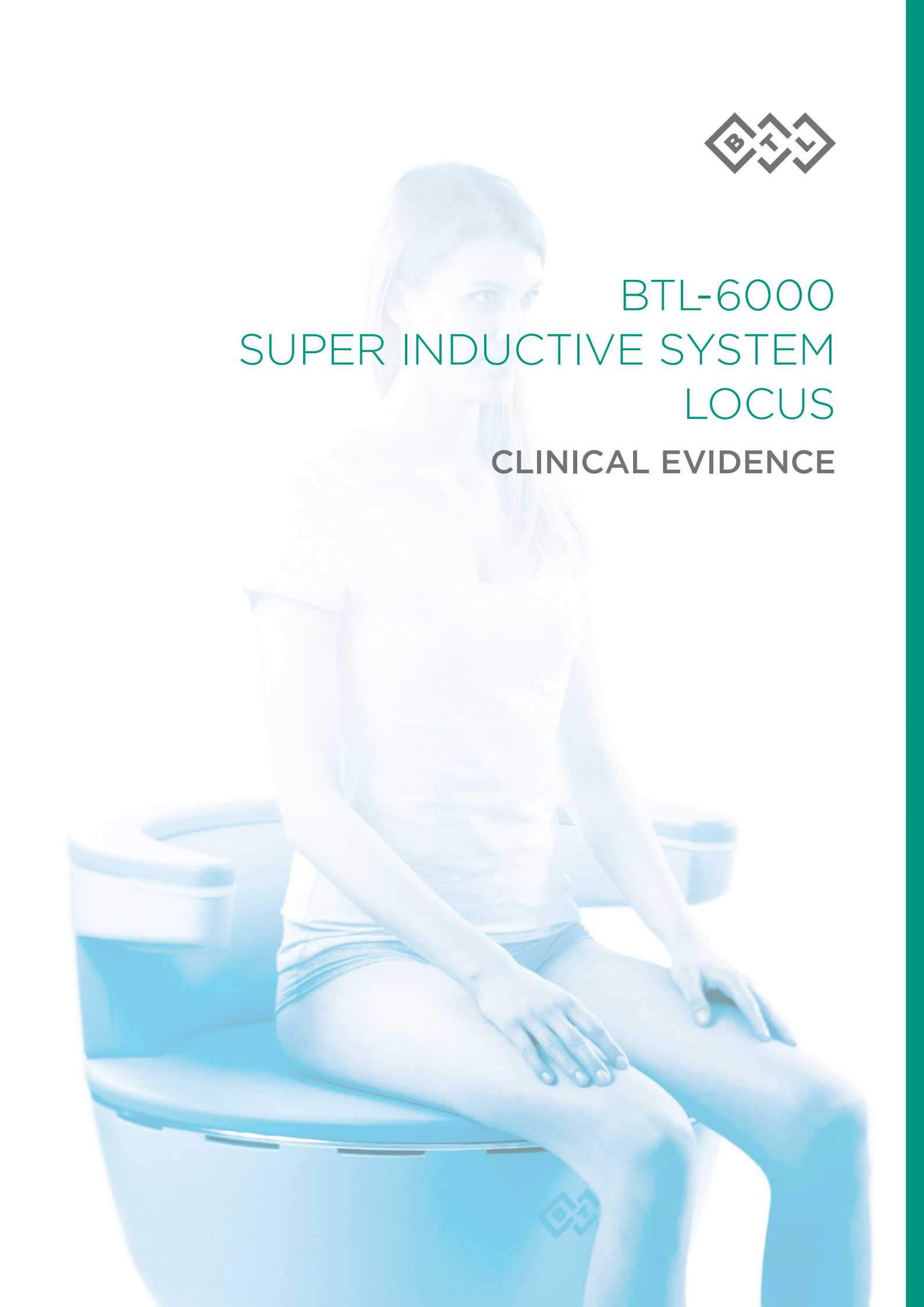

BTL-6000 SUPER INDUCTIVE SYSTEM LOCUS

CLINICAL EVIDENCE

CONTENT

1. INCONTINENCE

TITLE: SUPER INDUCTIVE SYSTEM LOCUS IN URINARY INCONTINENCE TREATMENT – A PILOT STUDY

Author: Bajkaiová Z.[1]
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ABSTRACT:

Background:
Urinary incontinence (UI) is a condition negatively affecting patient´s quality of life. Commonly, incontinence treatment requires combination of therapeutic approaches (i.e. intravaginal electrostimulation, Kegel exercises etc.) and drug treatment, which has negative side-effect. Therefore a comprehensive and non-invasive therapy without adverse events is desirable.

Aim:
Aim of this pilot study was to investigate the efficacy of a high-intensity electromagnetic field stimulation of pelvic floor muscles in incontinent patients.

Methods:
21 women (mean age 57,5 yrs) with stress incontinence (SI) were included in pilot study with high-intensity electromagnetic field stimulation device (Super Inductive System Locus, BTL Industries Ltd.). All patients underwent a 1-month therapeutic protocol, which included sessions 2-3x times a week. Average number of underwent therapies was 12 treatments. Patients were evaluated by a physician´s clinical examination and completed with subjective patient´s evaluation. Comparison of patient´s condition before and after treatment was completed.

Results:
A pilot study was conducted and analyzed on 21 women with SI. In clinical evaluation physician concluded amelioration of patient´s condition, which was highly correlated with patient´s subjective evaluation. In 67 % of patients (N = 14) significant remission of urinary leakage was observed; 24 % of patients (N = 5) noted moderate remission of urinary leakage. Only 9 % (N = 2) of patients reported no therapy progress. There were no adverse events.

Conclusions:
In this pilot study we concluded a positive effect of high-intensity electromagnetic field stimulation in 91 % of all treated patients. Significant decrease of urinary leakage was observed. Therefore we suggest that high-intensity electromagnetic field stimulation represents effective treatment of incontinence. For further investigation, addition in methodological part of the pilot study as well as long-term follow-up needs to be accomplished.

TITLE: ELECTROMAGNETIC PELVIC FLOOR STIMULATION FOR URINARY INCONTINENCE AND BLADDER DISEASE

Authors: Goldberg R.P.[1], Sand P.K.
Affiliations: [1]Sand Evanston Continence Center, Division of Urogynecology & Reconstructive Pelvic Surgery, Department of Obstetrics & Gynecology, Northwestern University Medical School, Evanston Northwestern Healthcare, Evanston, IL USA
Published: International Urogynecology Journal, 2001, 12, 401–404

ABSTRACT:

Electromagnetic stimulation of the sacral nerve roots and pelvic floor continues to evolve as a non-invasive treatment alternative for pelvic floor and bladder dysfunction. Magnetic innervation can be offered to well-selected patients as first-line therapy for incontinence and irritative voiding symptoms, and to those who are intolerant or refractory to medical therapy, poor surgical candidates, or unable to use electrical stimulation devices. Prospective clinical trials have demonstrated efficacy for stress incontinence, urge incontinence, frequency and nocturia. Clinicians should have a basic understanding of the underlying technology, clinical efficacy and limitations of electromagnetic pelvic floor stimulation, in order to make appropriate recommendations regarding therapy.

TITLE: SYMPTOM CHANGE IN WOMEN WITH OVERACTIVE BLADDER AFTER EXTRACORPOREAL MAGNETIC STIMULATION: A PROSPECTIVE TRIAL

Authors: Choe J.H.[1], Myung S.Ch., Kyu S.L.
Affiliations: [1]Department of Urology, Cheil General Hospital, Sungkyunkwan University School of Medicine, Seoul, South Korea
Published: International Urogynecology Journal, 2007, 18, 575

ABSTRACT:

The purpose of this study was to prospectively evaluate symptom change after discontinuation of extracorporeal magnetic stimulation (EMS) in women with overactive bladder (OAB). A total of 48 women with OAB were included. We applied 10 Hz of repetitive magnetic stimulation with a “magnetic chair” for 20 min, twice weekly for 8 weeks. Changes in OAB symptoms at 2, 12, and 24 weeks after discontinuing the EMS were evaluated. Twenty-seven (56.3 %) patients were cured compared with the baseline at 2 weeks: the cure rate was determined as 68.8 % (33/48 patients), 56.3 % (27/48), and 50 % (8/16) for urgency, frequency, and urge incontinence, respectively. The mean number of voids per 24 h was decreased by 42.8 % (from 14.5 ± 4.3, to 8.3 ± 1.5, $p < 0.001$) at 2 weeks after treatment. Maximum voided volume did not change significantly, but the mean voided volume increased significantly after stimulation. Twenty-six (96.3 %) patients among the 27 patients who achieved a cure at 2 weeks, maintained improvement at 24 weeks; the therapeutic effect on urgency, frequency, and urge incontinence persisted in 26 (78.8 %) of 33 patients, 26 (96.3 %) of 27 patients, and six (75 %) of eight patients, respectively. There were no significant changes in urodynamic parameters. Of the 14 patients with detrusor overactivity, the condition was no longer observed in four (28.6 %) patients. EMS has a beneficial effect on women with OAB. Our data suggest EMS may have a significant carry-over effect in wellselected OAB patients.

TITLE: EXTRACORPOREAL MAGNETIC INNERVATION THERAPY FOR STRESS URINARY INCONTINENCE

Authors: Galloway N.T[1], El-Galley R.E., Sand P.K., Appell R.A., Russell H.W., Carlan S.J.
Affiliations: [1]Emory University School of Medicine, Atlanta, Georgia, USA
Published: Urology, 1999, 53(6), 1108-1111

ABSTRACT:

Objectives:
To report the first data from a prospective clinical study to determine the feasibility of using extracorporeal magnetic innervation (ExMI) for the treatment of stress urinary incontinence.

Methods:
We studied 83 women with demonstrable stress urinary incontinence. Treatments were for 20 minutes, twice a week for 6 weeks. For treatment, the patient sits fully clothed on a special chair; within the seat is a magnetic field generator that produces the rapidly changing magnetic field flux. Objective measures included bladder diaries, dynamic pad weight testing, urodynamic studies, and quality of life survey.

Results:
Fifty patients have been followed up for longer than 3 months (33 patients for less than 3 months); 17 patients (34 %) were dry, 16 (32 %) were using not more than 1 pad per day, and 17 (34 %) were using more than 1 pad per day. Pad use was reduced from 2.5 to 1.3 ($p<0.001$) and leak episodes per day were reduced from 3.3 to 1.7 ($p<0.001$). The pad weight was reduced from 20 to 15 g. Detrusor instability was found in 5 patients before but was demonstrated in only 1 patient after treatment.

Conclusions:
ExMI therapy offers a new effective modality for pelvic floor muscle stimulation. ExMI is painless, there is no need for a probe, and no need to undress for treatments. Longer follow-up is required to determine how long the benefits of treatment last and whether retreatment will be necessary.

TITLE: EXTRACORPOREAL MAGNETIC INNERVATION (EXMI)-EINE ERGÄNZUNG DER KONSERVATIVEN INKONTINENZTHERAPIE?

Authors: Wöllner J.[1,2], Neisius A., Hampel C., Thüroff J.W.

Affiliations: [1]Neuro-Urologie, Paraplegikerzentrum Universität Zürich, Uniklinik Balgrist, Schweiz
[2]Klinik und Poliklinik für Urologie, Universitätsmedizin der Universität Mainz, Deutschland

Published: Der Urologe, 2012, 51, 10, 1432-1437

ABSTRACT:

Objective:
Extracorporeal magnetic innervation (ExMI) is a non-invasive therapy for urinary incontinence (UI). Aim of the current study was to evaluate the efficacy of ExMI in a prospective case series.

Patients and methods:
Over a period of 1½ years 63 consecutive patients with clinical and urodynamic confirmed diagnosis of urinary incontinence were enrolled. All patients requested an additional non-surgical therapy option. We applied the ExMI system (Neo control™, Kitalpha LTD, USA). The therapy consisted of 12 treatment sessions two to three times a week. Primary outcome parameter was reduction of number of pads per 24 h, secondary outcomes were patient`s satisfaction, adverse events and duration of the therapeutic effect.

Results:
63 patients (57 male, 6 female), mean age 68 ± 7.1 years were recruited. After completion, a significant (p=0.001) reduction of number of pads use per 24 h was observed (5.4 ± 3.7 to 2.7 ± 2.5), which persisted after a median follow-up of 12.5 months (2.3 ± 2.2 pads per 24 h). Also patients suffering from UI after prostatectomy revealed a significant (p=0.001) reduction in number of pads from 4.8 ± 2.9 to 2.6 ± 2.6 with persistence at 2.5 ± 2.5 at follow-up. Transient, self-limiting perineal pain in three patients was the only reported side effect.

Conclusions:
ExMI is an additional non-invasive therapy option for patients with urinary incontinence. However, sham-controlled studies are required to corroborate the therapy effect.

TITLE: EFFICIENCY OF EXTRACORPOREAL MAGNETIC INNERVATION (EXMI) IN URINARY INCONTINENCE: A SYMPTOMATIC ASSESSMENT

Authors: Perianan M.[1], Huat Chye Peter L.
Affiliations: [1]Changi General Hospital, Singapore
Published: International Journal of Urology, 2004, 11, 602–606

ABSTRACT:

Aims of Study:
Urinary incontinence (UI) is a most common disorder in aging people (incidence of 9.5 to 49 %), with minimal occurrence in young. Several therapeutic and surgical modalities are available for this problem, conferring widely differing degrees of outcome in subjective and objective analyses. Electrical stimulation or magnetic innervation are the most common non-invasive methods employed for UI and studies have shown restoration of urinary continence. The present paper subjectively assess the efficiency of extracorporeal magnetic innervation on urinary incontinence in Singaporean patients by using NEOCONTROL™ pelvic floor therapy system.

Methods:
A total of 66 patients (23 males and 43 females) were subjected to ExMI tretament for urinary incontinence. The mean age of the males and females were 55.3 ± 18.5 (range 27-77 years) and 56.2 ± 15.3 (range 29-84 years), respectively. The mean number of treatment session was 7.7 ± 3.8 and 10.4 ± 4.8 for males and females. In both group, the treatment duration was 20 minutes with a slow and fast frequencies. Subjective evaluation was done according to the questionnaires developed by NEOTONUS Inc., which assessed patients conditions before and after treatment. Patients recorded the frequencies of voids and leaks, number of pads used and the impressions of magnetic innervation therapy system as improved, slightly improved and no improvement. Improved condition of incontinence was defined as reduced frequency by 50 % or more.

Results:
In men, improvement in 57.1 % and slight improvement in 9.5 % was recorded; while no improvement was cited by 29 %. Before treatment, 88.2 % men had frequency symptoms and after treatment frequency symptoms recurred in 53.8 %. Because of incovenience 13 % stopped the ExMI treatment. In women, improvement in 35.1 % and slight improvement in 37.8 % was observed; while no improvement was cited by 24.3 %. Before treatment, 66.7 % women had frequency symptoms and after treatment frequency symptoms recurred only in 7.4 %. Because of incovenience 9.3 % stopped the ExMI treatment. The symptom improvement rate was found to be higher in men with minmal treatment sessions. However, recurrence of frequency symptoms was more in men. In both sexes, no significant adverse events were evident, except a perineal itch in a single female patient.

Conclusions:
Subjective assessment revealed that ExMI provides satisfactory outcome in the restoration of continence in male and female patients, particularly frequency symptoms, without any pain during treatment. Satisfactory outcome was more evident in men and men needs less number of treatment session than women.

TITLE: EXTRACORPOREAL MAGNETIC INNERVATION TREATMENT FOR URINARY INCONTINENCE

Authors: Yokoyama T., Fujita O., Nishiguchi J., Nozaki K., Nose H., Inoue M., Ozawa H., Kumon H.
Affiliations: Department of Urology, Okayama University Graduate School of Medicine and Dentistry, Okayama, Japan
Published: International Journal of Urology, 11(8), 602-606

ABSTRACT:

Background:
Extracorporeal magnetic innervation (ExMI) is a new technology used for pelvic muscle strengthening for the treatment of stress urinary incontinence. We explored whether this new technology is effective for patients with urge incontinence, as well as those with stress urinary incontinence.

Methods:
We studied 20 patients with urge incontinence and 17 patients with stress urinary incontinence. The Neocontrol system (Neotonus Inc., Marietta, GA) was used. Treatment sessions were for 20 min, twice a week for 8 weeks. Evaluations were performed by bladder diaries, one-hour pad weight testing, quality-of-life surveys and urodynamic studies.

Results:
Of the urge incontinence cases, five patients were cured (25.0 %), 12 patients improved (60.0 %) and three patients did not show any improvement (15.0 %). Leak episodes per day reduced from 5.6 times to 1.9 times at 8 weeks ($p < 0.05$). Eight patients with urge incontinence recurred within 24 weeks after the last treatment (47.1 %). Of the stress incontinence cases, nine patients were cured (52.9 %), seven patients improved (41.1 %) and one patient did not show any improvement (6 %). In one-hour pad weight testing, the mean pad weight reduced from 7.9 g to 1.9 g at 8 weeks ($p < 0.05$). Three patients returned to the baseline values within 24 weeks after the last treatment (17.6 %). No side-effects were experienced by any of the patients.

Conclusion:
Although the results for urge incontinence were less effective than for stress urinary incontinence, ExMI therapy offers a new option for urge incontinence as well as stress urinary incontinence.

TITLE: FUNCTIONAL EXTRA CORPORAL MAGNETIC STIMULATION AS A TREATMENT OF FEMALE URINARY INCONTINENCE: THE CHAIR

Authors: Chandi D.D.[1], Groenendijk P.M., Venema P.L.
Affiliations: [1]Department of Urology, Leyenburg Hospital, The Hague, The Netherlands
Published: British Journal of Urology, 2004, 93(4), 539-542

ABSTRACT:

A prospective study was performed to evaluate the efficiency and applicability of functional magnetic stimulation (FMS) of the pelvic floor in the treatment of urinary incontinence in women. The stimulation was provided by a magnetic chair (Neocontrol™). 24 patients were treated during eight weeks. Twelve patients suffered from urge incontinence and in twelve patients a mixture of urge and stress incontinence was present. In 58 % of the patients an objective improvement of the incontinence was observed. Three patients were completely dry. 71 % of the treated patients noticed a subjective improvement ($p < 0.001$). FMS is a safe, non invasive and painless treatment for urinary incontinence. Treatment with FMS is effective and easy to perform in out patients circumstances.

TITLE: THE LONG TERM EFFECT OF EXTRACORPOREAL MAGNETIC INNERVATION THERAPY WITH PELVIC FLOOR MUSCLE EXERCISE FOR STRESS URINARY INCONTINENCE

Authors: Jae Sik Kim, Hana Yoon, Woo Sik Chung, Bong Suk Shim
Affiliations: Department of Urology, College of Medicine, Ewha Womans University, Seoul, Korea
Published: Korean Journal of Urology, 2006, 47(12), 1334-1338

ABSTRACT:

Purpose:
Extracorporeal magnetic innervation (ExMI) therapy has been known to be safe and immediately effective in stress urinary incontinence (SUI). However, no long term follow-up results have been reported. Therefore; herein, are reported our results from a two year follow-up study on ExMI therapy, with pelvic floor muscle exercises, for SUI.

Materials and Method:
The study group was comprised of 94 patients with SUI. ExMI therapy was performed for 20 minutes (10 Hz and 50 Hz for each 10 minutes), twice a week, for 6 weeks. Thereafter, 44 of the 94 patients underwent pelvic floor muscle exercises. Objective measures (quality-of-life surveys, pad changes, and leak episodes per day) were evaluated before, immediately after and 24 months after the ExMI therapy.

Results:
After 6-weeks of ExMI therapy, the quality-of-life score improved from 5.1 ± 0.9 to 1.8 ± 1.1. The mean frequency of pad changes was reduced from 2.1 ± 1.6 to 1.1 ± 1.0. The mean frequency of leak episodes was also reduced from 2.8 ± 1.8 to 1.7 ± 1.5 times. After 24 months, the 44 patients having also undergone pelvic floor muscle exercise had persistent improvements in their leak episodes per day compared to the 50 patients that had not.

Conclusions:
When ExMI therapy was followed by pelvic floor muscle exercises, the favorable effect in leak episodes per day after ExMI therapy may persist for at least 24 months.

TITLE: THE ACUTE EFFECT OF MAGNETIC STIMULATION OF THE PELVIC FLOOR ON INVOLUNTARY DETRUSOR ACTIVITY DURING NATURAL FILLING AND OVERACTIVE BLADDER SYMPTOMS

Authors: Bradshaw H.D., Barker A.T., Radley S.C., Chapple C.R.
Affiliations: Department of Urology, Medical Physics and Clinical Engineering Obstetrics and Gynaecology, Sheffield Teaching Hospitals, United Kingdom
Published: British Journal of Urology, 2003, 91(9), 810-813

ABSTRACT:

Objective:
To evaluate the effect of magnetic stimulation of the pelvic floor (MSPF) on involuntary detrusor activity observed during natural filling, and on the overactive bladder symptom complex.

Patients And Methods:
Eighteen women with detrusor overactivity on conventional cystometry underwent ambulatory urodynamic monitoring over two filling cycles. Fluid intake was standardized, provocative manoeuvres applied at regular intervals and symptoms documented contemporaneously. During the second filling cycle MSPF was delivered whenever the detrusor pressure increased by > 5 cmH2O. The women were subsequently treated with MSPF for 6 weeks; their lower urinary tract symptoms were assessed before and after treatment.

Results:
Comparing the second (stimulated) cycle with the first (unstimulated) cycle, cystometric capacity was higher (373 vs 224 mL, $p < 0.03$) and involuntary detrusor activity of shorter duration (370 vs 427 s, $p < 0.82$) and lower amplitude (53 vs 63 cmH2O, PŁ 0.05). All women tolerated the procedure comfortably, but nine found it too time-consuming and withdrew. In the nine women who completed treatment there was no consistent change in overactive bladder symptoms.

Conclusions:
In this pilot study, MSPF during natural filling was associated with a decrease in the amplitude of involuntary detrusor contractions and a significant increase in cystometric capacity. However, MSPF had a variable effect on sensations of urgency, both acutely and after treatment, and currently there is no evidence to suggest that MSPF has an enduring effect on symptoms of the overactive bladder.

TITLE: UPDATE ON EXTRACORPOREAL MAGNETIC INNERVATION (EXMI) THERAPY FOR STRESS URINARY INCONTINENCE

Authors: Galloway N.T[1], El-Galley R.E, Sand P.K, Appell R.A, Russell H.W, Carlin S.J.
Affiliations: [1]Department of Urology, Emory University School of Medicine, Atlanta, Georgia, USA
Published: Urology, 2000, 56(6A), 82–86

ABSTRACT:

Pulsed magnetic technology has been developed for pelvic floor muscle strengthening for the treatment of urinary incontinence. This report includes an update of the prospective multicenter study of extracorporeal magnetic innervation (ExMI) therapy for stress incontinence and a discussion of the possible mechanisms of action. Issues of patient selection for ExMI therapy will also be discussed. One hundred and eleven women with demonstrable stress urinary incontinence were studied. The mean age was 55 ± 13 years, and the mean duration of symptoms was 11 years. Ninety-seven completed ExMI therapy and analysis. Evaluation before treatment included bladder diaries, dynamic pad weight test, urodynamics, and a quality-of-life survey. For treatment the patients were seated fully clothed in a Neocontrol chair with a magnetic field therapy head in the seat. Treatment sessions were for 20 minutes, twice a week, for 6 weeks. After ExMI therapy, all of the measures were repeated at 8 weeks, including the dynamic pad weight testing and quality-of-life survey. At 6 months, further data were added, including repeat bladder diary, pad use and quality-of-life survey. Forty-seven women completed 6 months of follow-up; of the 47, 13 patients were completely dry (28 %) and 25 used no pad or less than 1 pad per day (53 %). Pad use was reduced in 33 patients (70 %). The median number of pads was reduced from 2.16 to 1 per day (Wilcoxon signed rank test, $p < 0.005$). The frequency of leak episodes was reduced from 3.0 to 1.7 at 6 months (Wilcoxon signed rank test, $p = 0.004$). Detrusor instability was demonstrated in 10 before and 6 after ExMI ($p < 0.05$). ExMI offers an alternative approach for the treatment of urinary incontinence. ExMI therapy is effective for both stress and urge incontinence. The best results are achieved in those patients who use no more than 3 pads a day and have had no prior continence surgery.

TITLE: PELVIC FLOOR MUSCLE TRAINING TO IMPROVE URINARY INCONTINENCE AFTER RADICAL PROSTATECTOMY: A SYSTEMATIC REVIEW OF EFFECTIVENESS

Authors: MacDonald R.[1], Fink H.A., Huckabay Ch., Monga M., Wilt T.J.
Affiliations: [1]Minneapolis Veterans Affairs Center for Chronic Disease Outcomes Research and the Cochrane Review Group in Prostate Diseases and Urologic Cancers, Department of Urology, Veterans Affairs Medical Center, Minneapolis, USA
Published: British Journal of Urology, 2007, 100(1), 76-81

ABSTRACT:

Objective:
To evaluate the effectiveness of pelvic floor muscle training (PFMT) for treating urinary incontinence (UI) after radical prostatectomy (RP) by reviewing evidence from randomized trials.

Methods:
Randomized trials published in English were included if they involved men with UI after RP and compared PFMT with a control group. Data were abstracted onto a standardized form using a prospectively developer protocol.

Results:
Eleven trials randomizing 1028 men (mean age 64 years) met the inclusion criteria; the duration of the trials was 3 – 12 months. One trial of 300 men found that those assigned to PFMT achieved continence more quickly (after 1, 3 and 6 months) than men not assigned to PFMT. Men receiving biofeedback-enhanced PFMT were more likely to achieve continence or have no continual leakage than those with no training within 1 – 2 months after RP (relative benefit increase 1.54; 95 % confidence interval 1.01 – 2.34; four trials reporting). The relative benefit increase (1.19, 0.82 – 1.72; five studies) was no longer significant after 3 – 4 months. Biofeedback enhanced PFMT was comparable to written / verbal PFMT instruction. Extracorporeal magnetic innervation (ExMI) and electrical stimulation (ES) were found to be initially (within 1 – 2 months) more effective than PFMT in one trial, but there were no significant differences between groups at 3 months.

Conclusion:
Based on available evidence, PFMT with or without biofeedback enhancement hastens the return to continence more than no PFMT in men with UI after RP. Additional trials are needed to confirm whether ExMI and ES are effective conservative treatment options.

TITLE: THE THERAPEUTIC EFFICIENCY OF EXTRACORPOREAL MAGNETIC INNERVATION TREATMENT IN WOMEN WITH URINARY TRACT DYSFUNCTION FOLLOWING RADICAL HYSTERECTOMY

Authors: Sun M.J.[1], Sun R., Chen L.J.
Affiliations: [1]Division of Urogynecology and Reconstructive Pelvic Surgery, Department of Obstetrics and Gynecology, Changhua Christian Hospital
Published: Journal of Obstetrics and Gynaecology, 2015, 35(1), 74-78

ABSTRACT:

Data on 32 consecutive women with demonstrable urinary tract dysfunction for at least 6 months following radical hysterectomy (RH) for uterine cervical cancer, who received 24 sessions of extracorporeal magnetic innervation (ExMI) treatment twice-weekly were collected. The 1-h pad test weight decreased from 27.2 g pre-treatment to 12.1 g post-treatment ($p < 0.05$). Both the median UDI-6 and IIQ-7 scores showed statistically significant improvements ($p < 0.001$) at every stage of the ExMI treatment and in the 24.2 months mean follow-up duration after treatment. The symptoms of frequency, stress incontinence, urge incontinence and voiding difficulty showed statistically significant improvements ($p < 0.001$) after 8 and 24 sessions of ExMI treatment. The urodynamic parameters between pre-treatment and post-treatment after 24 sessions revealed no statistically significant changes. Based on the objective and subjective measures observed in this study, 24 sessions of twice-weekly ExMI treatment is an additional non-invasive therapy option for patients with the symptoms of lower urinary tract following RH.

TITLE: SUPER INDUCTIVE SYSTEM LOCUS IN PROSTATITIS TREATMENT – A PILOT STUDY

Author: Bajkaiová Z.[1]
Affiliations: [1]RMA centre, Prague, Czech republic

ABSTRACT:

Background:
Prostatitis represents a painful condition in the pelvic floor area and leads to worsening of patient´s quality of life and dyscomfort. Prostatitis usually requires drug treatment, which is indicated in acute condition. However, patient may have persisting pelvic pain due to chronic inflammation. Therefore a non-invasive pain management is desirable.

Aim:
Aim of this pilot study was to investigate the efficacy of a high-intensity electromagnetic field stimulation in prostatitis pain management.

Methods:
44 men (mean age 51.5 yrs) with chronic prostatis condition were included in pilot study with high-intensity electromagnetic field stimulation device (Super Inductive System Locus, BTL Industries Ltd.). All patients were treated in frequency 2 - 3x times a week during a 1-month period. Average number of underwent therapies was 12 treatments. Patients were evaluated by a physician´s clinical examination and completed with subjective patient´s evaluation. Comparison of patient´s condition before and after treatment was completed.

Results:
A pilot study was conducted and analyzed on 44 men with prostatitis. In clinical evaluation physician concluded amelioration of patient´s condition, which was highly correlated with patient´s subjective evaluation. In 43 % of patients (N = 19) significant remission of pain was reported; 29 % of patients (N = 13) noted moderate remission of pain. 26 % (N = 12) of patients reported no therapy progress.

Conclusions:
In this pilot study we concluded a convincing pain relief effect of high-intensity electromagnetic field stimulation in 72 % of all treated patients. Therefore we suggest that high-intensity electromagnetic field stimulation can be effective method in prostatitis pain management. For further investigation, addition in methodological part as well as long-term follow-up needs to be accomplished.

TITLE: EFFECTS OF REPETITIVE MAGNETIC STIMULATION (RMS) IN THE TREATMENT OF CHRONIC PELVIC PAIN SYNDROME (CPPS) AND FLOOR DYSFUNCTION (FD)

Authors: Scisciolo G.D.[1], Del Corso F., Caramelli R., Schiavone V., Cassardo A., Provvedi E., Donati M., Pinto F., Del Popolo G.
Affiliations: [1]SOD Neurophysiology, AOU Careggi, Florence, Italy
Published: Clinical Neurophysiology, 2011, 122(1), 129

ABSTRACT:

Introduction:
CPPS is a pain condition present in men and above all in women, that involves the pelvic-organ system. Traditional therapies (antibiotics, anti-inflammatories, muscle relaxants) have poor efficacy. It has been suggested that these various disorders might have a unifying pathophysiology, with different manifestation. The rMS technique was used in different pathologies (hemicranias, psychiatric disease, painful syndromes, etc.) with incostant results. The application of rMS in CPPS and other neurourology disease is a moot point.

Aim of the study:
To value the short, medium and long-term effects of rMS in CPPS patients and in few patients with FD.

Method and Materials:
We have studied 48 patients affected by CPPS and 5 with FD in whom neurophysiological and urological examinations so that neuroimaging were unable to explain the clinical features. Unlike previous data of literature, the patients were stimulated in two different place: on sacral spinal cord region (0.5 Hz) and on the painful area (10 Hz). All patients were treated twice a week for five weeks. The outcome was measured with the visual analogic scale (VAS) and with Quality Life test (QoL-36). The patients have performed these tests at different times: at the beginning of treatment, at the end of therapy and in follow ups (6 months).

Results and Conclusions:
Our results are encouraging: we have obtained a good remission of pain in 67 % patients at the end of treatment. Now we are evaluating the same treatment in a new group of patients with CPPS using sham stimulation so that to confirm the real efficacy of this treatment.

TITLE: A PROSPECTIVE, RANDOMIZED, PLACEBO CONTROLLED, DOUBLEBLIND STUDY OF PELVIC ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF CHRONIC PELVIC PAIN SYNDROME WITH 1 YEAR OF FOLLOW UP

Authors: Rowe E.[1], Smith C., Laverick L., Elkabir J., Witherow R.O., Patel A.
Affiliations: [1]Department of Urology, St. Mary's Hospital, London, United Kingdom
Published: Journal of Urology, 2005, 173(6), 2044-2047

ABSTRACT:

Purpose:
Male chronic pelvic pain syndrome is a condition of uncertain etiology and treatment is often unsatisfactory. There is evidence that the symptom complex may result from pelvic floor muscular dysfunction and / or neural hypersensitivity / inflammation. We hypothesized that the application of electromagnetic therapy may have a neuromodulating effect on pelvic floor spasm and neural hypersensitivity.

Materials and Methods:
Following full Stamey localization men with National Institute of Diabetes and Digestive and Kidney Diseases category III prostatitis were prospectively randomized to receive active electromagnetic or placebo therapy. Active therapy consisted of 15 minutes of pelvic floor stimulation at a frequency of 10 Hz, followed by a further 15 minutes at 50 Hz, twice weekly for 4 weeks. Patients were evaluated at baseline, 3 months and 1 year after treatment using validated visual analog scores.

Results:
A total of 21 men with a mean age of 47.8 years (range 25 to 67) were analyzed. Mean symptom scores decreased significantly in the actively treated group at 3 months and 1 year ($p < 0.05$), unlike the placebo group, which showed no significant change ($p < 0.05$). Subanalysis of those receiving active treatment showed that the greatest improvement was in pain related symptoms.

Conclusions:
The novel use of pelvic floor electromagnetic therapy may be a promising new noninvasive option for chronic pelvic pain syndrome in men.

TITLE: THE EFFICACY OF EXTRACORPOREAL MAGNETIC STIMULATION FOR TREATMENT OF CHRONIC PROSTATITIS / CHRONIC PELVIC PAIN SYNDROME PATIENTS WHO DO NOT RESPOND TO PHARMACOTHERAPY

Authors: Kim T.H.[1], Han D.H., Cho W.J., Lee H.S., You H.W., Park C.M., Ryu D.S., Lee K.S.
Affiliations: [1]Department of Urology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, Korea
Published: Urology, 2013, 82(4), 894-898

ABSTRACT:

Objective:
To investigate the effect of extracorporeal magnetic stimulation (EMS) on symptoms of chronic prostatitis / chronic pelvic pain syndrome (CP / CPPS) in men who did not respond to pharmacotherapy.

Methods:
Patients with chronic pelvic pain and / or voiding symptoms in the absence of urinary tract infection for at least 3 months in spite of medication were included in this study. All patients underwent EMS for 6 weeks for a total of 12 sessions. The primary endpoint was the changes in total and pain scores of the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) at 24 weeks after treatment. Patients were also evaluated by International Prostate Symptom Score (IPSS), voiding diary, Benefit Satisfaction and Willingness (BSW) questionnaire, and patient perception of symptom improvement (PPSI).

Results:
A total of 46 men were included, and data from 37 patients who completed this study were analyzed. The baseline vs 24 weeks mean NIH-CPSI score was total score 25.0 ± 6.9 vs 15.6 ± 7.7, pain score 11.8 ± 3.7 vs 6.9 ± 4.7 (all $p < 0.0005$). Total and subdomain sums of IPSS improved significantly after treatment, and the improvements were maintained until 24 weeks. Patient voiding diaries demonstrated a tendency toward a decrease in all subdomains after treatment. In BSW, > 70 % of patients reported positive answers to each domain at 24 weeks after treatment. PPSI measured by the visual analog scale was maintained from immediately after treatment until 24 weeks.

Conclusion:
EMS offers a new treatment option for patients with CP/CPPS who do not respond to pharmacotherapy.

TITLE: CAN EXTRACORPOREAL MAGNETIC INNERVATION BE A TREATMENT MODALITY FOR PRIMARY DYSMENORRHEA?

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Published: Gynecologic and Obstetric Investigation, 2014, 77(4), 250-254

ABSTRACT:

Background/Aims:
To evaluate the efficacy of extracorporeal magnetic innervation (ExMI) as a treatment for primary dysmenorrhea compared with nonsteroidal anti-inflammatory drugs (NSAIDs) and combined oral contraceptives (COCs).

Methods:
The cases were randomized into three groups (NSAID = 51, ExMI = 53, COC = 54). ExMI was applied for a total of 10 sessions. Women in the NSAID group used an oral NSAID at the start of each menstruation. Women in the COC group were given combined pills. Of the treatment options, ExMI was applied for only a single period, whereas NSAID and COC use continued for 12 months.

Results:
At the first menstruation, visual analog scale (VAS) scores improved significantly in all groups ($p < 0.001$). NSAIDs and COCs continued to show efficacy over the entire study period ($p < 0.05$). However, in the ExMI group, VAS values increased from the first menstruation until 12 months. The VAS score at the 12th month was significantly higher in the ExMI group than in the other groups ($p < 0.05$), but markedly lower than the pretreatment value (49.9 ± 8.3 vs. 71.1 ± 10.1, $p < 0.001$).

Conclusions:
ExMI therapy might be a promising novel noninvasive option for primary dysmenorrhea. Efficacy began to decline after 3 months, but continued for 12 months.

4. SEXUAL DYSFUNCTION

TITLE: MAGNETIC STIMULATION OF THE CAVERNOUS NERVE FOR THE TREATMENT OF ERECTILE DYSFUNCTION IN HUMANS

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Published: International Journal of Impotence Research, 2000, 12(3), 137-142

ABSTRACT:

A recent study in dogs has demonstrated that magnetic stimulation (MS) of the cavernous nerve produced an increase of the intracorporeal pressure and full penile erection. In view of these results, we tested the possible application of this procedure in humans with erectile dysfunction (ED). The study comprised 32 patients with ED (age 38.3 ± 9.6 y) and 20 healthy volunteers (age 36.8 ± 8.8 y). Routine erectile function tests suggested that impotence was neurogenic. A magnetic coil was placed over the dorsal aspect of the penis in the vicinity of the symphysis pubis. MS was performed using a stimulation of 40 % intensity, 20 Hz frequency, 50 s on and 50 s off for 10 minutes duration. In the healthy volunteers, the coil was placed as aforementioned but was not activated. The intracorporeal pressure was recorded and penile tumescence and rigidity observed during MS in the patients and without stimulation in the controls. MS led to gradual increase in length and diameter of the penis until full erection was achieved; the penis became firm, rigid and pulsatile. The intracorporeal pressure increased significantly ($p < 0.0001$) at full erection. Mean latency to full erection was 19.3 ± 3.4 s. Upon off-stimulation, penile erection and intracorporeal pressure returned to baseline after a mean of 22.7 ± 3.2 s. Penile and pressure response to MS was resumed after an off-time of 50 s. The response was reproducible infinitely if the off-time was observed. The controls showed no penile tumescence or rigidity or increase of the intracorporeal pressure. In conclusion, MS of the cavernous nerve is effective in inducing penile rigidity. It is a simple, easy and non-invasive method which has no adverse effects. It might prove to be suitable for application in patients with ED.

