa was performed in all patients.

The trial comprised two intervention groups (A and B). All the participants in both groups were individually informed of the anatomy and function of the pelvic floor muscles and how to correctly contract the muscles. Feedback was provided by the physiotherapist. Correct pelvic floor muscle contraction was assessed (digital anal palpation) and muscle strength measured preoperatively and postoperatively at 6 weeks, 3, 6 and 12 months.

Both groups were encouraged to train the pelvic floor muscles (3 x 10 contractions daily at home). Group A were offered additional follow up training instructions by a physiotherapist throughout the one year period, either by attending group training sessions or by using a training Digital Versatile Disc (DVD). About half of the participants in group A followed a pelvic floor muscle exercise course consisting of intensive pelvic floor muscle training guided by a physiotherapist for 45 minutes once weekly. The other half of the men randomised to group A, whom were unable to participate in weekly training sessions at the hospital due to long travelling distance, were given a Digital Versatile Disc (DVD) where the physiotherapist instructed the patients through the pelvic floor muscle training program.

Patients randomised to group B received oral and written description by a nurse/urotherapist of the standard postoperative training program.

All participants answered the questionnaire UCLA-PCI and were examined by a physiotherapist preoperatively and postoperatively at 6 weeks, 3, 6 and 12 months.

Primary outcome measurement was self-reported continence (0 pads) status, and secondary were perceived problems with urinary function and pelvic floor muscle strength 6 weeks, 3, 6 and 12 months postoperatively.

Results

Eighty patients (38 in group A and 42 in group B) completed the trial. Drop out rate was 6%. No statistically significant preoperative differences were found between the two groups.

At the three months follow up visit we found no statistically significant ($p=0.73$) difference in continence (0 pads) status between groups. However, there was a significant difference in perceived problems with urinary function ($p=0.010$): In group A 97 % reported no or only mild problems compared to 78 % in group B.

After six months there was a clinically relevant difference in continence status between groups, 79% were continent in group A compared to 58% in group B, a trend towards statistical significance ($p=0.061$). Twelve months after surgery the difference in continence status was both clinically relevant and statistically significant ($p=0.028$).

Comparison of proportion of continent patients in group A and group B after surgery.

	Group A	Group B	Difference		P-value**
			Estimate	95% CI*	
6 Weeks	5/31(16%)	6/35 (17%)	-1.0%	-19 to 18%	P= 0.87
3 Months	16/35 (46%)	17/40 (43%)	3.2%	-19 to 25%	P= 0.73
6 Months	27/34 (79%)	22/38 (58%)	22%	-0.2 to 41%	P= 0.061
12 Months	33/36 (92%)	28/39 (72%)	20%	1.7 to 36%	P= 0.028

* Agresti-Caffo confidence intervals ** Fisher's exact mid p test

The first six to ten weeks postoperatively the training frequency was similar in both groups, while a statistically significantly ($p=0.043$) higher frequency was reported in group A in the following period up to six months.

Pelvic floor muscle strength increased consistently from baseline assessment to the one year follow up test. We found no significant differences ($p>0.05$) in pelvic floor muscle strength between groups.

Interpretation of results

Our results indicate that follow up instructions by a physiotherapist may increase long term adherence to pelvic floor muscle training and thereby improve continence rates over time more than plain information to train on their own, in patient with postoperative incontinence. According to findings in previous studies [2] individual and closer follow up by a physiotherapist may be needed to achieve earlier return to continence.

Concluding message

Thorough instruction in correct pelvic floor muscle contraction and pelvic floor muscle training guided by a physiotherapist throughout the first year after RP, enhance regular pelvic floor muscle training and reduce urinary incontinence in patients significantly more than training on their own.

References

1. Conservative management for postprostatectomy urinary incontinence. Cochrane Database Syst Rev. 2007;2:CD001843. Review.
2. Effect of pelvic-floor re-education on duration and degree of incontinence after radical prostatectomy: a randomised controlled study. Lancet 2000;355:98-102.

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	Yes
<i>Specify Name of Public Registry, Registration Number</i>	Trial registration: ClinicalTrials.gov Protocol Registration System Account NCT00239824.
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Regional Committee for Medical and Health Research Ethics, Norway
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes