Multicenter, randomized, double-blind, sham-controlled parallel-group trial to evaluate the efficacy of magnetic stimulation (rTPM) for stress urinary incontinence.

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Abstract /

Background: There is currently a lack of randomized, sham-controlled trials that are adequately powered, using validated outcomes, to allow for firm recommendations on the use of magnetic stimulation for stress urinary incontinence. We report a protocol of a multicenter, randomized, double blind, and sham-controlled parallel-group trial to evaluate the efficacy of magnetic stimulation for stress urinary incontinence.

Methods/Design: One hundred twenty subjects with stress urinary incontinence will be randomized in a 1:1 allocation to either active or sham magnetic stimulation using computer-generated, permuted blocks of variable sizes. Subjects will receive 2 sessions of magnetic stimulation (rTPM) per week for 8 weeks (16 sessions total). The primary outcome is the improvement in severity of involuntary urine loss based on the International Consultation on Incontinence Questionnaire for Urinary Incontinence Short Form at the end of treatment sessions compared with baseline. Secondary outcomes include cure, stress urinary incontinence–related symptoms (incontinence episode frequency, urine loss in 1-hour pad test, pelvic floor muscle strength) and health-related quality of life (Patient Global Impression of Improvement, International Consultation on Incontinence Questionnaire–Lower Urinary Tract Symptoms Quality of Life and EQ-5D). The safety of magnetic stimulation will also be assessed. Besides evaluation of clinical treatment effectiveness, cost-effectiveness analysis using patient-reported outcomes will be performed.

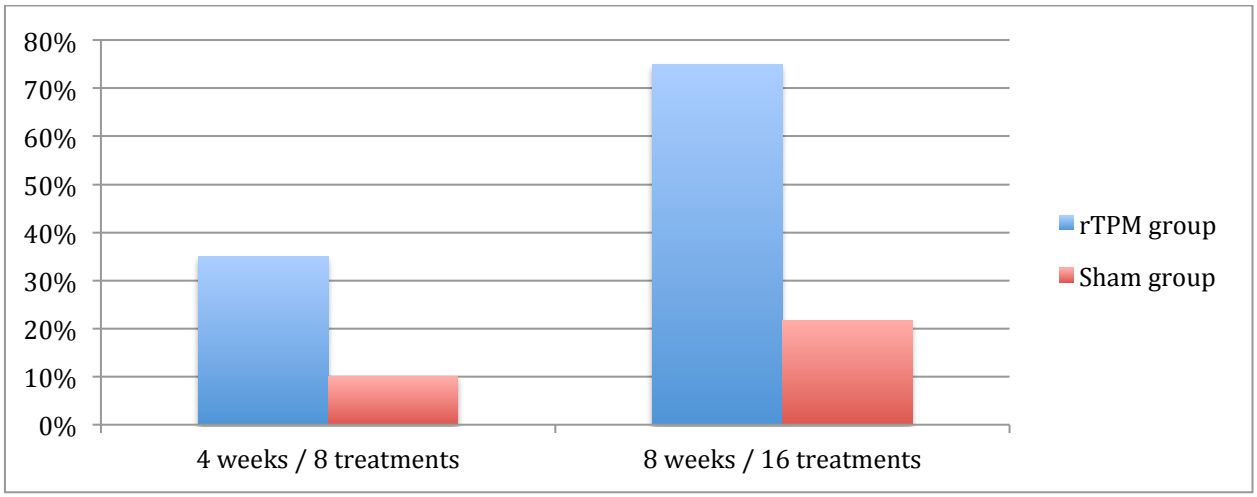
Discussion: This trial is designed to provide pending outcome information on this non-invasive treatment option. We intend to acknowledge the existing flaws in previous clinical trials and determine conclusively whether magnetic stimulation (rTPM) is effective for stress urinary incontinence.

Trial results: The primary outcome measure consist of the number of patients having ≥ 5 point reduction on the ICIQ-UI SF scale (1-21), results: rTPM Stimulation group: **75%** responder after 16 treatments, Sham group: **21,7%** responder after 16 treatments. P value < 0,001.

