J Chin Med Assoc

ORIGINAL ARTICLE

Effect of pelvic floor muscles exercises by extracorporeal magnetic innervations on the bladder neck and urinary symptoms

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Abstract

Background: This study aimed to investigate the changes in the bladder neck (BN) and urinary symptoms using extracorporeal magnetic innervation (ExMI) therapy before and after performing passive pelvic floor exercises.

Methods: Twenty women with stress urinary incontinence (SUI) were assessed by transperineal ultrasound and questionnaires before and after the ExMI therapy from January 2011 to February 2021.

Results: The incidence of urinary frequency and SUI were significantly decreased after the therapy (McNemar test, $p < 0.01$). The therapeutic efficacy of SUI was 75%. A significant decrease was noted in pad test results (paired t test, $p < 0.05$). At the same time, there was a considerable difference in Urinary Distress Inventory-6 scale measures (paired t test, $p < 0.001$). However, results for the Incontinence Impact Questionnaire-7 showed a marginally significant difference (paired t test, $p = 0.066$). Three domains of lubrication, orgasm, and satisfaction in the Female Sexual Function Index showed significant differences (paired t test, $p < 0.05$). Transperineal ultrasound found that BN mobility and Q-tip straining angle were not statistically significant (paired t test, $p > 0.05$).

Conclusion: The ExMI is effective for SUI by strengthening the pelvic floor muscle without significantly decreasing BN mobility.

Keywords: Female; Incidence; Lubrication; Orgasm; Stress urinary incontinence

1. INTRODUCTION

Stress urinary incontinence (SUI) is a critical healthcare problem that can impact those who are affected socially, sexually, mentally, and financially. The principal mechanism of SUI is the weakening of pelvic floor support, which eventually leads to urethral hypermobility, while the minor mechanism is intrinsic sphincter deficiency. Any damage to the pelvic floor's nerves, muscles, and connective tissue can weaken the pelvic floor. Injury during childbirth, aging, menopausal status, and activities or medical conditions causing long-term increasing intra-abdominal pressure are all contributory factors,[1] which explains why SUI is most common in older women.

Patients, especially those with less severe symptoms, usually opt for nonsurgical treatment initially. With the advancement of technology, several less invasive novel treatments have sprung up and shown promising potential. Electrical stimulation to improve pelvic floor function was developed by Caldwell[2] in 1963, where the electrical current is induced directly to excite the pelvic nerves and muscle, creating a muscle response similar to the Kegel exercise. Other mechanisms have also involved the reorganization of spinal reflex and regulation of cortical activity, which is suggested to be effective for frequency, urgency, and urge of incontinence.[3]

However, in the clinical setting, the electrical stimulation requires the insertion of a probe into the vagina, which is considered inconvenient and less welcomed by female patients. The electric current needs to pass through the skin, subcutaneous tissues, and bone, causing high impedance and leading to higher current emitted through local tissue with pain and discomfort such as local skin irritation being occasionally reported.

Extracorporeal magnetic innervation (ExMI) was developed by Galloway et al[4] in 1998 as the alternative to electrical stimulation and was approved by the US Food and Drug Administration (FDA) in 2000. Electrified coils can induce an eddying current and produce a pulsed magnetic field that depolarizes the motor nerves and provokes muscle contractions.[4,5] Similarly, though the exact mechanism remains unclear, Galloway et al[5] claimed that ExMI treatment is also effective for frequency, urgency, urge, and mixed incontinence. The magnetic field can penetrate all body tissues without significant alteration and passes uninterrupted through clothing[4,5]; so as there is no need for intravaginal probing and undressing, ExMI is more accepted by patients, providing a more comfortable and convenient treatment experience.

Most of the current literature has found ExMI treatment to be promising and effective, but objective measures are relatively

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Author contributions: Dr Chieh-Yu Chang and Dr Feng-Hsiang Tang contributed equally to this work.

Conflicts of interest: The authors declare that they have no conflicts of interest related to the subject matter or materials discussed in this article.

Journal of Chinese Medical Association. (2023) 86: 1096-1100.

Received July 10, 2022; accepted October 3, 2022.

doi: 10.1097/JCMA.0000000000001003

lacking; accordingly, the present prospective study aimed to investigate the exact change in the mobility and position of the bladder neck (BN) and urinary symptoms before and after ExMI therapy. Questionnaires, 1-hour pad test, and transperineal ultrasound were all used for both objective and subjective improvement assessment.

2. METHODS

This study enrolled 20 female patients from January 2011 to February 2021 with demonstrable SUI, and all received the same ExMI treatment sessions, which took 20 minutes and were administered twice a week, for 12 weeks. A complete evaluation was carried out before the treatment and, once again, 6 months after treatment. The evaluations included a 1-hour pad test, transperineal ultrasound, and a personal interview to complete the Urogenital Distress Inventory (UDI-6), the Incontinence Impact Questionnaire (IIQ-7),[6] the Female Sexual Function Index[7] questionnaires, and urinary symptoms with the standardized questionnaire taking into account the 2002 International Continence Society (ICS) definitions.[8] The exclusion and inclusion criteria through the selection process are provided in the flowchart (Fig. 1).

The results of the ExMI treatment were assessed subjectively and objectively. "Cure" was defined as a patient who had no more SUI symptoms with urine loss of <2 g on pad test; "Improvement" was defined as urine loss of 2 to 5 g on pad test, whereas leakage of more than 5 g on pad test was deemed a "Failure".[9]

The BN's anatomical position and dynamic mobility were evaluated by transperineal ultrasound with the patient in the supine position. The curved linear-array transducer was placed sagittally, and the symphysis pubis, vesicourethral junction, urethra, and bladder were all visualized; then, the BN position was measured in the x-y coordinate system with the inferior edge of the pubic bone as the reference point (Fig. 2). Patients were then told to perform a Valsalva maneuver to record the point of maximal BN descent.

The ethics committee of Kaohsiung University and Teaching Hospital approved the study protocol. A statistical analysis of the data was calculated using paired t test for parametric continuous variables, McNemar test for categorical variables, and Fisher exact test for small sample sizes. A difference was considered statistically significant for a p value of <0.05.

3. RESULTS

The average age of all participants was 46.8 years, with mean parity being 2.2. The mean body mass index was 23.8 kg/m^2.

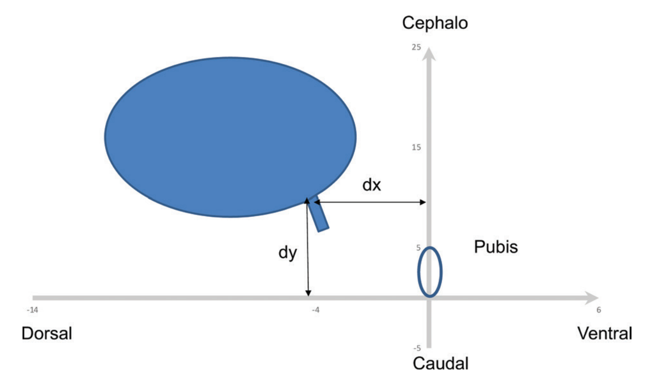

Fig. 1 Evaluation of bladder neck location on introital ultrasonography relative to reference coordinate system. dx = the distance between the bladder neck and the central line of the symphysis; dy = the distance between the bladder neck and the axis perpendicular to the central line of the symphysis.

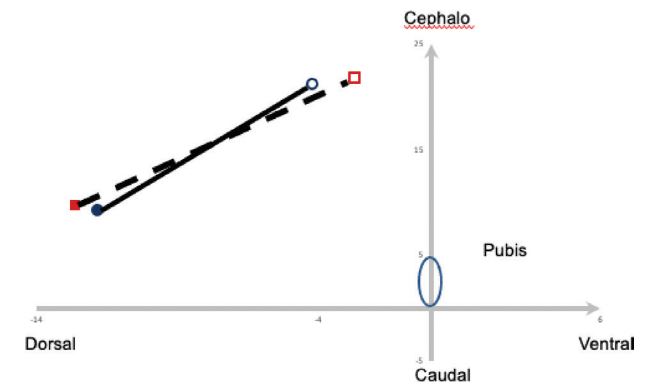

Fig. 2 Bladder neck localization of the patients before and after extracorporeal magnetic innervation treatment. The bladder neck position is represented as follows. Before treatment: ○ is at rest; ●is during straining; and straight line represented mobility; after treatment: □ is at rest; ■ is during straining; and dotted line represented mobility.