TITLE: EXTRACORPOREAL MAGNETIC STIMULATION OF THE PELVIC FLOOR: IMPACT ON ANORECTAL FUNCTION AND PHYSIOLOGY. A PILOT STUDY

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Published: Diseases of the Colon & Rectum, 2005, 48(10), 1945-1950

ABSTRACT:

Purpose:

This study was designed to investigate the effect of extracorporeal magnetic stimulation on anorectal function and physiology.

Methods:

A pilot study comparing the physiology of ten incontinent (9 females) and five continent (4 females) patients with and without perineal magnetic stimulation (10 Hz and 50 Hz) was performed. The ten incontinent patients were treated with two sessions weekly for five weeks of perineal magnetic stimulation. At treatment completion, precontinent and postcontinent scores and resting and squeeze anal pressure were compared. Patients also reported symptom improvement and satisfaction on a linear analog scale.

Results:

The patients' mean age was 57 years. Sitting resting and squeeze anal pressures were significantly greater than lying pressures ($p = 0.007, 0.047$). Both 10-Hz and 50-Hz stimulation effected a significant increase in anal pressures compared with the baseline resting pressure ($p = 0.005$). The baseline squeeze pressures were significantly higher than the stimulated pressures compared with 50-Hz pressures ($p = 0.022$). After six weeks of treatment, there was a statistically significant increase in resting and squeeze anal pressures and a significant decrease in continence scores ($p = 0.007$, $p = 0.008$, $p = 0.017$). The mean percentage subjective improvement was 16 percent, and the mean patient satisfaction score was 3.3, positively correlating with an improvement in the continence score.

Conclusions:

Extracorporeal magnetic stimulation results in a significant increase in anal resting pressure irrespective of pretreatment continence. Although the subjective improvement in continence after treatment is small, there is a significant improvement in both resting pressures and patient continence scores.

TITLE: EXTRACORPOREAL MAGNETIC INNERVATION THERAPY IN CHILDREN WITH REFRACTORY MONOSYMPTOMATIC NOCTURNAL ENURESIS

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Published: Urology, 2007, 70(3), 576-580

ABSTRACT:

Objectives:

To evaluate the effect of extracorporeal magnetic innervation (ExMI) therapy in children with refractory monosymptomatic nocturnal enuresis (MNE).

Methods:

A total of 55 children (34 boys and 21 girls, median age 8.0 years, range 5 to 13) who wetted the bed more than twice per week because of MNE that was refractory to treatment with desmopressin, anticholinergics, and enuretic alarm were assessed prospectively using a voiding diary before and after ExMI, administered once a week for at least 4 weeks with a size-adjusted magnetic chair (each session lasted 20 minutes).

Results:

After all sessions of ExMI, the mean frequency of nocturnal enuresis decreased significantly to 2.09 ± 2.47 in all patients ($p = 0.04$), and the mean functional bladder capacity increased 1.88 times in all patients ($p = 0.00$). In total, 63.6 % of our patients had a nocturnal enuresis frequency of less than 50 % after a mean of 6.62 ± 4.26 ExMI sessions.

Conclusions:

From our results, reduced functional bladder capacity might be the main pathophysiologic cause in children with MNE refractory to established treatment. ExMI might have an acute inhibitory effect in these children with refractory MNE by increasing functional bladder capacity. However, long-term follow-up data and controlled study with a sham-stimulation group are necessary to determine the durability of this new therapy for refractory MNE.

TITLE: EFFECTS OF PULSED ELECTROMAGNETIC FIELDS ON BENIGN PROSTATE HYPERPLASIA

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Published: : International Urology and Nephrology, 2011, 43(4), 955-960

ABSTRACT:

Introduction:

Benign prostate hyperplasia (BPH) has been treated with various types of electromagnetic radiation methods such as transurethral needle ablation (TUNA), interstitial laser therapy (ILC), holmium laser resection (HoLRP). In the present study, the effects of a noninvasive method based on the exposure of patients with BPH to a pulsative EM Field at radiofrequencies have been investigated.

Materials and methods:

Twenty patients with BPH, aging 68–78 years old (y.o), were enrolled in the study. Patients were randomly divided into two groups: the treatment group (10 patients, 74.0 ± 5.7 y.o) treated with the a-blocker Alfusosin, 10 mg/24 h for at least 4 weeks, and the electromagnetic group (10 patients, 73.7 ± 6.3 y.o) exposed for 2 weeks in a very short wave duration, pulsed electromagnetic field at radiofrequencies generated by an ion magnetic inductor, for 30 min daily, 5 consecutive days per week. Patients of both groups were evaluated before and after drug and EMF treatment by values of total PSA and prostatic PSA fraction, acid phosphate, U/S estimation of prostate volume and urine residue, urodynamic estimation of urine flow rate, and International Prostate Symptom Score (IPSS).

Results:

There was a statistically significant decreasebefore and after treatment of IPSS (p\0.02), U/S prostate volume (p\0.05), and urine residue (p\0.05), as well as of mean urine flow rate (p\0.05) in patients of the electromagnetic group, in contrast to the treatment group who had only improved IPSS (p\0.05). There was also a significant improvement in clinical symptoms in patients of the electromagnetic group. Follow-up of the patients of this group for one year revealed that results obtained by EMFs treatment are still remaining.

Conclusion:

Pulsed electromagnetic field at radiofrequencies may benefit patients with benign prostate hyperplasia treated by a non-invasive method.