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The therapeutic efficiency of extracorporeal magnetic innervation treatment in women with urinary tract dysfunction following radical hysterectomy

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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.

Keywords: Cervical cancer, ExMI, radical hysterectomy, urinary tract dysfunction

Introduction

Functional disorders of the lower urinary tract are the most common long-term complications following radical surgery for cancer of the uterine cervix (8–80%) (Zullo et al. 2003). These complications are thought to be caused by damage to the pelvic nerve plexus (Ralph et al. 1991). The following three main observed disturbances were found: detrusor overactivity (21%), mixed urinary incontinence (24%) and *de novo* stress incontinence (21%) (Benedetti-Panici et al. 2004). Up to 15% of the patients experienced voiding dysfunction and required urethral catheterisation for more than 30 days. In total, 3% needed catheterisation for more than 6 months (Manchana et al. 2009). To our knowledge, there have been few reports on effective therapy models for the improvement of long-term lower urinary tract dysfunction following radical hysterectomy (RH), so preventing and treating these complications remains a challenge for gynaecological oncologists and urogynaecologists.

In recent years, extracorporeal magnetic innervations (ExMI) therapy has offered a new, non-invasive, effective and painless treatment for females with urge incontinence as well as stress urinary incontinence and therefore enhances participant motivation and compliance (Yokoyama et al. 2004b). It is based on the principle of physics, whereby a changing magnetic field induces a flow of electrons within that field. This fundamental property induces the controlled depolarisation of the adjacent nerves and subsequent muscular contraction (Evans et al. 1990). ExMI can directly stimulate the pelvic floor muscles and sacral roots without pain or the insertion of a vaginal plug, and can prove more efficient and comfortable than conventional electrical stimulation (Yamanishi et al. 2000b). Although a great deal of research has been done on the use and effectiveness of physical therapy in urinary incontinence, to date, no report has been published on ExMI treatment for urinary tract dysfunction following RH. Since ExMI therapy offers earlier continence compared with the control group following radical prostatectomy (Yokoyama et al. 2004b), we hypothesised that ExMI may be effective in the treatment of those patients.

The aim of this study is to assess the efficiency of ExMI therapy for women with urinary tract dysfunction following RH for uterine cervical cancer. The pilot study aims prospectively to follow and observe the clinical outcomes, measured both qualitatively (Urogenital Distress Inventory-Short Form, Incontinence Impact Questionnaire-Short Form) and quantitatively (1-h pad weight test, changes in urodynamic parameters), following the ExMI treatment of patients with demonstrable urinary tract dysfunction at least 6 months following RH for uterine cervical cancer, and also to find the improvement in the symptoms of frequency, stress incontinence, urge incontinence and voiding difficulty during and following ExMI treatment.

Materials and methods

From May 2009 to March 2012, we recruited 34 consecutive patients who received RH, either with or without chemotherapy, for cervical cancer stages I or IIa with demonstrable urinary tract dysfunction for at least 6 months post-surgery. All patients who received RH were referred from the outpatient clinic of the Department of Gynecologic Oncology of Changhua Christian Hospital (CCH), a tertiary medical centre situated in central Taiwan. All patients were ambulatory without neurological anomaly or urinary tract infection. Patients with prosthesis, cardiac pacemaker, arrhythmia, advanced pelvic organ prolapse, previous surgery

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for urinary incontinence or ongoing radiotherapy were excluded from this study. The study followed principles in the declaration of Helsinki and written informed consent was obtained from the patients for the ExMI treatment. All patients were evaluated prior to treatment via a detailed history, physical examination, 1-h pad test, and urodynamic testing. Patients' urinary symptoms, such as frequency, urgency, urge incontinence, stress incontinence and voiding difficulties, were recorded.

The patients completed two validated quality-of-life questionnaires: the Urogenital Distress Inventory-Short Form six-item questionnaire (UDI-6) and the seven-item Incontinence Impact Questionnaire-Short Form (IIQ-7) (Uebersax et al. 1995), both of which were scored according to the established protocols. The mean values for all completed IIQ-7 (range 0–3) and UDI-6 items (range 0–4) were calculated.

During the treatment, the patients were seated, fully clothed, on a special chair (BioCon-2000WTM, Mcube Technology Co, Korea), the seat of which was fitted with a magnetic field generator (therapy head) that was powered and controlled by an external power unit. The adjustable parameters included the amplitude (25–100%); on-interval (in seconds, s); off-interval (in seconds, s) and frequency of the pulsed magnetic field (1–50 Hz).

Unlike patients with other lower urinary tract symptoms, the patients with cervical cancer and RH included in this study were given an additional 3 weeks of ExMI treatment, making a total of twice-weekly treatments for 12 weeks. Since the changes in urinary tract function following RH might be related to partial sympathetic and parasympathetic denervation during radical dissection, a longer treatment was needed to enhance the depolarisation of the few remaining functional pelvic nerves and improve the treatment efficacy.

The treatment frequency and mode were programmed into the machine with intermittent stimulation to avoid causing muscle fatigue. The pulsed magnetic field was delivered at a cycle of 3 s on / 6 s off for 10 min, followed by a rest period of 2 min and a second treatment (3 s on / 6 s off) for 10 min. The patients were allowed to mobilise during the rest period. Patients with stress incontinence and urge incontinence were treated with two episodes of 10 min at 50 Hz and 10 Hz, respectively, while those with mixed incontinence were treated at 10 Hz for the first 10 min and 50 Hz for the second.

The subjective outcomes were collected after 8 and 24 sessions, and also via follow-up telephone interviews conducted by an experienced nurse, using the UDI-6, IIQ-7. The symptoms of frequency, stress incontinence, urge incontinence and voiding difficulty, which were included in UDI-6 questions 1, 2, 3 and 6, were separated to evaluate the patients' improvement rate (improvement being defined as at least a 1 point decrease compared with pre-treatment, worsening being defined as at least a 1 point increase compared with pre-treatment and unchanged being defined as the same score) following ExMI. The objective outcomes included the 1-h pad test. To avoid the need to repeat the invasive urodynamic test, only the uroflowmetry was measured using a bladder scan after the completion of 24 treatment sessions.

A statistical analysis was performed using the Student's *t*-test for parametric and non-parametric continuous variables, and the Wilcoxon signed rank test or Fisher's exact test for the categorical variables. Median and minimum–maximum range was chosen as measures of variance for non-parametric factors. A p value of < 0.05 was considered statistically significant.

In this study, the methods, definitions and units used conform to the standards jointly recommended by the International Urogynecological Association (IUGA) and the International Continence Society (ICS), except where specifically noted (Haylen et al. 2010). The complications are described according to IUGA/ICS terminology and classification (Haylen et al. 2011).

Table I. Demographics and clinical features of the patients ($n = 32$).

	Median	Minimum–maximum range
Age (years)	61.0	52.0–80.0
Duration post-RH (years)	6.0	0.6–37.0
Body mass index (kg/m^2)	28.7	23.3–34.2
Pre-treatment 1 h-pad test (g)	25.3	0.0–86.0
Pre-treatment UDI-6	50.0	8.3–75.0
Pre-treatment IIQ-7	71.4	4.2–75.0
Follow-up duration post-treatment (M)	23.5	8.0–36.0

RH, radical hysterectomy for cervical cancer; UDI-6, Urogenital Distress Inventory six-item short form questionnaire; IIQ-7, Incontinence Impact seven-item short form Questionnaire.

Results

Data on 32 females with demonstrable urinary tract dysfunction for at least 6 months following RH for uterine cervical cancer, who received 24 treatment sessions, were collected and were available for analysis at the end of the study. Only two patients were unable to complete the 24 regular sessions and so were excluded from the analysis. All patients were comfortable throughout the ExMI treatment process. The basic background of the study subjects is shown in Table I. The median age of the patients was 61.0 (52.0–80.0) years; the median duration following RH was 6.0 (0.6–37.0) years; the median body mass index (BMI) was 28.7 kg/m^2 (23.3–34.2); the median score of UDI-6 was 50.0 (8.3–75.0); the median score of IIQ-7 was 71.4 (4.2–75.0) and the median follow-up duration following the 24 treatment sessions was 23.5 (8.0–36.0) months. The pre-treatment urodynamic diagnosis included detrusor overactivity (7, 21.8%); urodynamic stress incontinence (16, 50%); mixed incontinence (6, 18.7%) and other (3, 9.3%).

Both the UDI-6 and IIQ-7 scores showed statistically significant improvements ($p < 0.001$) at post-8 sessions and 24 sessions, then slightly increased after treatment at mean follow-up at 24.2 ± 9.2 months, but still indicated significant improvements compared with the pre-treatment level (Figures 1 and 2).

The effects of urinary symptoms following ExMI treatment showed significant improvements after 8 and 24 treatment sessions, including frequency, urge incontinence, stress incontinence and voiding difficulty ($p < 0.001$). Except for symptom frequency ($p = 0.133$), these improvements continued to the last follow-up at a mean follow-up of 24.2 ± 9.2 months (Table II). The objective outcome was measured by a 1-h pad test after 24 treat-

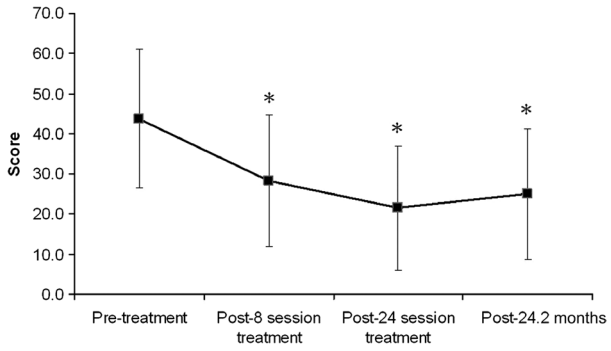

Figure 1. UDI-6 scores post-ExMI treatment in patients with urinary tract dysfunction following RH. Values are expressed as mean ± SD, $^*p < 0.05$.

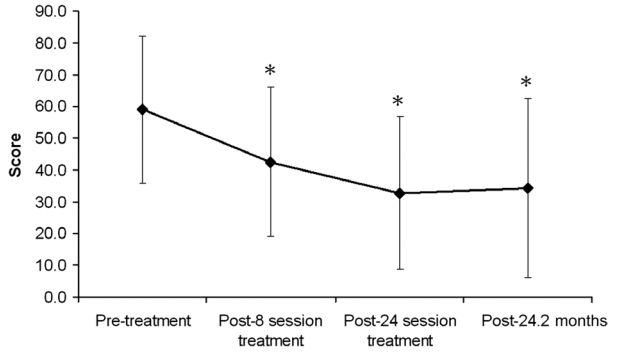

Figure 2. IIQ-7 scores post-ExMI treatment in patients with urinary tract dysfunction following RH. Values are expressed as mean ± SD, $^{*}p < 0.05$.

ment sessions. The 1-h pad test weight decreased from 27.2 g pre-treatment to 12.1 g post-treatment ($p < 0.05$). A comparison of the urodynamic parameters between pre-treatment and post-treatment after 24 sessions revealed no statistically significant changes.

Discussion

Lower urinary tract dysfunction is the most common complication occurring after radical pelvic surgery (Oh et al. 2012), with an adverse impact on the patient's quality of life. The changes in urinary tract function following RH might be related to partial sympathetic and parasympathetic denervation during radical dissection (Chen et al. 2002). Both somatic and autonomic demyelination, with or without denervation, might be responsible for the temporal changes in vesicourethral function following RH and recovery to baseline condition within 6 months (Zullo et al. 2003), so we only enrolled patients with bladder dysfunction for at least 6 months following RH in this study. Although many studies focus on evaluating urinary tract dysfunction and its impact on urodynamic findings for patients with cervical cancer following RH, few investigate the response of relatively invasive treatment methods for lower urinary tract dysfunction following RH. Kuo (2005) reported that the urethral injection of botulinum A toxin proves to be an effective treatment for patients with detrusor under activity and non-relaxing urethral sphincter following RH with few adverse effects (Kuo 2005). Chuang and Kuo (2009) reported active urological management, including the pubovaginal sling procedure, urethral injection of botulinum toxin, transurethral incision of the bladder neck and augmentation enterocystoplasty, with 88.9% of participants being satisfied with the outcome (Chuang and Kuo 2009).

Most recent investigations indicate that ExMI therapy offers a new, effective modality for pelvic floor muscle stimulation as well as a non-invasive and painless treatment for females suffering from stress urinary incontinence and urge incontinence (Galloway et al. 1999; Yokoyama et al. 2004a; Hoşcan et al. 2008; Bakar et al. 2011).

Since detrusor overactivity, mixed urinary incontinence and *de novo* stress incontinence are the three main observed disturbances following RH (Benedetti-Panici et al. 2004) and ExMI therapy has been shown to offer earlier continence compared with the control group following radical prostatectomy as Yokoyama et al. (2004b) reported (Yokoyama et al. 2004b), we hypothesised that ExMI may also be effective in treating patients with lower urinary tract dysfunction following RH.

ExMI can directly and painlessly stimulate the pelvic floor muscles and sacral roots without the insertion of a vaginal plug, and can be more efficient and comfortable than conventional electrical stimulation (Yamanishi et al. 2000a). The application of non-invasive ExMI therapy due to changes in urinary tract function following RH related to partial sympathetic and parasympathetic denervation may be effective by inducing the controlled depolarisation of the non-damaged adjacent nerves and subsequent pelvic muscle contraction. In the present study, ExMI therapy resulted in significant improvements: the 1-h pad test weight significantly 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 ($p < 0.001$), which improved the adverse impact on most patients' quality of life, even though complete continence was not achieved in most patients. Based on the satisfactory outcomes observed in this study, ExMI may provide a good alternative treatment for alleviating the common post-radical hysterectomy complication of urinary tract dysfunction and thereby improving the quality of life for women with cervical cancer.

Efficacy has been shown to improve with the number of sessions and most study protocols advocate 12–16 sessions (Galloway et al. 2000; Almeida et al. 2004; Bakar et al. 2011). Galloway et al. (1999) reported that the application of ExMI twice-weekly for 6 weeks (12 sessions) significantly improved the symptoms of stress incontinence, and that this efficacy was maintained 3 months later. Yamanishi et al. (2000b) reported that the magnetic stimulation of the pelvic floor twice-weekly for 5 weeks (10 sessions) significantly improved stress as well as urge incontinence. Bakar et al. (2011) reported a twice-weekly treatment programme for 6 weeks (12 sessions). However, the long-term efficacy of ExMI remains unclear. Doğanay et al. (2010) report that 16 treatment sessions do not constitute an effective or definitive therapy, and that the benefits are temporary, with a high rate of recurrence. Hoşcan et al. (2008) concluded that ExMI's effect continued for approximately a year after the therapy but then gradually decreased, falling close to baseline by the 2nd year post-therapy. Since the changes in urinary tract function following RH might be related to partial sympathetic and parasympa-

Table II. The effects of urinary symptoms after ExMI treatment.

	Post-8 sessions		Post-24 sessions		Post-24.2 months*	
	n	*p* value	*n*	*p* value	*n*	*p* value
Frequency						
Improved	15	0.007	16	< 0.001	13	0.133
Worse	1		1		5	
Unchanged	16		15		14	
Urge incontinence						
Improved	19	< 0.001	19	< 0.001	20	0.006
Worse	0		1		3	
Unchanged	13		12		9	
Stress incontinence						
Improved	21	< 0.001	22	< 0.001	21	< 0.001
Worse	0		1		2	
Unchanged	11		9		9	
Voiding difficulty						
Improved	7	0.040	10	0.006	9	0.011
Worse	1		1		2	
Unchanged	24		21		21	

*Mean. *p* value by Wilcoxon signed ranks test, compared with pre-ExMI treatment.

thetic denervation during radical dissection, longer treatments of up to 24 sessions may be needed to enhance the depolarisation of the few remaining pelvic nerves and thereby improve the treatment efficacy. The treatment sessions for the present study were empiric. Our patients underwent treatment twice-weekly for 12 weeks in the present study, which is a longer duration than used in most studies and may help to maintain longer efficacy. The results may indicate that higher numbers and longer periods of non-invasive ExMI treatment may benefit patients with pelvic denervation following RH.

ExMI is relatively painless: there is no need for a probe, and it is non-invasive, free of side-effects and also convenient, since the magnetic fields pass through clothing (Bakar et al. 2011). In addition, ExMI does not appear to have an adverse effect on oncological outcome. In this study, we have not observed any recurrence of cancer or other significant side-effects in the patients at a median follow-up of 23.5 (8.0–36.0) months post-RH. However, further studies are needed to conclusively determine possible influences of ExMI on oncological outcome. Despite its apparent safety and effectiveness, ExMI cannot be used at home and can only be accessed through an outpatient clinic, which can be stressful, especially for older women. For these reasons, two older patients withdrew from the treatment during our study. Clearly, further trials are needed to determine the optimum stimulation protocol for changes in urinary tract function following RH.

