452

Kirschner-Hermanns R[1], Kahle C[1], Jakse G[1]
1. Clinic of Urlogy, University Clinic RWTH Aachen

SINGLE CENTER EXPERIENCE WITH EXTRA CORPORAL MAGNETIC INNERVATION, OR EXMI TREATING STRESS-, URGE INCONTINENCE AND PELVIC PAIN SYMPTOMS

Hypothesis / aims of study
ExMI as provided by NeoControl Pelvic Floor Therapy System is a non-surgical therapy for stress incontinence and a well tolerated therapy with hardly any side effects for urge and pelvic pain symptoms. Aim of this study is to investigate wether ExMI™ treatment is sucessfull and which patients benefit the most.

Study design, materials and methods
In our clinic 87 patients are treated with ExMI™. 61 patients are women and 16 patients men, mostly after surgical procedures for localised prostate cancer. Cleared by the US Food and Drug Administration (FDA) in June 1998 NeoControl has been the first product to utilize ExMI. ExMI technology produces highly focused pulsed magnetic fields. During treatment, a patient sits fully clothed in a specially designed chair that has the ExMI technology embedded in the seat. The treatments, which are typically performed twice a week, are painless and take approximately 20 minutes. A complete course of treatment may take eight weeks or more, depending on the condition treated.
We include patients with mild and moderate stress incontinence who are not aware of their pelvic floor muscles (lLaycock 0-2) and therefore not able to perform correct pelvic floor exercise and patients with urge incontinence who fail on bladder training and drug treatment alone. We further include patients with pelvic pain symptoms before going on with more invasive treatment modalities. Prior to treatment all patients have a thorough investigation including a full medical history, a complete physical investigation, a three day bladder diary, urine status, I-Qol Fragebogen, and in over 62% a standardized video Urodynamic study to establish the correct diagnosis

Results
Most of our patients (24 women and 13 men) were treated to gain awareness of pelvic floor muscles and to improve muscle strength) 31 patients were treated for urgency or mixed incontinence. Only one of them was male. 19 patients complained about pelvic pain, two of them were men with a chronic non infectious prostatitis.
Seven patients (8%) didn't complete treatment, most of them because of difficulties coming into the hospital twice a week. 19 of the 24 women (79%) learned how to contract willingly their pelvic floor muscles (Laycock 4-5) and went on with physiotherapy. 11 men 84% benefited from ExMI™ by subjective and objective means (bladder diary and ICS male questionnaire). Only 48% of all patients treated with urge incontinence benefited from ExMI™ by subjective and objective measurements. Only four women and one man with pelvic pain symptoms have longer lasting improvement of their symptoms (more than six months). The majority of the patients are on additional treatment modalities including infravesical instillation therapy, medication therapy with analgetics or antidepressants, infravesical electro stimulation (EMDA) or infiltration therapy with Botox.

Interpretation of results
ExMI™ seems effective in rebuilding pelvic floor muscles in women as well as in men and in helping patients regain continence in those suffering from mild and moderate stress incontinence . Since nearly 50% of patients with difficult to treat urge incontinence benefit from a treatment regime with ExMI™ magnetic stimulation of the pelvic floor is a treatment option with nearly no side effects. No single treatment modality has been demonstrated as being effective in treating patients with pelvic pain symptoms. Although only very few of these patients benefit from ExMI™, it might be an option in those who are very reluctant to invasive forms of treatment.

Concluding message
Because of ethical reasons placebo controlled studies are not possible in our setting. Further studies are warranted for better comparison to other conservative treatment options. More advanced studies should also include costs. Whether ExMI™ will be an optional treatment modality for patients with incontinence or bladder pain will be influenced if and how well ExMI™ is reimbursed under different health providers.

FUNDING: NONE
DISCLOSURES: NONE
CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.
HUMAN SUBJECTS: This study did not need ethical approval because Because it is an observational study this was not necessary but followed the Declaration of Helsinki Informed consent was obtained from the patients.