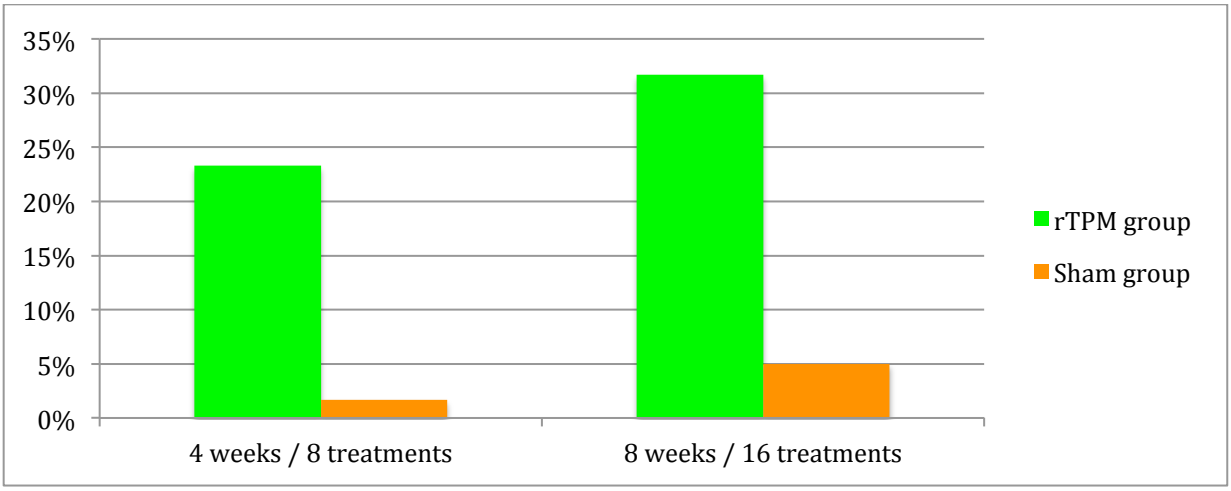
The secondary outcome measures, consist of: the **objective cure**, which is determinate by the number of **patients** which were **dry** (1hour pad test); results: rTPM group: **31,7%** responder (after 16 treatments), Sham group: **5%** responder (after 16 treatments). The **subjective cure**, which is determinate by: the perception of dry ICIQ, **incontinence Episode Frequency** (IEF); rTPM group: **76,7%** responder (after 16 treatments), Sham group: **18,3%** responder (after 16 treatments), the **average number of leaks** with the

rTPM decreased **from 1,77 to 0,46** / day. **1 hour pad test**; results: rTPM group: **81,7%** responder (after 16 treatments), Sham group: **26,7%** responder (after 16 treatments), **incontinence severity** (at least one scale reduction on the ICIQ-UI SF scale); results: rTPM group: **81,7%** responder (after 16 treatments), Sham group: **36,7%** responder (after 16 treatments), **quality of life** (PGI-I / ICIQ-LUTS / EQ-5D); results: rTPM group: **65%** responder (after 16 treatments), Sham group: **18,3%** responder (after 16 treatments).

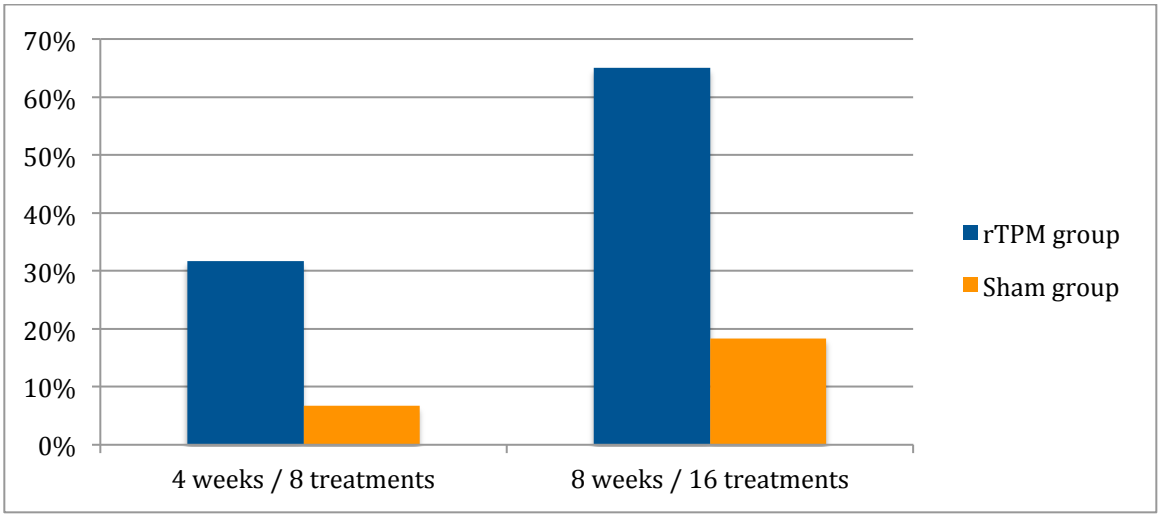
Conclusions: There is a significant difference between rTPM and Sham results. Patients receiving the rTPM treatment are 3,5 times more likely to improve and 6 times more likely to be completely dry with the rTPM Stimulation. 65% of the rTPM patients reported „significant benefits" on quality of life after 16 treatments. Success rate increases with 20 or 24 treatments. The rTPM treatment does not have a negative effect on the flow of urine, on the contrary, the data shows that the obtained results indirectly improve the voided volume and in the remaining bladder volume as well as in the maximum flow rate. The results shown also, a significant improvements in strength of Pelvic floor muscles, but not statistically significant as compared to Sham. Reason are: the used measurement tool and high stochastically deviations in measurements.



