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PELVIC FLOOR MUSCLE THERAPY COMPARED TO TREATMENT WITH ALPHA-1 BLOCKING AGENTS FOR LOWER URINARY TRACT SYMPTOMS IN OLDER MEN IN PRIMARY CARE

Hypothesis / aims of study
Lower urinary tract symptoms (LUTS) are common in men and their prevalence increases with age. LUS are a non-specific group of symptoms with a multifactorial etiology. Standard therapy in primary care is drug treatment with α1-receptor blocking agents. This therapy is only moderately effective and has side-effects and contra-indications. There is evidence suggesting dysfunction of the pelvic floor to be one the factors associated with LUTS. Therefore, pelvic floor muscle (PFM) rehabilitation might be an alternative for drug therapy in the initial treatment of LUTS in men in primary care. The objective of this study was to compare the effectiveness of PFM therapy with α1-blocker therapy in men with LUTS in primary care.

Study design, materials and methods
The design of the study is that of an open label, exploratory, randomized controlled trial. In the Academic General Practice of the University Medical Center of Groningen, the Netherlands, 41 men aged 51 to 82, with moderate to severe LUTS were enrolled in the trial. Enrollment began on June 27, 2011, follow-up ended on March 28, 2012. Inclusion criteria were LUTS (defined as an International Prostate Symptom Score, IPSS, ≥8), an interpretable flow (voided volume ≥100 ml), no treatment for LUTS in the preceding six months, no urogenital malignancy or infection, no indwelling catheter or intermittent catheterization and a normal prostate gland by digital rectal examination (DRE). Patients were 1:1 randomized to a medication group or a PFM training group. In the medication group, tamsulosin 0.4 mg for 90 days was prescribed. In the PFM therapy group, patients were referred to a registered pelvic floor physical therapist. They were treated according to a protocol for LUTS, developed for this study, and visited the therapist 6 times. Therapy consisted of guided pelvic floor muscle training, home exercises, monitoring with bladder diaries, education on pelvic floor function and dysfunction and on the relation of dysfunction with LUTS. For biofeedback therapy, the electrical activity of the pelvic floor muscles was recorded in all patients by superficial electromyography, using an anal probe. The primary outcome measurement was the change in the IPSS. Secondary outcomes were mean and maximum flow rate, sexual functioning, quality of life and the patient's global rating of improvement (GPI). Intention to treat analyses were done. Loss to follow up and missing values were analyzed using last observation carried forward. A per protocol analysis, best and worst case scenario and correction for baseline analysis were also performed. The Mann Whitney test for independent variables, the Wilcoxon signed ranks test for dependent variables and logistic regression analysis were used.

Results
A reduction in IPSS of -6.4 points was found in the PFM therapy group (p=<0.001) and of -6.8 in the medication group (p=0.001). These changes did not differ between the two groups (p=0.989). An improvement of ≥3 points was achieved by 72% in the PFM therapy group and by 81% in the medication group. Changes in uroflow parameters, sexual functioning and quality of life and did not differ significantly between both groups. The perception of improvement score (GPI) was different (p=0.002) in favor of the PFM Therapy group. A per protocol, best and worst case scenario or correction for baseline measurements did not show significant differences in outcome parameters. Three out of 19 men in the medication group reported side effects. One men discontinued treatment because of side effects. In the PFM therapy group no side effects were reported.

Interpretation of results
To our knowledge, this is the first trial to compare the effects of PFMT and α1-blockers in LUTS patients. We could not demonstrate a difference between the two groups. The change in IPSS score of -6 of the men in the medication group in our study is comparable to the changes found in studies with α1-blockers: mean change of baseline IPSS score for tamsulosin 0.4 mg in various trials ranges from -5.1 to -8.3. In placebo arms of medication trials with tamsulosin, a symptom reduction of 18 to 28% was achieved. In this study a median symptom reduction of 43% was achieved in the PFMT group and 47% in the medication group. The findings of our study warrant an equivalence study with lager numbers of patients. If effects of medication and PFM therapy are comparable, PFM therapy might a better alternative as initial treatment in primary care because of the higher patient satisfaction and the absence of side effects and contra-indications

Concluding message
In this randomized controlled trial among men with LUTS in primary care, we could not demonstrate a difference between medication with alpha-blocking agents and pelvic floor muscle therapy. Larger studies are needed to show equivalence between the two treatment modalities.

References
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Disclosures
Funding: This study was funded by a grant from the University Medical Center Groningen, The Netherlands. **Clinical Trial:** Yes **Public Registry:** Yes **Registration Number:** Dutch Trial register, registration number 2954. (http://www.trialregister.nl/trialreg/admin/rctview.asp?TC=2954) **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** The Institutional Review Board of the University Medical Center of Groningen (UMCG), the Netherlands. **Helsinki:** Yes **Informed Consent:** Yes