EXTRACORPOREAL MAGNETIC INNERVATION THERAPY FOR STRESS URINARY INCONTINENCE

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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.

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Pulsed magnetic technology has been developed for the stimulation of pelvic floor muscles. This technology was approved for marketing by the Food and Drug Administration in June 1998. Initial investigations of clinical applications for extracorporeal magnetic innervation (ExMI) of the pelvic floor have focused on the treatment of stress urinary incontinence. This is the first report of data from a prospective multicenter clinical trial to evaluate the feasibility of this therapy for stress urinary incontinence. Urologists are familiar with the principles of magnetic resonance imaging, but may not be as familiar with other magnetic technologies. Everywhere electric currents flow, there are magnetic fields, and everywhere there is a rapidly changing magnetic field, there will be flow of electric current within the field, if charged particles are present. This fundamental property means that current will be induced in living tissues adjacent to a changing magnetic field, just as electric current is induced to flow in the copper wire of a dynamo. The electrical properties of living tissues are diverse, and some elements are better conductors. As one might expect, it is the nerves that are most sensitive to electrical depolarization by a changing magnetic field. When the nerve is a motor nerve, depolarization will cause a propagating impulse that will release neurotransmitters at the motor end plates and provoke muscle contraction.1

In recent years, magnetic stimulation has been investigated as an alternative to electrical stimulation for clinical neurodiagnostic applications. There are unique advantages to magnetic stimulation when it is necessary to stimulate nerve structures that are encased in bone, such as the motor cortex of the brain or the nerves of the spinal cord.2,3 A magnetic field penetrates all body tissues without significant alteration, and the magnitude of the field falls off only as the inverse square of the

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distance. A magnetic field passes uninterrupted through clothing; thus, it is not necessary to undress for treatment.

MATERIAL AND METHODS

Eighty-three female patients with demonstrable stress urinary incontinence were enrolled in this study. All were ambulatory and neurologically normal with normal urinalysis, and none was pregnant. Patients were excluded if younger than 25 years old. Patients with a cardiac pacemaker or other implanted metallic devices or a history of pelvic irradiation were excluded. Patients with clinical findings of marked atrophic vaginitis or total vaginal prolapse or features of severe urethral sphincter weakness were also excluded, as were pregnant women.

Sixty-four patients have completed the treatment, and these data are included in the analysis. The mean age was 55 ± 12 years (range 35 to 83). The duration of symptoms ranged from 2 to 40 years (mean 12 ± 11). Thirty-two patients had undergone hysterectomy. All patients had demonstrable stress incontinence on examination, but most patients complained of multiple lower urinary tract symptoms. The worst symptom reported was stress urinary incontinence in 33, urinary urgency in 11, urge incontinence in 9, increased diurnal frequency in 7, nocturia in 3, and nocturnal wetting in 1 patient.

All patients used pads for protection. The number used per day was 1 to 9 pads (mean 3 ± 1.6), with 53 patients using 2 or more pads per day. The frequency of voiding ranged from 5 to 16 times per day (mean 9 ± 3), and nocturia ranged from 1 to 5 times (mean 2 ± 1). Nocturnal wetting was reported by 8 patients (12.5%); 2 patients having more than 10 episodes per month. There were social problems for 31 patients because of incontinence. Three had problems with their spouse. Twenty-one reported mild problems, 6 had moderate problems, and for 1 patient the incontinence was a severe social problem. Thirty patients reported having to withdraw from their usual social activities because of the urinary problems.

On physical examination, there was evidence of bladder neck hypermobility in 44 patients. There was cystocele in 46 (grade I in 32, grade II in 13, and grade III in 1), rectocele in 28 (grade I in 21 and grade II in 7), vault prolapse to the middle third of the vagina in 3, and enterocele in 3 patients. The pretreatment evaluations included a 3-day bladder diary that was recorded in 2 successive weeks to establish a baseline pattern. All patients underwent a standardized dynamic pad weight test to measure the severity of leakage and urodynamic evaluation. All patients completed a validated quality of life survey.