Two patients were postmenopausal, one patient was under hormone replacement therapy before initiating the therapy and during the follow-up months, one patient had diabetes mellitus, whereas eight had hypertension under medical control (Table 1). All the patients were neurologically normal and nonpregnant, whereas none had pelvic organ prolapse of more than stage 1 (ie, any most-distal portion of prolapse was ≥1 cm above the level of vaginal introitus).

In the present study, with 20 patients enrolled in the 12 weeks of ExMI therapy, urinary frequency, SUI, and nocturia were the most common pretreatment symptoms. The urinary frequency and SUI incidences were significantly decreased after the ExMI therapy (McNemar test, $p < 0.05$), with the therapeutic effect of SUI revealed as 75%, the cure group accounting for 50%, and the improvement group for 25%. Nocturia was improved in five patients, which presented as marginally significant (McNemar test, p value slightly >0.05). Profound decrease with statistical significance was noticed in the pad test (paired t test, $p < 0.05$). Any difference in the pre- vs post-therapy incidence of other urinary symptoms was not statistically significant. There was a significant difference in UDI-6, but in IIQ-7, the result was found to be marginally significant (paired t test, $p = 0.066$) (Table 2).

As for female sexual function, significant differences over three domains, lubrication, orgasm, and satisfaction, were noted after the ExMI therapy (paired t test, $p < 0.05$). Sexual desires and sexual arousal had no significant difference before and after the therapy, whereas dyspareunia showed no significant improvement as well (Table 3).

Transperineal ultrasound was performed pre- and post-therapy to evaluate the BN mobility at rest and during straining with the topography of the BN revealing no significant difference for either position (paired t test, $p > 0.05$), whereas BN mobility

Table 1

Demographic data (N = 20) are given as mean ± SD or n (%)

Mean age, y	46.8 ± 11.9
Mean parity	2.2 ± 1.2
Mean BMI, kg/m^2	23.8 ± 3.3
Menopause	2 (10)
Current hormone therapy	1 (4)
Diabetes mellitus	1 (4)
Hypertension	8 (32)
Follow-up, mo	3

BMI = body mass index.

Table 2

Urinary symptoms and pad tests before and 6 mo after ExMI

Symptoms	Pre-ExMI (N = 20)	Post-ExMI (N = 20)	*p*
Urinary frequency	12 (60)	2 (10)	0.002*
SUI	20 (100)	15 (75)[a]	<0.001*
Cure		10 (50)	
Improvement		5 (25)	
Failure		5 (25)	
Urgency urinary incontinence	7 (35)	2 (10)	0.113**
Feeling of incomplete emptying	1 (5)	0 (0)	0.912**
Hesitancy	1 (5)	0 (0)	0.946**
Nocturia	8 (40)	3 (15)	0.063**
Pad test, g	307	25	0.046***
UDI-6	44.4 ± 14.4	24.1 ± 16.6	<0.001***
QII-7	43.6 ± 41.3	21.2 ± 23.7	0.066

Data are given as n (%).
*McNemar test;
**Fisher exact test;
***Paired *t* test.
ExMI = extracorporeal magnetic innervation; IIQ-7 = Incontinence Impact Questionnaire-7; SUI = stress urinary incontinence; UDI-6 = Urinary Distress Inventory-6.
[a]SUI post-ExMI treatment was categorized into three groups. Cure & improvement group (total N = 15) showed statistical significance in ExMI treatment.

Table 3

Changes in scores of female sexual function index before and 3 mo after ExMI

Domains	Pre-ExMI (N = 20)	Post-ExMI (N = 20)	*p**
Sexual desire	2.8 ± 0.5	2.6 ± 0.8	0.773
Sexual arousal	2.9 ± 0.9	3.4 ± 0.6	0.483
Lubrication	4.1 ± 0.8	4.7 ± 1.3	0.027*,**
Orgasm	3.4 ± 0.9	4.1 ± 0.5	0.012*,**
Satisfaction	3.7 ± 0.9	4.6 ± 0.8	0.016*,**
Dyspareunia	4.6 ± 1.3	4.9 ± 1.3	0.186
Total scores	21.5 ± 4.8	24.3 ± 5.6	0.697

Data are given as mean ± SD.
*Paired *t* test;
**statistical significance.
ExMI = extracorporeal magnetic innervation.

also showed no statistically significant difference (paired *t* test, $p > 0.05$) (Table 4). In conclusion, from the transperineal ultrasound, no significant difference was indicated over the BN hypermobility, and for the Q-tip straining angle, no statistical difference was also noted (paired *t* test, $p > 0.05$) (Table 4).

4. DISCUSSION

The importance of pelvic floor muscle (Kegel) exercise in treating women with SUI is beyond description, although this requires proper technique and commitment to long-term performance to produce better outcome.[10] For women who cannot identify the proper muscle or regularly conduct the exercise, treatments such as electric stimulation and ExMI can be introduced while sharing the same goal: to strengthen the pelvic floor muscles passively. In the clinical situation, the strong point of the ExMI is convenience and comfort compared to electrical stimulation.

In our observation, most current studies discussing the therapeutic effect of ExMI lack objective measurements; accordingly, the 1-hour pad test and transperineal ultrasound were explicitly performed in this study, as transperineal ultrasound is a cheap, real-time, and noninvasive method to evaluate genitourinary displacement.[11]

Table 4

Topography of the BN at rest and during straining, and its mobility assessed by perineal ultrasonography in the pre- and post-operative evaluation

	Rest		Straining				
ExMI group (N = 16)	dx	dy	dx	dy	Mobility, mm	BN hypermobility	Q-tip straining angle, °
Pre-ExMI	−4.2 ± 6.1	21.2 ± 2.2	−11.8 ± 6.9	9.2 ± 10.9	10.9 ± 4.7	9 (56.3)	41.1
Post-ExMI	−2.7 ± 5.1	21.8 ± 3.9	−12.6 ± 5.3	9.7 ± 9.9	11.8 ± 6.4	11 (68.8)	44.4
p	0.243*	0.491*	0.693*	0.865*	0.426*	0.574*	0.574*

Values are given as mean ± SD (mm) or n (%).
*Paired *t* test.
BN = bladder neck; ExMI = extracorporeal magnetic innervation.

In the present study, the incidence of SUI decreased significantly after treatment, whereas pad test results also showed considerable improvement. The therapeutic effect of SUI was calculated to be 75%, although the topography of the BN collected from the ultrasound showed no significant improvement for BN hypermobility. These results are reasonable with the primary mechanism of the ExMI, which helps the pelvic floor muscle strengthen by contracting passively. Even though the hypermobility of the BN remains, the stronger pelvic floor muscle can help with the closure of the urethra and compensate for the descent of the BN at straining.

In the study, urinary symptoms related to the detrusor muscle and pelvic plexus nerve systems such as urgency incontinence, incomplete emptying, and hesitancy showed no significant difference after treatment; however, the incidence of micturition frequency had significantly decreased after treatment. The complicated mechanism of electrical stimulation and ExMI treating detrusor overactivity involves stimulating the afferent pudendal nerve or sacral root to inhibit the pelvic efferent (parasympathetic) or activate the hypogastric efferent (sympathetic) nerve.[12]

ExMI penetrates the body tissue, and the magnitude of the field only falls off as the inverse square of the distance, which helps activate deeper proximal nerves that are difficult to reach by electrical stimulation without hurting the skin. In a review article, Yamanishi et al[13] reported that for urgency incontinence and mixed urinary incontinence, neuromodulation could be the treatment alternative to drug therapy because of its efficacy and much fewer side effects.

