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URGENCY IMPROVEMENT AFTER FUNCTIONAL MAGNETIC STIMULATION – MAGNOLIA DEVICE

Hypothesis / aims of study

Urgency and urgency urinary incontinence (UUI) represent two overactive bladder (OAB) symptoms which greatly influence the quality of life (QoL) of affected women. Antimuscarinics represent a treatment of choice for this disorder, however, the use of these drugs is sometimes limited due to the side effects (dry mouth), which might lead to drug discontinuation. Functional magnetic stimulation (FMS) represents a new promising non-invasive treatment of OAB with proven efficacy which was confirmed in previous studies. In present study we tested a second-generation smart magnetic stimulator (MAGnolia device, Picture 1) in OAB with women who experienced urgency and urgency incontinence. The primary study outcome was to evaluate the impact of FMS, produced by MAGnolia device on intensity, frequency and botherness of urgency. The secondary study outcome was the quality of life (QoL) analysis.

Picture 1: MAGnolia device; a second-generation magnetic stimulator, capable of generation of a pulsating magnetic field of up to 40 μT at the 50-70 mm distance from the stimulator (waterproof) housing. Pulsating frequency can be set from 10 to 40 Hz and the pulse width from 40 μs to 100 μs. The rechargeable battery of 240 mAh provides enough power to keep the stimulator continuously operating for 75 days using the standard set-up (10 μT/40 μs/20 Hz).

Study design, materials and methods

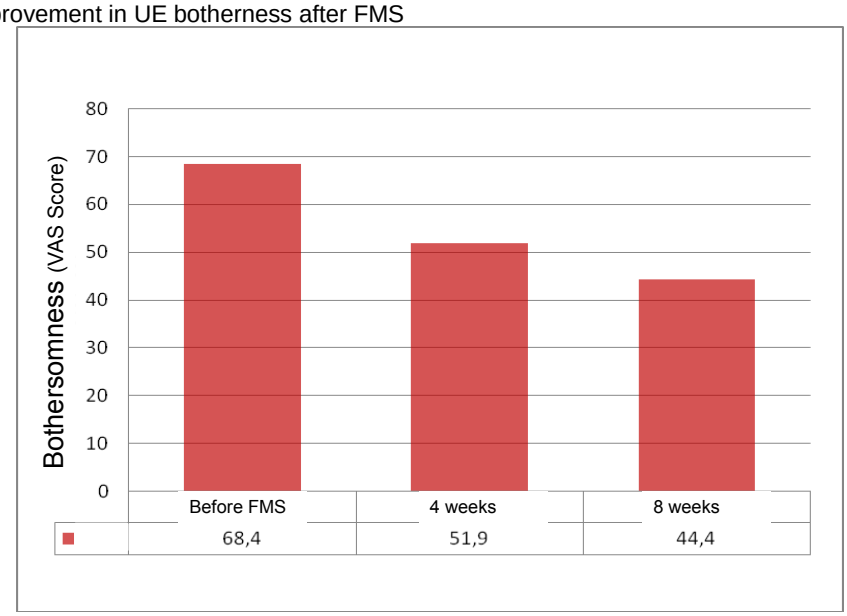
In this prospective study we invited 20 consecutive women with OAB who experienced at least one urgency episode (UE) daily (with or without incontinence). We asked them to wear MAGnolia device attached on a tape (which enabled prepubical position of device) day and night for two months. MAGnolia device delivered a continuous pulsating magnetic field of *10* μT at the frequency of 20 Hz. The pulse width was set to 40 μs. After the urogynecological examination we measured the magnetic field power (B) produced by MAGnolia device (located on the pubic bone) with a special 3D probe, which was placed intravaginally. All patients signed the Informed Consent Form and filled out the validated questionnaires (UDI – Urogenital Distress Inventory and IIQ – Incontinence Impact Questionnaire) and a 3-day voiding diary. We calculated the Irritative Score from the UDI questionnaire (values between 0 – no irritative symptoms and 100 – maximal irritative symptoms). IIQ values ranged between 0 and 400, the higher the score the worse QoL. Urgency was assessed by a simple 4-step Urgency Perception Score (UPS), where steps 3 and 4 represented urgency and urgency incontinence, respectively. Frequency of urgency episodes (UE) was expressed by 7 categories, where 0 meant no UEs, category 1 - 1-2 UEs a month, category 2 – one UE per week, category 3 – 2-3 UEs per week, category 4 – one UE daily, category 5 – 2 UEs daily, category 6 – 3-4 UEs daily and category 7 meant 5 or more UEs a day. The UE botherness was assessed on a VAS (Visual Analog Scale) score, where number 0 meant no bother and number 100 represented unbearable bother. The efficacy and tolerability of FMS was evaluated after the first and the second month of treatment of all patients.

