Towards evidence based practice in pelvic floor physiotherapy

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Chapter 6

Effects of magnetic stimulation in the treatment of pelvic floor dysfunction

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Introduction

Pelvic floor dysfunction is primarily managed by behavioural or pharmacological treatment. The Dutch Urological Association states in its guidelines that, in cases of urge and stress urinary incontinence and urgency/frequency, pelvic floor physiotherapy is the treatment of first choice.

Except in very specific cases, surgery should only be considered after behavioural and pharmacological interventions have been tried (1). Dysfunction of the pelvic organs can be treated by biofeedback training, electrical stimulation and pelvic floor muscle exercises. Quantification of the function of the pelvic floor muscles is not easy, because of the lack of simple and reliable measurement techniques and the lack of threshold values for pathological conditions. Furthermore, the reproducibility of testing is questionable. Strengthening the pelvic floor musculature as developed by Kegel (2) popularized nonsurgical treatment for stress urinary incontinence, and since then, various other rehabilitative techniques were introduced. Biofeedback training allows a more selective control of the pelvic floor musculature, resulting in a reduction in micturition, defecation or sexual symptoms (3). Electrical stimulation of the pelvic floor was reported to be an effective alternative treatment (4), and there are several different techniques, e.g. intra-anal or vaginal stimulation, tibial nerve stimulation (5) and sacral nerve stimulation (6).

Extracorporeal magnetic innervation therapy (ExMI) is a more recent technique (7–9) that uses a classic principle of physics. Faraday's law of magnetic induction states that a current will flow in a conducting medium in response to a changing magnetic field, and ExMI uses this to induce a controlled depolarization of adjacent nerves and subsequent muscle contraction. Published results vary from a >50% improvement in 69% of patients, including 44% dry at 2 weeks, to objective improvement in 58% of patients. Magnetic stimulation was developed to stimulate the central and peripheral nervous system noninvasively. A varying magnetic field will induce an electrical field in any specified loop in its vicinity (10). The roots of sacral nerves S2–S4 provide the primary autonomic and somatic innervation of the lower urinary tract, including the pelvic floor, urethra,

bladder, vagina wall and rectum, and stimulation of these roots is an efficient way to modulate the pelvic floor and subsequently control the pelvic organs (11). In sphincter stress incontinence, the ultimate target of electrostimulation is to reinforce the external sphincters and/or pelvic floor muscles, but the actual primary targets are the pelvic and/or pudendal nerves. In urge incontinence, two modes of action have been described: stimulation of pudendal nerve afferents, which results in detrusor inhibition via central reflexes, and stimulation of efferents, which results in enhancement of pelvic floor and urethral sphincter musculature tone, inducing detrusor inhibition via the guarding reflex (12). Hence, it is important to correlate the clinical results of this treatment with functional changes in the pelvic floor musculature.

In the present pilot study we evaluated the effects of ExMI, focusing on these correlations to assess whether ExMI is suitable for our patients.

Material and Methods

From July 2002, 74 patients (65 women and nine men) with urge incontinence, urgency/frequency, stress incontinence, mixed incontinence and defecation problems were included in a prospective study of the electromagnetic chair (Neocontrol®, Neotonus, Marietta, GA, USA). Patients with a history of radiotherapy, a pacemaker or other metal implants, as well as concurrent pregnancy, malignancy or physiotherapy during the study, were excluded.

During treatment, the patients sat on the electromagnetic chair; stimulation was provided by an electromagnetic generator in the seat, and was controlled by an external unit. The generator creates pulses of 275 µs. The chair is operated by patients using programmed prescription cards. The physiotherapist or clinician can control the magnetic field by adjusting the frequency and amplitude of stimulation. The amplitude determines the volume of the field, and thus whether it is strong enough to induce a nerve impulse. The magnetic coil is integrated in the seat; the effect is greatest at the centre of the field, so the perineum must be in the middle of the seat. The stimulus intensity was gradually increased up to the limit of tolerability as indicated by the patient (average 80–100% of

the maximum). The control unit displays the status, the pulse generation and the possibility for external communication via a modem.

All patients were treated twice a week for 8 weeks. Previous studies showed that a stimulation frequency of 10 Hz was most effective for inducing bladder inhibition, and 50 Hz was most effective for urethral closure (13). At each treatment session, we treated patients with urge incontinence for two episodes of 10 min at 10 Hz, with an interval of 1 min. Patients with stress incontinence were treated for two episodes of 10 min at 50 Hz, with a interval of 1 min. Patients with mixed incontinence were treated for 10 min at 10 Hz and for 10 min at 50 Hz.

