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Title

**FACTORS INFLUENCING SUCCESS WITH EXTRACORPOREAL
MAGNETIC INNERVATION (ExMI) TREATMENT OF MIXED
URINARY INCONTINENCE**

Aims of Study Determine a population most likely to respond to extracorporeal magnetic innervation.

Methods. This was a prospective outcomes study of extracorporeal magnetic innervation treatment in women with stress and urge incontinence. Secondary analysis of the data was performed to identify risk factors, which might predict treatment failure. Seventy-six women were enrolled in a 6 month prospective outcomes trial of twice weekly extracorporeal magnetic therapy for 6 weeks, with each treatment consisting of 10 minutes at 5 Hertz and 10 minutes at 50 Hertz. Subjects were evaluated at baseline with a 3 day voiding diary, pad weight test, urodynamic testing, perineometry, and quality of life questionnaires at 8 and 24 weeks (18 weeks after therapy). Initial analysis revealed 4 primary risk factors which were analyzed for their impact on short and long-term continence. These were selected from a group of 67 covariates from the history, vital signs, urodynamic data, pelvic exam, and perineometry. Statistical evaluation was performed using Stat Graphics with one-way ANOVA with a Duncan's test. The changes in outcomes data at 8 and 14 weeks were evaluated using t-tests and one-way ANOVA, respectively.

Results Seventy-six women were evaluated at 8 weeks (2 weeks after stimulation) and 58 women at 24 weeks. These 76 women had a mean age of 55.9 years (range 36-83 years). Subjects had been incontinent for an average of 10.7 years (range 1-40 years). Forty-two women (55%) had undergone prior hysterectomy. Twelve (16%) had prior anti-incontinence surgeries. Seven (9%) were taking medications that could cause incontinence. Incontinence episodes on voiding diaries at 8 and 24 weeks were ranked as worse than baseline, <25% improved, 25-50% improved, 51-75% improved, 76-99% improved and 100% improved. These outcomes were compared against risk factors of prior hysterectomy, prior anti-incontinence operations, incontinence >10 years, and use of medications that could cause incontinence.

At 8 weeks, 13 (17%) had more incontinence episodes on 3-day voiding diary than at baseline. Seventeen (22%) were <50% improved and 46(61%) were >50% improved or cured. Twenty-five (33%) were cured (no leakage). Fifty-eight women were analysed at 24 weeks. Of these, 13 (22%) had worsening of incontinence on voiding diaries. Nineteen subjects (33%) were <50% improved and 26 (45%) were >50% improved. Seventeen (29%) were free of leakage (cured) at 24 weeks. The average number of daily leakage episodes on the 3 day diaries improved from a baseline of 3.5 (S.D. 3.0) to 1.9 (S.D. 2.7) at 8 weeks ($p=0.0003$). Daily leakage episodes improved from 3.0 (S.D. 2.3) to 2.2 (S.D. 2.9) at 24 weeks ($p=0.04$).

Pad weight testing revealed no significant change from baseline [0.7g (S.D. 1.1)] to 8 weeks [0.5g (S.D. 1.0)] ($p=0.12$), nor in the long-term group from baseline [0.7g (S.D. 1.0)] to 24 weeks [0.6g (S.D. 1.1)], $p=0.04$.

The short term and long term populations were divided into two subgroups whom did or did not have >50% improvement in daily leakage from baseline on the voiding diary. These subgroups were analyzed for impact of the 4 risk factors. The populations with medications that could cause incontinence and those with prior anti-incontinence operations were too small for valid analysis.

Four of 16 (25%) with prior hysterectomy were completely dry on voiding diary at 8 weeks and 12 (75%) were improved by >50%. Prior hysterectomy was significantly related to improvement on voiding diary at 8 weeks ($p=0.0005$). This association of hysterectomy and improvement was not noted in the long-term group (4 of the 11 subjects were improved by >50%).

Incontinence >10 years was found in both the short term ($p=0.01$) and long term group ($p=0.004$) to be associated with >50% reduction in leakage on voiding diaries. Eight of the 18 (44%) short-term subjects and 6 of the 14 (43%) long-term subjects were cured. Twelve (67%) of the short-term group and 7 (50%) of the long term group were improved by >50%. Sixteen subjects in the short-term group and 14 in the long-term group had none of the 4 risk factors. This group had the best response with 11 (69%) of the short-term group >50% improved ($p=0.00004$) and 7 (44%) completely dry. In the long-term group without risk factors, 8 (57%) had >50% improvement ($p=0.005$) and 6 (43%) were completely dry.

Conclusion Extracorporeal magnetic innervation was found to be an effective therapy as measured by voiding diary at 2 weeks and 18 weeks after therapy. This long-term response without continued treatment is not seen after physiotherapy or pelvic floor electrical stimulation. Analysis of risk factors suggests that patients without risk factors respond best with cure rates of 44% and 43% at 8 and 24 weeks, respectively. However, even women with prior hysterectomy or long standing incontinence do well.