For treatment, the patient is positioned in a chair provided with the Neocontrol system (Neotonus Inc., Marietta, Ga). Within the chair’s seat is a magnetic field generator (therapy head) that is powered and controlled by an external power unit (Fig. 1). The output of the power unit consists of pulses of current 275 μs in duration, which can be adjusted in amplitude by the clinician. Adjusting this amplitude determines the size and strength of the magnetic field. The leading edge of these pulses is quite steep, creating a steep gradient magnetic field that is concentrated and directed vertically through the seat of the chair. When the patient is seated, the perineum is centered naturally in the middle of the seat, which places the muscles of the pelvic floor and sphincters directly on the primary axis of the pulsing magnetic field. This allows all the tissues of the perineum to be penetrated by the therapeutic magnetic field flux (Fig. 2). No electricity enters the patient’s body from the device, only magnetic flux. All treatments in-
cluded 10 minutes of intermittent low-frequency stimulation (5 Hz), followed by a rest interval of 1 to 5 minutes, and 10 minutes of intermittent high-frequency stimulation (50 Hz). Treatments were given twice a week for 6 weeks.

Interval measures included the 3-day bladder diary, which was repeated every 2 weeks. The voided volumes, the number of leaks per day, and pad use were recorded in the bladder diary. After the treatment interval (weeks 1 to 6), all the measures were repeated at week 8, including the bladder diary, dynamic pad weight testing, urodynamic evaluation, and the quality of life survey. At 12 weeks, the bladder diary and quality of life surveys were repeated. To date, 30 patients have been followed up past the 12th week.

**Statistical Analysis**

Data were analyzed using SPSS 8.0 statistical software. Variables were checked for normal distribution, and normally distributed variables were compared using the Student t test or analysis of variance. Abnormally distributed variables were compared using nonparametric tests (Wilcoxon signed rank sum test). Variables were compared using parametric and nonparametric methods whenever possible.

**RESULTS**

Patient outcomes were measured at 3 months (n = 50). The changes in continence status were evaluated by comparing the bladder diary parameters before treatment and at 3 months. Of 50 patients, 17 (34%) were dry and used no pads, 16 (32%) were using not more than 1 pad per day, and 17 (34%) were using more than 1 pad per day. The average number of pads used per day was reduced from 2.5 ± 1.6 pads/day (median 2.2) to 1.3 ± 1.8 pads per day (median 0.8) before and after treatment, respectively (P = 0.001). This difference was significant when nonparametric analysis was performed. The mean rank for pad use was 26 before treatment versus 20 at 3 months (P = 0.0001, Wilcoxon signed rank sum test).

The frequency of leak episodes per day was reduced from 3.3 ± 2.5 (median 2.6) to 1.7 ± 2.3 (median 1.0) before and after treatment, respectively (P = 0.001) (Fig. 3). Using the Wilcoxon signed rank sum test, the mean rank for the leak episodes per day was 27, which was reduced to 20 after treatment (P = 0.001). The dynamic pad weight test was performed before and 8 weeks after treatment. The mean pad weight was reduced from 20 g before treatment to 15 g at 8 weeks. These two variables were not normally distributed, as shown by the Kolmogorov-Smirnov test (P = 0.0001); therefore, the difference was analyzed using nonparametric methods. The total rank for pad weight before treatment was 899, which was reduced to 377 after treatment (P = 0.012, Wilcoxon signed rank sum test).

On urodynamic testing, the mean bladder capacity increased from 355 ± 120 to 392 ± 121 after treatment, but this difference was not significant. The recorded increase in Valsalva leak point pres-

sure after treatment was not significant. Detrusor instability was demonstrated in 5 patients before treatment and was found in only 1 patient after treatment (P = 0.001).

**COMMENT**

Stress urinary incontinence is an important healthcare problem with significant personal, family, and economic costs. The cost to the United States has been estimated to be on the order of 10.3 billion dollars per year (1998 National Institutes of Health Consensus Conference on Incontinence). The prevalence of incontinence is expected to grow larger as demographics change and the elderly population continues to increase. Nonsurgical treatments are very popular in Europe, but currently there is less enthusiasm for conservative therapies in the United States. The urologist is more likely to advise surgical treatment, but patients are naturally reluctant to consider surgical treatments until incontinence symptoms are severe.

