

EFFECT OF PREOPERATIVE PELVIC FLOOR PHYSIOTHERAPY VERSUS STANDARD CARE ON INCONTINENCE IN MEN UNDERGOING RADICAL LAPAROSCOPIC PROSTATECTOMY: AN ONGOING STUDY

Hypothesis / aims of study.

Radical prostatectomy is one of the treatments of organ confined prostate cancer. Stress Urinary Incontinence (SUI) could be a consequence of this treatment.

Whether pelvic floor muscle physiotherapy including exercises, biofeedback and electro stimulation given prior to the radical prostatectomy could decrease the incidence of SUI after this procedure, is a matter of debate in literature at present (1).

Nowadays, in our hospital the radical prostatectomy is performed laparoscopic.

To our knowledge there are no randomized trials yet of the effect of pelvic floor muscle physiotherapy given prior to a laparoscopic radical prostatectomy.

The aim of this study is to investigate the effectiveness of preoperative pelvic floor muscle physiotherapy on SUI in men planned to undergo laparoscopic radical prostatectomy.

Study design, materials and methods.

Patients scheduled to undergo a laparoscopic radical prostatectomy are randomized into a group that will receive preoperative pelvic floor muscle physiotherapy or in a control group. All patients provide informed consent.

Exclusion criteria are neurological disorders that influence pelvic floor muscle function, invasive perineal and/or rectal surgery and preoperative existing SUI. Patients who do not master the Dutch language sufficiently are also excluded.

A validated questionnaire, the Pelvic Floor Inventories (PelFIs) (2), is administered preoperatively to both groups and a quantitative and qualitative examination of the pelvic floor is performed (3).

In addition both groups fill in the King's Health Questionnaire (KHQ), the International Prostate Symptom Score (IPSS) and a voiding diary and they conduct a 24h pad test.

Six weeks, three months, six months, nine months and one year postoperatively both groups are requested to fill in the KHQ, IPSS and the voiding diary and to conduct a 24h pad test. In addition the PelFIs is administered one year postoperatively and the quantitative and qualitative examination of the pelvic floor is repeated.

Patients from both groups receive the standard care of incontinence from the pelvic floor physiotherapist if they are still incontinent six weeks postoperatively.

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.

The statistical test used is the "two-sided Z test with pooled variance". This test is considered significant on a level of 0.05.

Results.

At the moment of analysis 67 patients have been included (mean age 63.9 ± 5.4 , mean Body Mass Index 27.3 ± 3.3). Preoperatively 50.7% showed overactive pelvic floor muscles, (3), 9.7% suffered from urgency urinary incontinence and 48.8% reported to have erectile dysfunction.

So far 40 patients have been evaluated three months postoperatively. 12 Patients are off study of which 4 received external radiotherapy, one patient suffered from esophagus carcinoma, one patient appeared to have preoperatively SUI, and two patients were excluded at their own request. One patient needed a catheter, two patients had positive lymph nodes and one patient underwent cardiac surgery in another hospital.

In the IPSS and in seven of the eight domains of the KHQ the score changed significantly over time. In the domain 'Physical/social limitation' of the KHQ preoperative pelvic floor muscle physiotherapy did have a significant influence on the course of the score. The pad test changed significantly over time.

Interpretation of results.

SUI after laparoscopic radical prostatectomy may not only be a result of a non-functioning pelvic floor, but can have more causes.

Although it is not completely clear yet whether pelvic floor physiotherapy given prior to a laparoscopic radical prostatectomy will be effective or not, it is to be expected, in view of the current preliminary results. Regarding these results we expect one year after the laparoscopic radical prostatectomy a significant effect of pelvic floor physiotherapy on SUI given prior to a laparoscopic radical prostatectomy.

Concluding message.

Data are too early to draw conclusions about the effect of pelvic floor muscle physiotherapy on SUI given prior to a laparoscopic radical prostatectomy, three months after a laparoscopic radical prostatectomy. This study will proceed as a multicentre study.

References

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3. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Report on the Terminology for Female Pelvic Floor Dysfunction. *Neurourol. Urodynam.* 29:4-20, 2010

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<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
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<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes