PELVIC FLOOR MUSCLE TRAINING REDUCES ERECTILE DYSFUNCTION AND CLIMACTURIA ONE YEAR AFTER OPEN AND ROBOT RADICAL PROSTATECTOMY: A RANDOMIZED CONTROLLED TRIAL.

Hypothesis / aims of study
Erectile dysfunction (ED) remains a significant consequence in 19-74% of men undergoing a nerve-sparing radical prostatectomy (RP).[1] Our primary aim was to determine whether patients, minimum 12 months after RP, with remaining ED, experienced a better recovery of erectile function with additional pelvic floor muscle training (PFMT) compared to patients without additional PFMT. The secondary aim was to investigate the effect of PFMT on orgasm-associated incontinence (climacturia).

Study design, materials and methods
Of 180 patients, who underwent open or robot RP,[2] all patients with remaining ED minimum 1 year postoperative, were eligible. The sample size needed to detect with 80% power a difference of 6 points concerning the erectile function domain of the International Index of Erectile Function (IIEF-EF), was 24 subjects. Hence, all eligible patients, who volunteered to participate, from the original sample were included (N=33). Patients were randomized into the treatment group (starting PFMT immediately) or the control group (starting PFMT 3 months later). All patients were followed up for another 3 months after the final treatment to check for maintenance of results. All patients received the same PFMT (12 weeks) and were evaluated using the IIEF and questioned regarding climacturia. Mann Whitney U was used to compare the change in IIEF-EF score between both groups at 3 months and Wilcoxon signed rank test to compare the proportion of patients with climacturia between first and final PFMT.

Results
Thirty-three patients were included, 17 patients were randomized to the treatment group and 16 patients to the control group. Three patients were lost to follow-up; one patient due to relational problems, one patient suddenly moved to abroad for several months and one patient had severe low back pain. Mean age of the treatment group was 61.1 years (SD 5.8) and 61.5 years (SD 7.3) for the control group (p=0.872). In the treatment and control group, respectively 81% and 65% underwent an open procedure and 19% and 35% underwent a robot RP. The mean preoperative IIEF-EF score was 26.9 (SD 3.8) for the treatment group and 23.8 (SD 6.8) for the control group. Mean IIEF-EF score at inclusion was 6.7 (SD 6.3) for the treatment and 9.5 (SD 7.3) for the control group.

At 3 months, the treatment group had a significantly better erectile function than the control group (p=0.025). Other sub-domains, like orgasmic function (p=0.899), sexual desire (p=0.271), intercourse satisfaction (p=0.248), overall satisfaction (p=0.059), remained constant for both groups. The effect of PFMT was maintained regarding erectile function at 3 months after finishing treatment. Figures 1 and 2 indicate the individual evolutions concerning erectile function over time.

After 3 months of PFMT, climacturia was significantly decreased between the starting and ending of the treatment for the group as a whole (N=33) (p=0.022) (Table 1).

Table 1 Number (percentage) of patients suffering from climacturia at each time-point

<table>
<thead>
<tr>
<th></th>
<th>Treatment group (N=16)</th>
<th>Control group (N=17)</th>
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<tbody>
<tr>
<td>0 months</td>
<td>9/16 (56%)</td>
<td>7/17 (41%)</td>
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<tr>
<td>3 months</td>
<td>3/14 (21%)*</td>
<td>8/17 (47%)</td>
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<tr>
<td>6 months</td>
<td>4/14 (29%)</td>
<td>2/16 (12%)*</td>
</tr>
<tr>
<td>9 months</td>
<td>4/16 (25%)</td>
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* Percentage of patients with climacturia after 3 months of PFMT (p=0.138)

Figure 1 Individual evolution of erectile function over time for the treatment group
Interpretation of results
Patients were not allowed to use phosphodiesterase-5 inhibitors or intracavernosal injections during the treatment phase, we are sure the effect of PFMT on the recovery of unassisted erectile function was evaluated. As a result, patients who followed an additional PFMT program at 12 months after radical prostatectomy, experienced a better recovery of erectile function. No effect of PFMT could be observed on the orgasmic function, sexual desire, intercourse satisfaction or overall satisfaction. Furthermore, PFMT provided a significant decrease in the proportion of patients suffering from climacturia or orgasm associated incontinence.

Concluding message
In conclusion, patients, minimum 12 months after RP, with remaining ED, experienced a better recovery of erectile function with additional PFMT compared to patients without additional PFMT. Additionally PFMT had a beneficial effect on climacturia.

References

Disclosures
Funding: Agency of Innovation by Science and Technology (IWT) Clinical Trial: Yes Registration Number: Netherlands Trial Register No NTR 3180 RCT: Yes Subjects: HUMAN Ethics Committee: Commission Medical Ethics of the University Hospitals KU Leuven responsible for human/animal experimentation (ML7136). Helsinki: Yes Informed Consent: Yes