For urodynamic evaluation, UD-200 equipment (Medical Measurement Systems, Enschede, the Netherlands) and MMS Unitip catheter with one urethral and one bladder sensor were used, at baseline and after completing the study. Digital palpation and electromyography (EMG) registration (Myomed 932® equipment, Enraf Nonius, Delft, the Netherlands) with a vaginal (EMG, two rings vaginal probe 2 mm, V.M.P. Bioparc®) or anal probe (EMG, two rings anal probe 2 mm, V.M.P. Bioparc), at baseline and after completing the study (1 week after the last treatment), were used to document pelvic floor function. During palpation and registration we evaluated the basal amplitude registered on EMG, the voluntary or involuntary contraction, a voluntary or involuntary relaxation of the pelvic floor, and whether the pelvic floor was not contracting, not relaxing or not functioning (14). A voiding diary, a pad-test (15), King's Health Questionnaire (KHQ) (16,17) and a visual analogue scale (VAS) were completed at baseline and at the end of the study (1 week after the last treatment) to evaluate voiding patterns and quality of life (QoL). The medical history and previous treatments were documented (drugs, physiotherapy, electrotherapy, Stoller Afferent Nerve Stimulation, or a combination of therapies). The therapy was considered successful if incontinent episodes or voiding frequency decreased by half or more. The range for 'mild incontinence' was 1.3–20 g of urine in 24 h, for 'moderate incontinence' was 21–74 g, and 'severe incontinence' was defined as ≥ 75 g (18). The KHQ was scored according to the developer's instruction and included the domains 'role limitation', 'physical limitation', 'social', 'personal/emotional', 'sleep/energy disturbance' and 'severity (coping) measures'.

The overall QoL was estimated by VAS on a scale of 0–10 from 'very good' (0) to 'terrible' (10).

As the Kolmogorov-Smirnov test indicated that the distribution of data deviated significantly from normality, we used non-parametric tests, i.e. the Mann-Whitney test for comparing two independent groups, and the Wilcoxon paired test for two related samples.

Results

The mean (range) age of patients was 54 (22–90) years. Five patients were unable to attend all sessions, but 69 (40 with urge incontinence and/or urgency/frequency, nine with stress incontinence, 10 with mixed incontinence and 10 with defecation problems) fulfilled the study endpoints. In all, 40 baseline and after-treatment bladder diaries, pad-tests, VAS scores, QoL and other evaluable data were completed satisfactorily. Evaluation of patients with defecation problems did not include a voiding diary, QoL, or a pad-test.

For the patients overall, there were no statistically significant differences between data before and after treatment for the voiding diary, pad-test, KHQ, VAS score, biofeedback registration or urodynamics. Furthermore, there were no significant improvements for any classified subgroup of patients, i.e. those with stress incontinence; urge incontinence; urgency/frequency; defecation problems; overactive pelvic floor (35 patients); those >50 years old, (35) or <50 years old (27); or those with previous treatments (35). Finally, the total patient group was stratified by the pre-treatment rest tone of the pelvic floor (>1–2 μV <, the basal amplitude registered on EMG). The only significant improvement was in the KHQ domain 'role limitations', which showed significant differences for all groups before and after treatment ($P < 0.05$).

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Discussion

Few published studies have measured the effects of ExMI, and most focused on changes in urodynamic data and not on pelvic floor function as such. Several studies have shown the efficacy of pelvic floor muscle exercises, biofeedback training, functional electrical stimulation (19), percutaneous peripheral neuromodulation, sacral nerve stimulation and sacral modulation (19–21).

Yamanishi et al. (8) studied the urodynamic effects of functional continuous magnetic stimulation on urethral closure in normal volunteers. They concluded that functional continuous magnetic stimulation is safe, and found a significant increase in both the maximum intraurethral pressure during stimulation and in the maximum urethral closure pressure after stimulation.

Galloway et al. (9) developed pulsed magnetic technology for pelvic floor muscle strengthening in the treatment of urinary incontinence. In that study they found a significant reduction in the median number of pads, as well as in the frequency of leakage episodes and detrusor instability. The best results were achieved in patients who used at most three pads/day and had not had previous continence surgery.

In a randomized comparative study, Yokoyama et al. (22) investigated the effects of ExMI and functional electrical stimulation on urinary incontinence after retro pubic radical prostatectomy, and concluded that both ExMI and functional electrical stimulation can be recommended for patients who want a rapid improvement of urinary incontinence after surgery. They also investigated ExMI treatment for urge incontinence; the results were less clear, but in their opinion ExMI therapy offers a new option for both urge incontinence and stress urinary incontinence (23).

