Does sacral pulsed electromagnetic field therapy have a better effect than transcutaneous electrical nerve stimulation in patients with neurogenic overactive bladder?

Lamyaa A. Fergany, Husain Shaker, Magdy Arafa, Mohamed S. Elbadry

Department of Surgery, Faculty of Physical Education, Cairo University, Cairo, Egypt

Department of Urology, Faculty of Medicine, Minia University, Minia, Egypt

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ABBRÉV IATIONS
CNS, central nervous system; FMS, functional magnetic stimulation; MCC, maximum cystometric capacity;

Abstract Objective: To compare the effectiveness of pulsed electromagnetic field therapy (PEMFT) and transcutaneous electrical nerve stimulation (TENS) on neurogenic overactive bladder dysfunction (OAB) in patients with spinal cord injury (SCI).

Patients and methods: In all, 80 patients [50 men and 30 women, with a mean (SD) age of 40.15 (8.76) years] with neurogenic OAB secondary to suprasacral SCI were included. They underwent urodynamic studies (UDS) before and after treatment. Patients were divided into two equal groups: Group A, comprised 40 patients who received 20 min of TENS (10 Hz with a 700 s generated pulse), three times per week for 20 sessions; Group B, comprised 40 patients who received PEMFT (15 Hz with 50% intensity output for 5 s/min for 20 min), three times per week for 20 sessions.

Results: In Group B, there was a significant increase in the maximum cystometric capacity (P < 0.001), volume at first uninhibited detrusor contraction (P < 0.002), and maximum urinary flow rate (P < 0.02).
OAB, overactive bladder; PEMFT, pulsed electromagnetic field therapy; $Q_{\text{max}}$, maximum urinary flow rate; SCI, spinal cord injury; TENS, transcutaneous electrical nerve stimulation; UDS, urodynamic studies

**Conclusion:** The UDS showed that the effects of PEMFT in patients with neurogenic OAB secondary to suprasacral SCI was better than TENS for inducing an inhibitory effect on neurogenic detrusor overactivity.

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**Introduction**

Neurogenic bladder is defined as dysfunction of the bladder resulting from damage to or disease of the central nervous system (CNS) [1], and thus is a broad diagnosis, as it describes bladder dysfunction resulting from any neurological insult to the CNS [2].

Neurogenic bladder dysfunction is present in all patients with spinal cord injury (SCI) with persistent neurological deficits and in 70% of ambulatory patients with SCI [3]. Bladder dysfunction is also common in spina bifida, which affects about one in every 1000 live births [4].

A novel technique for stimulating the nervous system non-invasively is magnetic field stimulation (MFS), which can activate deep neural structures via induced electric currents, without pain and discomfort. Also, several clinical trials including placebo-controlled studies have shown that MFS of the pelvic floor and sacral roots is effective for overactive bladder (OAB). MFS induces inhibitory effects on detrusor overactivity in a similar manner to electrical stimulation, with significant clinical advantages. MFS of the sacral nerve roots could be a promising alternative treatment for OAB [5].

Urodynamic studies (UDS) evaluate urinary functioning and includes: urinary flowmetry, bladder cystometrogram/electromyogram, Valsalva leak-point pressure measurement, and urethral pressure profiling. The most definitive and objective way to determine abnormalities in bladder and urethral functioning is by UDS in the filling/storage phase, as well as voiding phase in neurogenic bladder dysfunction [4]. In many patients, UDS are necessary to gain a complete diagnosis of how the neurogenic dysfunction has changed the function of different components of the lower urinary tract and their interaction [6].

The purpose of the present study was to compare the effects of pulsed electromagnetic field therapy (PEMFT) vs transcutaneous electrical nerve stimulation (TENS) on neurogenic OAB in patients with spinal cord injury (SCI).

**Patients and methods**

This study comprised 80 patients, 50 men and 30 women [mean (SD) age 40.15 (8.76) years], with neurogenic OAB following suprasacral SCI that occurred 6–18 months beforehand. They were referred from a neurologist and urologist to exclude the presence of other non-neurogenic causes of bladder dysfunction or other associated problems related to the bladder.