Results

Between April 2011 and October 2011 we recruited only 16 women with OAB. The average age of patients was 51.3 years (from 26 to 62 years), their average BMI amounted to 26.0 kg/m2. They experienced urgency for 90 months and UUI for 25.1 months on average. The irritative score from the UDI questionnaire was 55.5, and the IIQ score (QoL analysis) amounted to 208.6. The mean maximum magnetic field power delivered by MAGnolia device measured intravaginally was detected at the distance of -6.4 cm in the vagina and amounted to 6.0 μT. All 16 patients completed the 2-month FMS treatment.

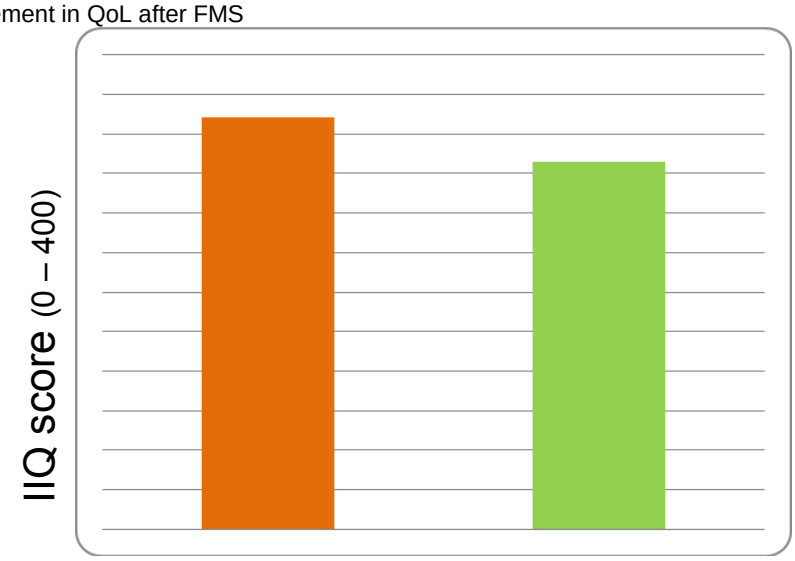
The first beneficial effect of FMS was noted between 7 and 10 days of the treatment. The intensity, frequency and botherness of urgency episodes significantly decreased after 2 months of FMS treatment ($p < 0.05$). The intensity of UE decreased from 2.9 to 2.4, the frequency of UE decreased from 5.6 to 4.8 (from 3-times daily to once a day on average), and the UE were less bothersome (43 % improvement after 2 months, Figure 1).

Figure 1: Improvement in UE botherness after FMS



UDI Irritative Score significantly improved after 2 months of FMS (from 55.5 to 40.3, $p < 0.05$). Also, the QoL significantly improved after FMS (IIQ score from 208.6 to 185.9, Figure 2).

Figure 2: Improvement in QoL after FMS



FMS was well tolerated by all patients, there were no side effects or other possible problems regarding the treatment.

Interpretation of results

The results of this study showed a significant improvement in urgency intensity, frequency and botherness after FMS, which was delivered by a new magnetic device – MAGnolia. Based on VAS score analysis the urgency botherness decreased by 43 % what was reflecting in an increase of QoL of patients. The FMS treatment proved to be safe and no adverse events were reported by patients.

Concluding message

The results of this study confirmed previous observations presented in literature that FMS is a safe, efficient and non-invasive mode of OAB treatment exerting a good control over urgency. The drawback of this study was a small sample size and the lack of placebo devices. Therefore, our findings need to be confirmed in a larger placebo-controlled study, which is a part of our short-term plans.

Disclosures

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