Conservative therapies include timed voiding, fluid restriction, medical management, Kegel exercises, biofeedback, and electrical stimulation. All are established in the treatment of urinary incontinence. The results of electrical stimulation therapy vary from center to center, according to treatment protocols and patient selection. Success with electrical stimulation requires a skilled staff and a motivated patient, but, in the best hands, the clinical results are excellent.

Patients will not always accept electrical stimulation as a treatment option. Some are reluctant to use a probe in the vagina or anus. Some complain of discomfort or irritation with a probe. Even the use of patches on the skin may cause local irritation and skin problems for some patients. ExMI makes use of the classical relationship between a changing magnetic field and the induction of electrical activity to depolarize the nerves and exercise the muscles of the pelvic floor. It is now possible to induce effective contractions of the pelvic floor and sphincter muscles using ExMI. We believe that ExMI will be much more attractive to patients than electrical stimulation, because patches or probes, skin contact or gel, and undressing for treatment are not necessary. The safety profiles of magnetic resonance imaging and ExMI technology have been studied and the devices have been approved for clinical use; a review of safety issues has been published.

ExMI is painless, and no electricity enters into the body, only a magnetic flux. In contrast, electrical stimulation injects current into the tissues, and the current lessens as a function of the impedance of the tissue between the stimulating electrodes.
and the neural tissue. Skin, subcutaneous fat, and bone all have high impedance, and to deliver effective current to the deeper nerve and muscle tissues, it is necessary to deliver a much higher current to the skin. Stimulation of the skin activates sensory receptors and C fibers that may cause sensations of discomfort or pain for the patient. It follows that for effective electrical stimulation of the deeper tissues, the current at the skin will be significant and, with increasing current, the threshold for pain will be closer. For the same effective current at the motor nerves, the current at the skin is much less with ExMI than with electrical stimulation.

One of the limitations of this study is the lack of a control group. It is difficult to design an effective placebo treatment, because the patient is aware of the strong, palpable and visible contractions of the pelvic floor muscles, gluteal muscles, and hamstring strings during treatment. It is unlikely that the changes in episodes of leakage and pad use observed and sustained at 12 weeks are due to placebo effect, but as with any new therapy, some element of placebo effect cannot be excluded.

The treatment parameters for this study were empirical. The traditional electrical stimulation protocols usually employ an interval of low frequency and an interval of higher frequency stimulation. We chose to follow this pattern. The treatment times of 10 minutes and 10 minutes were chosen for the convenience of scheduling patients. Similarly, it seemed reasonable to have patients attend twice a week for treatments. A treatment interval of 6 weeks was chosen because this would be enough to measure a change, but not so long that it would encourage patients to drop out of the study. It would be expected that a longer interval of treatment would have a greater impact on symptoms. For many patients, there was a pattern of improvement that had not reached an optimal plateau when treatment was stopped at 6 weeks. In clinical practice, we should expect that treatments would continue until no further improvement was noted.

To isolate and measure the contribution of ExMI therapy, no adjuvant therapies were used at any of the treatment sites. In clinical practice, it would be usual to employ complementary strategies that might include fluid management, timed or prompted voiding, and patient education. The use of these methods in addition to ExMI would be expected to further improve the outcomes in clinical practice. Furthermore, no strategies were used to try to sustain the benefits of pelvic floor muscle therapy. In particular, we did not teach patients to use Kegel exercises after treatment. It would be expected that the use of some or all of these strategies might serve to increase the benefits and prolong the continence interval after ExMI therapy.

As patients become aware of the availability of nonsurgical therapies for stress urinary incontinence and that treatment can be painless and easy, there will be an opportunity to change the prevailing paradigm. Currently, patients wait until symptoms are severe before seeking help, and the result is that many of our resources are committed to treating end-stage disease. The introduction of acceptable conservative therapies such as ExMI may provide an opportunity to develop strategies that focus on how to preserve continence rather than waiting until the symptoms of incontinence are so severe that only surgical interventions can be considered.

CONCLUSIONS

ExMI therapy offers a new approach for pelvic floor stimulation that improves both stress and urge leakage. ExMI is painless and neither a probe nor undressing is needed. A longer follow-up is required to determine how long the benefits of treatment will last and whether retreatment will be necessary. The early results suggest that ExMI therapy is an effective approach for the treatment of stress urinary incontinence.

REFERENCES