Lubrication, orgasm, and satisfaction had significantly improved after the therapy, although sexual arousal and desire showed no significant difference. The fear of coital incontinence can be a source of frustration, anxiety, and low self-esteem to women with SUI[14]; eventually, sexual functioning can be affected. Bekker et al[15] mentioned that improvement in coital incontinence could result in improvement of sexual function. The present study found similar results where ExMI could significantly improve the pelvic floor muscle and improve female sexual function. It is reasonable to postulate that women would appear to be more willing to relax and enjoy sexual activity when urinary incontinence resolves; on that account, sexual arousal and desire could well be improved.

As a result, ExMI can effectively improve SUI by providing pelvic floor muscle stimulation in a painless and convenient (no need for undressing) way. The ability of sexual function change is secondary to the improvement of pelvic floor muscle power. Lim et al,[16] in performing a 1 year follow-up, found high patient acceptance and low dropout rates. This can be interpreted as ExMI being an attractive and promising nonsurgical alternative for patients who do not wish to undergo surgery.

High-intensity focused electromagnetic (HIFEM) is a novel technology that offers supramaximal pelvic floor contraction using focused electromagnetic energy. The supramaximal pelvic floor contraction is brain independent and beyond physiological contraction in strength and repetitiveness, leading to pelvic floor stimulation, adaptation, and remodeling.[17] HIFEM is conducted with the patient being fully clothed and seated. As mentioned in several studies, urinary incontinence and sexual function were both significantly improved after HIFEM treatment.[18]

It is worth noting that transperineal ultrasound was widely used for its real-time convenience and objectiveness in many recent studies we reviewed. The diameter of the anteroposterior and laterolateral levator hiatus and hiatal area was significantly reduced in the group treated with HIFEM technology compared with the group treated with the electrical device.[19]

The US FDA approved the indication of the noninvasive Erbium-doped Yttrium Aluminium Garnet (Er: YAG) laser in the field of urogynecology in 2014. The Er: YAG vaginal laser produces a nonablative thermal effect that causes the remodeling of vaginal connective tissue, and hence provides the vaginal wall with strength and mechanical traction.[20] The benefit of remodeling can extend to the lower urinary tract anatomy and further improve SUI. Lin et al[21] found a significant decrease in the BN mobility via perineal ultrasonography. The mechanism of vaginal laser in treating SUI should be different from ExMI, as it mainly focuses on neocollagenosis and remodeling of connective tissue.

There are some limitations to our study. This study was inspired by the new technology of HIFEM, which we wished to compare with our prior ExMI treatments. As there are more and more new approaches to treating urinary incontinence and genitourinary syndromes, we began to review our previous experiences. We also noted that nowadays, the internet provides much information on treatments for patients, and they prefer to receive anything noninvasive firsthand. From the points of view above, this explains why (1) the study period was long, but the sample size was small, and the follow-up duration was short as well; and (2) patients with average pad test up to 307 g before the treatment were offered options of operation, but they still preferred to receive noninvasive treatments initially, although 2 patients out of the 20 included eventually received surgical intervention after the ExMI treatments were completed. Furthermore, more extensive evaluations such as difference urodynamic exams should be included in future studies. Again, this study was not considered until we wanted to compare the mechanism and effectiveness of ExMI and HIFEM.

However, in our recent studies on the vaginal laser in treating SUI, no noticeable urodynamic changes were noted either in Er: YAG and Pixel CO_2 vaginal lasers, whereas BN mobility was significantly decreased, so urodynamic exams seem to be affected the least or later than other tests in our experience and have now become an exciting topic for our future studies.

A randomized controlled trial including a control group and a larger sample size is necessary to support our findings. However, the strength of our study was applying objective transperineal ultrasound measurement instead of subjective questionnaires only.

In conclusion, the ExMI effectively treats SUI by strengthening the pelvic floor muscle painlessly and conveniently without a significant decrease in BN mobility, as determined by transperineal ultrasonography. The treatment mechanism of ExMI should be very different from vaginal laser and surgery. Whether HIFEM provides a more substantial or more extended effect remains inconclusive, with further randomized controlled studies and longer follow-up being expected to confirm and elucidate our findings.

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