

ORIGINAL PAPER

Electromagnetic stimulation to reduce the hypertonia of the pelvic floor muscles and improve chronic pelvic pain in women

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Summary *Background: The increased hypertonicity or activity of pelvic floor muscles can lead to chronic pelvic pain (CPP). It represents an aspecific and persistent pain with no apparent clinical reason, affecting an estimated 6% to 16% of women worldwide. This study aimed to evaluate with validated questionnaires the efficacy and the safeness of a new device that uses Top flat Magnetic Stimulation for the management of muscular hypertonia in women with CCP. Methods: All patients underwent 8 sessions of treatment with a non-invasive electromagnetic therapeutic device. The device produces a TOP Flat Magnetic Stimulation with a uniform profile so, the muscle work aims to reduce pain while also inhibiting muscle activity. The PISQ-12 questionnaire was used for the evaluation of improvements. Side effects were monitored. Results: The PISQ-12 total mean score decreases from 29.2 (± 3.3) to 17 (± 2). Regarding the behavioural-emotive items (1-4), a decrease from 12 (± 2) to 7 (± 0.9) was observed. Physical items (5-9) decrease from 10.6 (± 1.8) to 6 (± 1.4) and the Partner Related items (10-12) from 6.6 (± 1.6) to 3.9 (± 0.4). Conclusions: The device we used in this research demonstrated to be a valid tool for the treatment of chronic pelvic pain in female patients.*

KEY WORDS: Electromagnetic stimulation; Pelvic floor hypertonia; Chronic pelvic pain; Women.

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INTRODUCTION

The increased hypertonicity or activity of pelvic floor muscles can lead to *chronic pelvic pain* (CPP) or myofascial syndrome when the type of pelvic floor dysfunction called *Pelvic floor tension myalgia* (PFTM) occurs (1). CPP management is a tremendous concern for healthcare professionals and a significant financial burden for healthcare systems because it represents an aspecific and persistent pain with no apparent clinical reason. The *World Health Organisation* (WHO) has lately recognised chronic pain as

a separate condition, defining chronic primary pain as any pain without a clear cause (2). An estimated 4% to 16% of women worldwide (3, 4) are thought to experience chronic pelvic pain in their lives, which is also known as persistent noncancer pelvic discomfort. This condition frequently results in discomfort during sex (dyspareunia), orgasmic dysfunction, and decreased desire, arousal, and lubrication in addition to producing pain in or perceived to be in the pelvic tissues (5). Pelvic discomfort and symptoms of the lower urinary tract are the two main clinical hallmarks of *chronic pelvic pain syndrome* (CPPS). Different aspects of the CPP have been investigated through the years. According to scientific research in the literature, compared to women without chronic pelvic pain, women with chronic pelvic pain exhibited increased pelvic floor muscular tone, stronger resistance to pressure application, and slower stretching of the pelvic floor muscles by the index finger (6, 7). Additionally, they demonstrated lower pelvic floor muscular flexibility and increased pelvic floor muscle stiffness. Finally, *electromyography* (EMG) analysis revealed that the women with persistent pelvic discomfort had increased myoelectrical activity in both the superficial and deep pelvic floor muscles (6, 8). Although there are many theories on the aetiology of myofascial pain, none of them have been proven in the literature. According to one idea, metabolic alterations at the level of the motor endplate that result in muscular hyperactivity or microscopic muscle injury are the source of myofascial pain (9, 10). Additionally, it has been postulated that myofascial pain involves alterations in the central nervous system, such as glial cell proliferation and neuronal cell death, which could account for the referred pain patterns observed in myofascial pain pathologies (9, 11). Finally, it has been proposed that the persistent muscle spasm and contraction associated with myofascial pain represents a compensating strategy for pelvic floor dysfunction or defects in the design of the levator ani muscle (9, 10).

Table 1.
Baseline characteristics of the study participants (n = 40).

No	Characteristics	Frequency (n)	Proportion (%)
1	Age (mean \pm SD) (years)	34.7 \pm 8.1	
	18-30	12	30
	31-50	28	60
2	Marital status		
	Married	33	82.5
	Single	7	17.5
3	Education level		
	Primary	9	22.5
	Higher education	31	77.5
4	Past medical/surgical history		
	Yes	34	85
	No	6	15
5	Family history of Pelvic Inflammatory Disease (PID)		
	Yes	18	45
	No	22	55

Myofascial pain is the most common symptom in patients with CPP and it can be the primary source of pain, unrelated to organ disease, or it can be a secondary source of pain elicited by a reflex response (visceral-muscle reflex) (3). Trigger points often develop in the affected muscles. Trigger points are specific areas of tenderness that develop in the muscle wall and can begin as just a symptom of pelvic pain, or they can be the main source of the pain. For this reason, treating trigger points can significantly reduce pain.