ExMI therapy offers a new, effective modality for bladder dysfunction. With regard to urodynamic study, Yokoyama et al. (2004a) reported that bladder capacity at the first desire to void and maximum cystometric capacity significantly increased following ExMI treatment. Only uroflowmetry was measured after the completion of 24 treatment sessions to avoid repeat invasive urodynamic testing, which reveals that the post-void residual volume decreased from 62.0 ml to 21.0 ml, but no other statistical significance differences were found before and after ExMI treatment.

Conservative therapies used in disorders of the lower urinary tract include Kegel exercises, biofeedback and electrical stimulation. Pelvic floor muscle training is the most commonly used physical therapy treatment for women with stress urinary incontinence. It is sometimes recommended for mixed and less commonly, urge urinary incontinence, as most studies showed women who participated in pelvic floor muscle training (PFMT) were more likely to report that the symptoms were cured or improved than women who did not. They also experienced about one fewer incontinence episode per day. However, there is insufficient data to draw conclusions about effects on other outcomes, such as condition-specific quality of life. Overall, the review provides some support for the widespread recommendation that PFMT be included in first-line conservative management programmes for women with stress, urge or mixed, urinary incontinence. In addition, the treatment effect might be greater in younger women (in their 40s and 50s) with stress urinary incontinence alone (Hay-Smith et al. 2006). In a randomised controlled trial, the role of PFMT on the treatment of lower urinary tract dysfunction (LUTD) in multiple sclerosis (MS) patients showed that PFMT is an effective approach to treat LUTD in females with MS, which may significantly reduce pad weight ($p = 0.00$), number of pads ($p = 0.01$) and nocturia events ($p < 0.00$) (Lúcio et al. 2010).

The results of electrical stimulation have been reported to be effective for stress incontinence and urge incontinence, with success rates of 60–90% (Yamanishi et al. 1997). Furthermore, McClurg et al. (2008) reported that the addition of active neuromuscular electrical stimulation to a programme of pelvic floor muscle training and electromyography biofeedback should be considered as a first-line option in alleviating some of the symptoms of lower urinary tract dysfunction associated with multiple sclerosis. In comparison with subjects in the above studies, our patients are relatively older women with demonstrable urinary tract dysfunction, who are thought to have damaged pelvic nerve plexus following radical hysterectomy (RH). Although we lacked the randomised controlled trial, our data showed that ExMI treatment resulted in significantly decreased 1-h pad test weight from 27.2 g pre-treatment to 12.1 g post-treatment ($p < 0.05$). Unlike the two studies, we also measured treatment outcome subjectively using the UDI-6 and IIQ-7 scores, which 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 urination frequency, stress incontinence, urge incontinence and even voiding difficulty showed statistically significant improvements ($p < 0.001$) after 8 and 24 sessions of ExMI treatment. ExMI may also be preferable for most of our relatively older female patients compared with other methods, because some of the geriatric patients' learning is reduced due to visual or auditory incapacity and therefore biofeedback application is less effective. In addition, ExMI treatment is without pain or the insertion of a vaginal plug, and can prove to be more comfortable with higher compliance than conventional electrical stimulation.

This study suffers from several limitations: first, as with many previous studies, it is difficult to design an effective placebo treatment. Second, the small number of patients may limit the strength of our conclusions regarding the efficiency of ExMI treatment for patients with urinary tract dysfunction following RH. Third, there was no pre-operation (i.e. pre-RH) evaluation of the patients' incontinence. Long-term, placebo-controlled studies are crucial for the proper interpretation and evaluation of the efficiency of this treatment modality. Further studies involving a larger number of patients and longer follow-up period are required to evaluate how long the benefits of this treatment last and whether continuous treatment is necessary. As this is only an efficacy study without a control group, it is imperative that controlled randomised studies be first performed before routine clinical use of this technique. Until that time, ExMI must be used only in study settings.

Conclusions

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. Long-term, placebo-controlled studies are crucial for the proper interpretation and evaluation of the efficiency of this treatment modality.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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