Urine analysis was done for all patients to exclude any other causal problems and life style information (e.g. smoking and alcohol consumption) was ascertained. They were divided randomly into two equal groups: Group A, comprised 40 patients, 24 men and 16 women, with neurogenic OAB who had sacral TENS (10 Hz with a generated pulse of 700 s) applied for 20 min, three times a week for 20 sessions; Group B, comprised 40 patients, 26 men and 14 women, with neurogenic OAB who had sacral PEMFT (5 Hz, with a 15% intensity output for 5 s/min) applied for 20 min, three times a week for 20 sessions.

The patients were selected according to the following criteria: (i) diagnosed by a urologist and neurologist as having neurogenic OAB dysfunction based on careful neurological and urological investigations including patient history, physical examination, urine analysis, and UDS; (ii) patients aged 20–55 years; and (iii) onset of neurogenic OAB within 6–18 months after suprasacral SCI.

The exclusion criteria included: (i) other non-neurogenic causes of bladder dysfunction, (ii) other causes of neurogenic OAB, (iii) severe cognitive impairment, (iv) patients that had other associated problems related to the bladder, and (v) patients that had undergone a surgical procedure related to the bladder.

Every patient was assessed for pus cells, red blood cells and bilharziasis before treatment to exclude any other cause of OAB.

UDS included: maximum urinary flow rate ($Q_{\text{max}}$), maximum cystometric capacity (MCC) and first uninhibited detrusor contraction to measure bladder...
capacity, detrusor pressure at $Q_{\text{max}}$, and compliance. UDS was performed before and after treatment.

For TENS treatment an Intelect 37343 model was used (Chattanooga Group Inc., Hixon, TN, USA) and for the PEMFT a magnetotherapy unit was used (PMT Qs; ASALASER, Arcugnano, VI, Italy).

**Evaluation procedures**

Personal data of each patient were recorded on a data recording sheet. Before data collection, the purposes and procedures of the study were fully explained to each patient and each was evaluated individually. Therapy was conducted in a quiet room at about the same time of day for each patient.

UDS was performed twice for each patient, before and after treatment, in the Urology Department, Faculty of Medicine, Al-Minia University. For UDS, patients were instructed to arrive early, not to pass urine for 30 min before UDS, bring a complete list of all the medications and not to put on oils, petroleum jelly, or lotions from the waist down on the day of the test.

In Group A, the patients received low-frequency PEMFT (15 Hz, 50% intensity output for 5 s/min for 20 min) three times per week for 20 sessions. The patients were placed in a prone position for repetitive stimulation of the sacral roots.

In Group B, the patients received 20 min of TENS (10 Hz with a generated pulse of 700 s [7]), three times per week for 20 sessions.

**Statistical analysis**

Descriptive statistics were used to compare each group before and after treatment, and for comparisons between the two groups. Means, standard deviations (SDs) and percentages were calculated. The chi square test was used for categorical variables and $t$-test for continuous variables. A $P < 0.05$ was considered to indicate statistical significance Table 1.

**Results**

The mean (SD) MCC (measured by UDS) in Group A, was 212.25 (24.26) mL before treatment and 266.25 (26.70) mL after treatment, a highly significant increase of 25.44% from the baseline value ($P < 0.001$). The mean (SD) MCC in Group B was 210.40 (15.95) mL before treatment and 296.36 (21.78) mL after-treatment, also a highly significant ($P < 0.001$) increase of 40.85% from the baseline value. Comparing Groups A and B, there was no significant difference in MCC before treatment ($P > 0.05$), but after treatment the MCC was significantly more in Group B than in Group A ($P < 0.001$; Table 2).