In addition, it has been noted that it is a very common finding that the origin of the pain area was previously affected by gynaecological (ovarian cysts, endometriosis, dyspareunia, vulvodynia, recurrent candidiasis), or urological (interstitial cystitis/painful bladder syndrome, urgency/frequency, urge incontinence), or colorectal (constipation, proctalgia fugax, irritable bowel syndrome), or tissue adherence (scarring following surgery) disorders, or other musculoskeletal or neural (pudendal neuralgia, coccygodynia, post-surgical or postnatal pelvic pain) conditions (12).

However, there is currently no standardized and reliable technique for evaluating myofascial pain. An evidence-based physical examination for myofascial pain is required considering the mounting evidence linking myofascial pain to chronic pelvic pain syndromes and new information pointing to a connection between subclinical myofascial pain and lower urinary tract symptoms (LUTS). In addition, although some aspects of the pelvic floor myofascial evaluation may be the same in men and women, the method used to access these muscles differs, hence for the purposes of this research study, we chose to concentrate on examination techniques in women (13, 14).

There are numerous treatment methods for managing PFTM and CPP, including pharmaceutical (analgesics and muscle relaxants) and non-pharmacological therapies. Between these, there are *high-voltage electro-galvanic stimulation* (HVGS), *transcutaneous electrical nerve stimulation* (TENS) devices, ultrasound, short wave diathermy, massages, posture training and strengthening exercises, biofeedback, botulin toxin injections, hydrotherapy, and sitz baths seem to be the most effective treatments.

Nevertheless, some women do not react to conventional

treatments such as medical/pharmacological management, physical therapy methods or surgery (15, 16).

It is important to remember that all these levels of pain should be treated together with a multidisciplinary therapy approach to be effective. The treatment can therefore include, in addition to the rehabilitation treatment with a midwife, also a psychological, and medical consultation and/or the use of supplements or drugs. It may happen that it is not possible to completely solve the pain. An effective treatment means that the pain has decreased to a level where you can once again enjoy your life and the activities you did before the pain began (17, 18).

In this study, we explored the effectiveness of extracorporeal Top flat Magnetic Stimulation (FMS) for improving chronic pelvic pain conditions. After its approval by the FDA in 1998, FMS is now mostly used for the treatment of Urge Urinary Incontinence (UUI). It is a viable option with the significant advantage of letting patients remain comfortable in their clothes throughout a procedure.

Depending on the protocol, the FMS technology allows the improvement of muscle mass by neuromuscular stimulation since it depolarizes motor neurons, inducing large and deep muscle contractions. On the other hand, it can help in the treatment of muscular hypertonia inducing fibres relaxation while maintaining a uniform profile and preventing any areas of irregular stimulation intensity (19).

Moreover, because magnetic stimulation has no impact on cutaneous receptors, the discomfort associated with electrostimulation is also avoided.

This study aimed to evaluate with validated questionnaires the efficacy and the safeness of a new device that uses Top flat Magnetic Stimulation for the management of muscular hypertonia in women with CCP.

MATERIALS AND METHODS

A retrospective evaluation study was conducted at the Pelvic Pain Centre, Florence, Italy between January, and September 2023.

Study population

Patients presenting secondary chronic pelvic pain due to cystitis, endometriosis or vulvodynia, and non-responders to the current available pharmacological or physical solutions, were considered in this study. To make a precise diagnosis of chronic pelvic pain, we have ruled out all other pathologies that might be causing the same kind of excruciating symptoms. These conditions included menopause, pelvic organ prolapses, genital infections, menstruation, malignant tumours, severe neurological diseases, pregnancy, obesity, and those who had metal implants or pacemakers. Patients with hypertonicity of the pelvic floor and persistent pelvic discomfort met the inclusion criteria. An experienced gynaecologist manually evaluated the pelvic floor muscles in all patients to diagnose hypertonic pelvic floor (19). Also, any previous gynaecological surgery was considered as an exclusion criterion for enrolment in the investigation. Lastly, patients were asked to avoid any other pharmacological (also painkillers) and non-pharmacological medications from 15 days before the study began and for the whole duration of the study. Other contraindications include the presence of cardiac pacemakers, implanted defibrillators/

neurostimulators, electronic or metal implants, bleeding conditions, cardiac diseases, pulmonary deficiency, malignant cancerous lesions, pregnancy, severe inflammatory conditions, fever and weight over 160 kilograms.

Study device

For this study, was used a non-invasive electromagnetic therapeutic device (*DR ARNOLD, DEKA M.E.L.A. Calenzano, Italy*) with a chair applicator and a main unit. The chair has a coil in the centre of the seat to target the deep pelvic floor area. Before each session, a gynaecologist set the patient's position to guarantee the best result. The patient's legs are set up perpendicularly so that the thighs are parallel to the floor and the feet are flat. Patients should bend their knees to a 90-degree angle or slightly higher. This way, the perineum of the patient is perfectly aligned with the centre of the seat, and the local stimulation of the sphincter muscles and pelvic floor is at maximum. The device produces a TOP Flat Magnetic Stimulation electromagnetic field with a uniform profile. The magnetic fields transmit current directly to the muscle tissue in-, contracting or relaxing it. The electromagnetic stimulation's spatial profile (Figure 1) distinguishes *DR ARNOLD* from other devices. It covers a larger area, is uniformly dispersed. Because of this configuration, electromagnetic radiation can be distributed deeply, symmetrically, and uniformly, reaching deep neural areas inside the pelvis without dispersing superficially.