Unsal et al. (24) evaluated the efficacy of ExMI in stress and urge urinary incontinence and found ExMI to be a non-invasive, effective and painless treatment for stress and urge incontinence in women. Chandi et al. (1) evaluated the efficacy and applicability of functional magnetic stimulation of the pelvic floor for treating urinary incontinence in

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women, stating that it is a safe, non-invasive and painless treatment for urinary incontinence, and is effective and easy to administer as an outpatient treatment. Few studies have focused on the impact of ExMI on pelvic floor function. Culligan et al. (25) studied its effect on pelvic muscle strength (measured by perineometry) in primiparous women, but found no difference between women receiving active or sham ExMI treatments in the early postpartum period.

In the present study we found no significant improvement in urodynamics, pelvic floor muscle strength, pad-test, voiding diary or VAS scores. There was a significant improvement only in the 'role limitations' domain of the KHQ.

We noted that in some of the present patients the rest tone of the pelvic floor (the basal amplitude registered on EMG) was higher after treatment than before. This might be a side-effect of stimulation of the efferents and/or afferents of the pudendal nerve. The question remains as to whether the present results were flawed by this motor effect of ExMI.

Some authors state that ExMI strengthens the pelvic floor muscles, but that the mode of action of electrical stimulation remains unclear. There is still little known about how to administer pelvic floor treatment most effectively. Fall et al. (26) investigated electrode positioning and the electrical variables used for stimulation. For electrical stimulation to be effective, the intensity must be sufficient to elicit impulses in a relevant nerve. The threshold intensity varies with the nerve fibre diameter, the distance between the nerve and the stimulating electrode, and the pulse configuration, so an optimum response requires a specific probe design. From the present findings, we conclude that the probes presently used for electrostimulation and biofeedback training to treat pelvic floor dysfunction is not optimal for the structures that we want to stimulate or to register (27).

Concerning the significant improvement in the domain of 'role limitations' of the KHQ, Kelleher et al. (17) designed and validated a condition-specific QoL questionnaire for assessing women with urinary incontinence, and used it to assess women with specific urodynamic diagnoses. Reese et al. (18) used country-specific psychometric analysis of health-related QoL, concluding that psychometric testing supports the reliability and

validity of the KHQ. The findings for QoL in these groups of patients are inconsistent; there is a discrepancy between the degree of negative feelings as reported by the patients and those we think they are actually experiencing (28, 29). This phenomenon of under-reporting (the 'response shift') is most common in self-reported measures. The response shift refers to a change in a respondent's evaluation of a target construct as a result of: (i) a change in the respondent's internal standards of measurements, (ii) a change in the respondent's values, or (iii) a redefinition of the target construct. An effective clinician-patient communication might 'teach' response shifts, by training people to change their internal standard values or the conceptualization of QoL (Table 1).

Table 1 The KHQ domains

Domain	Cronbach's α	Mean (SD)	P
Role limitations	0.8029	0.59 (1.60)	0.04
Physical limitations	0.8384	0.13 (1.68)	0.68
Social	0.7707	0.17 (1.43)	0.51
Personal	0.8422	0.23 (1.59)	0.70
Emotional	0.6451	-0.031 (1.71)	0.95
Sleep/energy disturbance	0.7522	0.29 (0.94)	0.20
Severity (coping) measures	0.7695	0.40 (2.75)	0.42
Symptom severity*	NA	NA	NA

Symptom severity is a symptom checklist weighted by severity, thus Cronbach's α was not calculated. Incontinence impact and general health perception are one-item domains and are thus excluded from this table.

This response shift might be responsible for the improvement of the domain 'role limitations' in the present study.

In conclusion, there were no differences in pelvic floor muscle activity, pad-test, QoL, voiding diary and urodynamics in patients treated with ExMI. ExMI appeared to have no

beneficial effect on pelvic floor function in the present patients, and in some, we even noticed an adverse effect. The selected patient population may pose a limitation to the findings of the present study. In our opinion, 'the chair' is suitable to train awareness of the location of the pelvic floor, but the need for active pelvic floor muscle exercises remains.

The varying outcomes of several studies show that we need more tools to evaluate the effect and the mode of action of electrostimulation. There is also a lack of knowledge of the way to administer pelvic floor treatment most effectively. We need more information about the efficacy of the pad-test, voiding diary and a standardization of registering pelvic floor muscle activity. In short, we need more randomized studies.

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