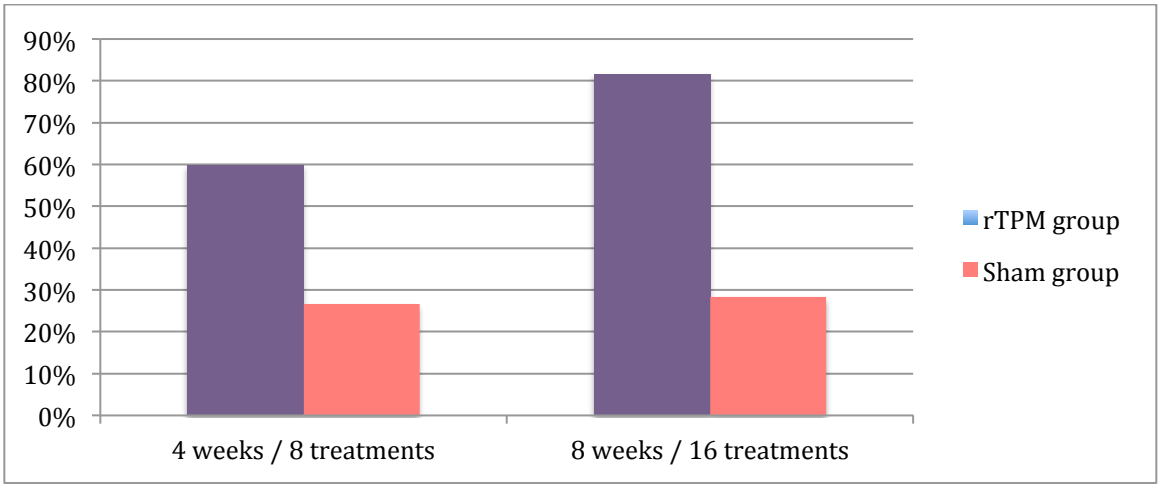
Results: the number of patients having ≥ 5 point reduction on the ICIQ-UI SF scale (1-21),



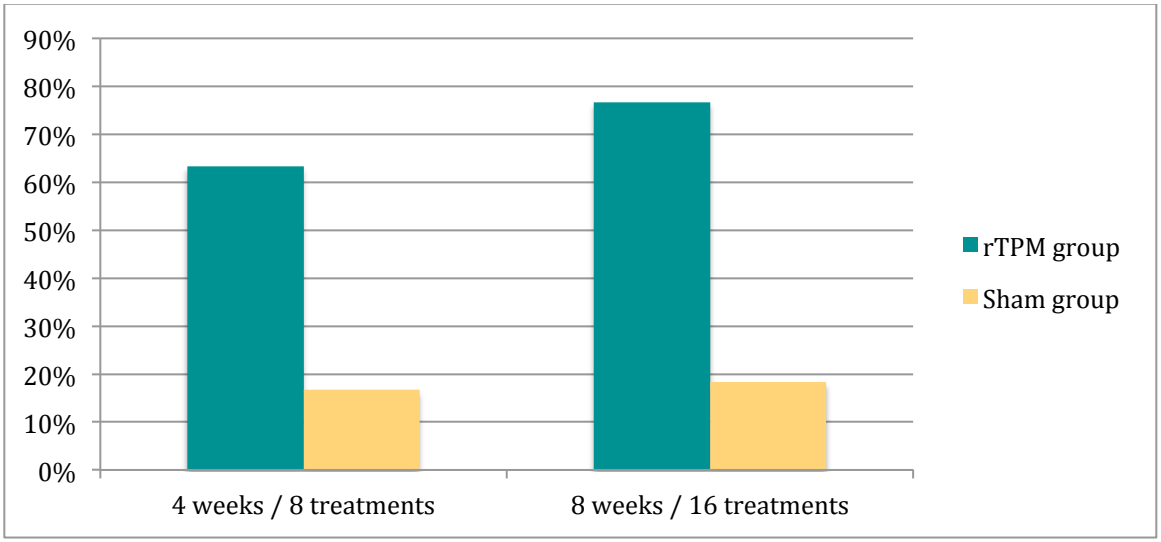
Subjective cure: Amount of leak



Results: Quality of life PGI-I



Results: 1 hour Pad test



Results IEF (Frequency of leak)