The mean (SD) volume at first uninhibited detrusor contraction (measured by UDS) was 188.15 (14.80) mL before treatment and 236.30 (23.14) mL after treatment, a highly significant increase of 25.59% from the baseline value ($P < 0.001$). The mean (SD) volume at first uninhibited detrusor contrac-

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**Table 1** Demographics of the study groups.

|                | TENS     | PEMFT    | $P$   |
|----------------|----------|----------|-------|
| Number of patients | 40       | 40       | 0.620 (NS) |
| Age, years, mean (SD) | 39.45 (9.30) | 40.85 (8.37) |       |
| Sex, n (%)        |          |          |       |
| Female            | 16 (40.0) | 14 (35.0) | 0.744 (NS) |
| Male              | 24 (60.0) | 26 (65.0) |       |

NS, not significant.

† $t$-Test.

* Chi-square test.

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**Table 2** Intra- and inter-group comparison between mean values of MCC in the study groups measured before and after treatment.

| MCC (mL) | TENS ($n = 40$) | PEMFT ($n = 40$) | $P$   |
|----------|-----------------|------------------|-------|
| Mean (SD): |                |                  |       |
| Before treatment | 212.25 (24.26) | 210.40 (15.95) | 0.777 (NS) |
| After treatment  | 266.25 (26.70) | 296.35 (21.78) | 0.001 ** |
| Difference      | −54.0          | −85.95           |       |
| % change        | 25.44 ††       | 40.85 ††         |       |
| $P$             | 0.001 **       | 0.001 **         |       |

NS, not significant.

† $t$-Test.

** Highly significant.
tion in Group B was 186.95 (14.25) mL before treatment and 259 (20.89) mL after treatment, also a highly significant increase of 38.81% from the baseline value \( (P < 0.001) \). Comparing Groups A and B, there was no significant difference in volume at first uninhibited detrusor contraction before treatment \( (P > 0.05) \), but after treatment it was significantly more in Group B compared with Group A \( (P < 0.001; \text{Table 3}) \).

The mean (SD) \( Q_{\text{max}} \) (measured by UDS) in Group A was 13.00 (2.20) mL/s before treatment and 17.80 (3.19) mL/s after treatment, a highly significant increase of 36.92% from the baseline value \( (P < 0.001) \). The mean (SD) \( Q_{\text{max}} \) in Group B was 13.25 (2.36) mL/s before treatment and 20.20 (3.14) mL/s after treatment, also a highly significant increase of 52.45% from the baseline value \( (P < 0.001) \). Comparing Groups A and B, there was no significant difference in \( Q_{\text{max}} \) before treatment \( (P > 0.05) \), but after treatment and \( Q_{\text{max}} \) was significantly greater in Group B compared with Group A \( (P < 0.001; \text{Table 4}) \).

Discussion

PEMFT has become an alternative option for the treatment of urge and/or stress urinary incontinence and OAB (especially neurogenic detrusor overactivity). The advantages of this treatment are its completely non-invasive nature, and excellent safety and tolerability. It is thought that nerves are particularly sensitive to the effects of PEMFT, which may also regulate local blood flow and other factors. Its stimulation activates efferent nerves and motor endplates of the pelvic floor muscle, which provide better muscle strength and endurance. It also may affect the somatic nerve firing rate responsible for pelvic muscle and sphincter tone [8].

It is thought that MFS suppresses detrusor contraction through various pathways that inhibit the micturition reflex. In response to filling of the bladder, increased activity of the urethral sphincter induces relaxation of the detrusor muscle, as afferent branches of the nerves of the muscles of the limbs prohibit voiding during fight-or-flight reactions and afferent anorectal nerve branches prohibit voiding during defecation, also there is increased activity of the sympathetic nervous system in response to filling of the bladder (Edvardsen’s reflex) [9].

The present study agrees with the study of Bycroft et al. [10], in which they describe that functional magnetic stimulation (FMS) induced voiding in their patients as a result of direct parasympathetic (bladder efferent) stimulation and the differential fatigue characteristics of the detrusor and periurethral striated sphincter.

### Table 3

| First uninhibited detrusor contraction, mL | TENS \( (n = 40) \) | PEMFT \( (n = 40) \) | \( t \) value | \( P \) |
|------------------------------------------|------------------|-----------------|-------------|------|
| Mean (SD):                               |                  |                 |             |      |
| Before treatment                         | 188.15 (14.80)   | 186.95 (14.25)  | 0.261       | 0.795 (NS) |
| After treatment                          | 236.30 (23.14)   | 259.50 (20.89)  | \(-3.328\)  | 0.002** |
| Difference                               | \(-48.15\)       | \(-72.55\)      |             |      |
| % change                                 | 25.99 ↑↑         | 38.81 ↑↑        |             |      |
| \( t \) value                            | \(-15.765\)      | \(-32.318\)     |             |      |
| \( P \)                                  | 0.001**          | 0.001**         |             |      |

NS, not significant. \( \dagger \) \( t \)-Test. \( ** \) Highly significant.

### Table 4

| \( Q_{\text{max}} \) (mL/s) | TENS \( (n = 40) \) | PEMFT \( (n = 40) \) | \( t \) value | \( P \) |
|-----------------------------|------------------|-----------------|-------------|------|
| Mean (SD):                  |                  |                 |             |      |
| Before treatment            | 13.00 (2.20)     | 13.25 (2.36)    | \(-0.347\)  | 0.731 (NS) |
| After treatment             | 17.80 (3.19)     | 20.20 (3.14)    | \(-2.399\)  | 0.021 |
| Difference                  | \(-4.80\)        | \(-6.95\)       |             |      |
| % change                    | 36.92 ↑↑         | 52.45 ↑↑        |             |      |
| \( t \) value               | \(-17.941\)      | \(-28.280\)     |             |      |
| \( P \)                     | 0.001**          | 0.001**         |             |      |

NS, not significant. \( \dagger \) \( t \)-Test. \* Significant. \( ** \) Highly significant.
ter. Whilst FMS as a method of bladder emptying may have certain advantages over electrical stimulation of the sacral nerve roots, there is little evidence to suggest that it induces direct parasympathetic nerve stimulation in humans. Bycroft et al. [10] hypothesised that any significant detrusor contractions or bladder emptying related to FMS were attributable to a ‘rebound effect’ of bladder suppression removal.

Quek [9] concluded that magnetic stimulation penetrates tissues without alteration and only declines as the inverse square of the distance, unlike direct electrical stimulation that decreases as a function of tissue impedance. Thus, magnetic stimulation has a greater effect on neural tissue at greater depths and with less discomfort at the point of application. Therefore, magnetic therapy is relatively painless, non-invasive and free from side-effects. It is also convenient that magnetic fields pass through clothing.

A preliminary study by Sherief et al. [11] in 1996, showed that FMS could suppress unstable detrusor contractions in humans. Therefore, FMS may provide a more acceptable and convenient method of neuromodulation and it may even be a more effective alternative to electrical stimulation through implanted electrodes.

Our present results are in agreement with the study of Kim et al. [12], who reported an acute inhibitory effect of FMS of the pelvic floor in children with voiding dysfunction. The authors suggested that this was consistent with acute inhibition of detrusor hyper-reflexia. This inhibitory stimulus in the efferent nerve of the bladder, by stimulating the afferent sacral nerve, may induce an interneuronal change in the spinal reflex arc or spinobulbospinal reflex arc to inhibit the activity of the C-fibres that become dominant under conditions of neurological injury and thereby inhibit bladder overactivity.

The present results are also in agreement with the study of Choe et al. [13] who stated that observations may translate into real and durable symptomatic improvements defined as a ‘carry-over’ effect. Although, this phenomenon may be similar to the effect often seen in the pelvic floor with electrical stimulation. It is conceivable that optimal stimulation may have resulted in a carry-over effect, suggesting that bladder reflexes have sufficient plasticity to allow reconditioning or remodelling.

Conclusion

The present study provides evidence that PEMFT, as a non-invasive management option, has a greater effect on neurogenic OAB after SCI than TENS.

Conflicts of interest

None.

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