Pulsed Magnetic Stimulation for Stress Urinary Incontinence: 1-Year Follow-up Results

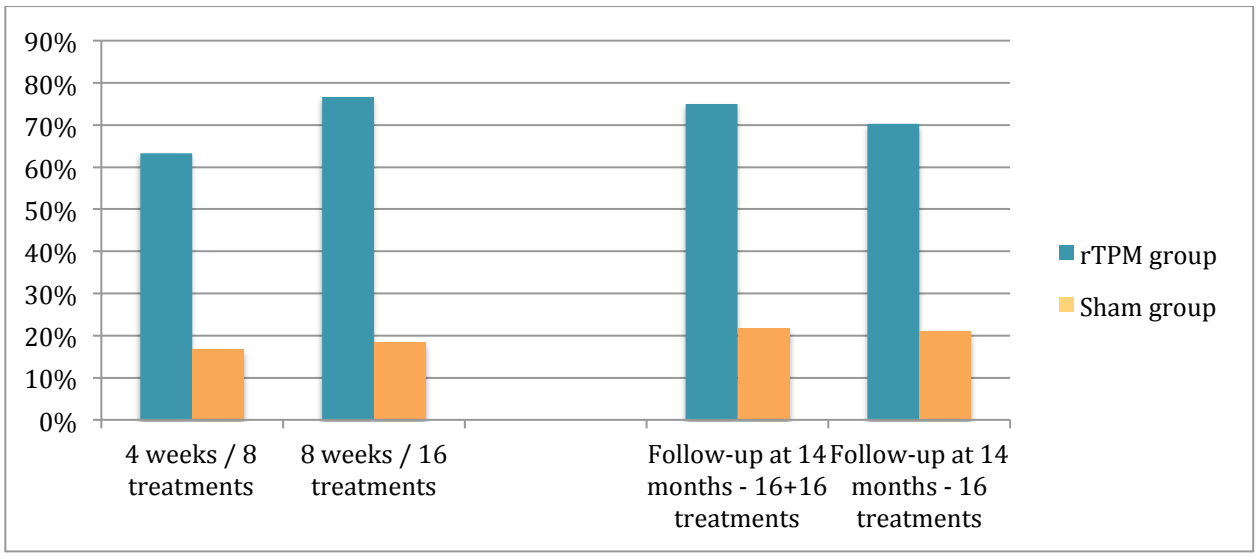
Supplemental materials / Follow-up

Purpose: despite significant differences in success rates between surgical and nonsurgical treatments for female stress urinary incontinence, a few cross-sectional surveys showed that most patients still prefer the latter. We evaluated the efficacy of the under studied nonsurgical treatment using pulsed magnetic stimulation for female stress urinary incontinence.

Materials and Methods: this randomized, double-blind, sham controlled study was performed in 120 female subjects at least 21 years old with stress urinary incontinence. Treatment involved pulsed magnetic stimulation for 2 sessions per week for 2 months (16 sessions). After 2 months, subjects could opt for 16 additional sessions regardless of initial randomization. The primary response criterion was a 5-point reduction in the ICIQ-UI SF (International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form) score. Key secondary response criteria included objective and subjective cure, supplemented by other secondary criteria. Follow-ups were performed at months 1, 2, 5, 8 and 14.

Results: at 2 months 45 of 60 subjects (75%) in the active arm vs 13 of 60 (21.7%) in the sham arm were treatment responders ($p < 0.001$). After 2 months 24 subjects (40%) in the active arm and 41 (68%) in the sham arm elected additional active pulsed magnetic stimulation. At 14 months, subjects who received 32 sessions of active pulsed magnetic stimulation had the highest percentage of treatment responders (18 of 24 or 75.0%), followed by those who received 16 sessions (26 of 36 or 72.2% and 28 of 41 or 68.3%) and those who did not receive any active pulsed magnetic stimulation (4 of 19 or 21.1%) ($p < 0.001$).

Conclusions: the encouraging long-term response rates show that pulsed magnetic stimulation is an attractive nonsurgical alternative for patients who do not want to undergo surgery.



Results: the number of patients having ≥ 5 point reduction on the ICIQ-UI SF scale (1-21), At 4 weeks (8 treatments) / 8 weeks (16 treatments) & follow-up at 14 months (16 treatments and 32 treatments)

Abstract from : journal of Urology – May 2017

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