Study protocols

Procedure protocols for reducing hypertonicity with low-frequency stimulations (around 10 Hz), were used. A total of 8 treatment sessions for every patient were performed. Sessions were held twice weekly for 4 weeks in a row, lasting ca 30 minutes depending on the patient's

muscle condition. After the first two minutes of warm-up for all patients, the Overtone/Pain protocol was chosen (19). The warm-up phase is a gentle muscle activation; it is a preparation step in which blood circulation is increased with low frequencies (about 5 Hz). Using frequencies of about 10 Hz, the overtone/pain protocol produces low-level electric currents on neuromuscular tissue, which depolarizes neurons and causes decontraction of the pelvic floor muscles. So, the muscle work aims to reduce pain (hyperactivity and hypertonia) while also inhibiting muscle activity. Data were gathered at the beginning of the study, at the end of each treatment session, and three months later.

Potential side effects and adverse events such as muscle soreness, momentary muscle spasms, joint/tendon pain, or local erythema/skin redness were monitored throughout the treatment period.

Validated questionnaires

CPP was assessed using the *Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire* (PISQ-12) (20). It is a test of sexual function and a condensed version of the PISQ-31 (21). The PISQ-12 has three domains: partner-related (items 10-12), physical (items 5-9), and behavioural-emotive (items 1-4). Lower scores imply enhanced sexual function. Scores are calculated by totalling the scores for each question, going from 0-never to 4-always. Reverse scoring is used for items 1, 2, 3 and 4 (20). It was administered before the first treatment and right after the last session.

Moreover, a *Visual Analogue Scale* (VAS) was used to collect information from every patient about the pain intensity perceived before and after the last treatment. The scores ranged from 0 (No Pain) to 10 (Very Painful, not bearable).

Figure 1.

Spatial profile of the uniform distribution of Flat Magnetic stimulation. Courtesy of DEKA M.E.L.A company.

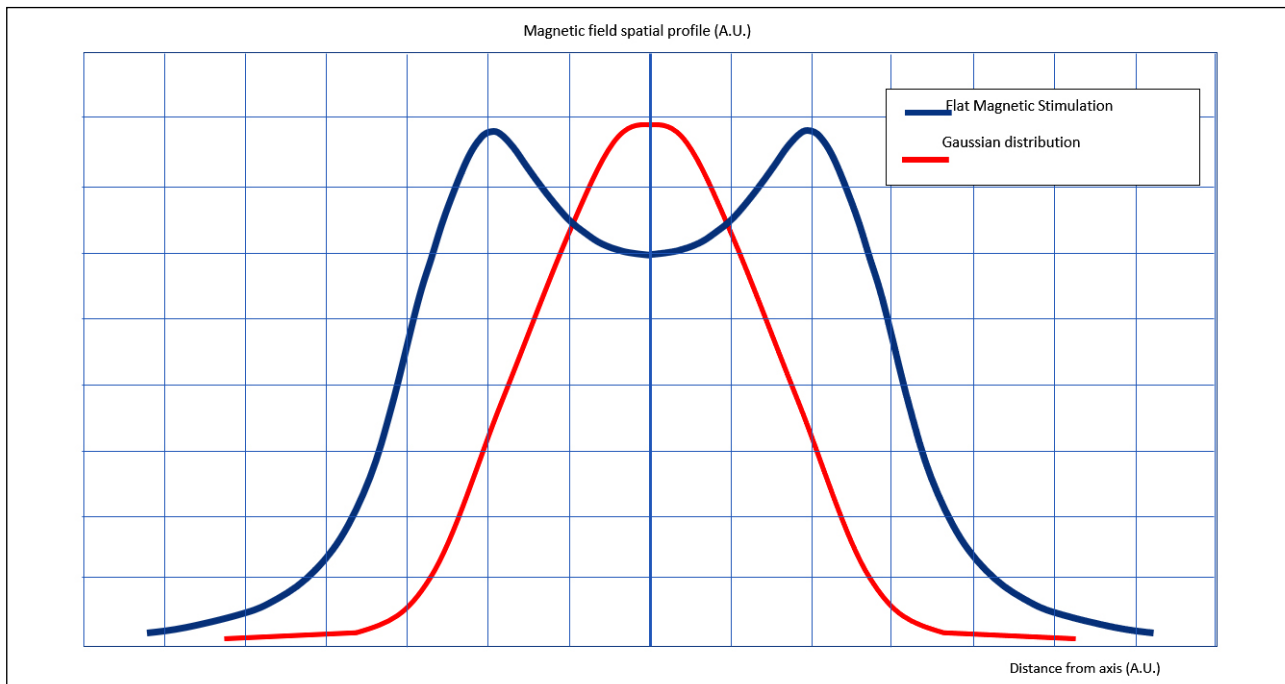
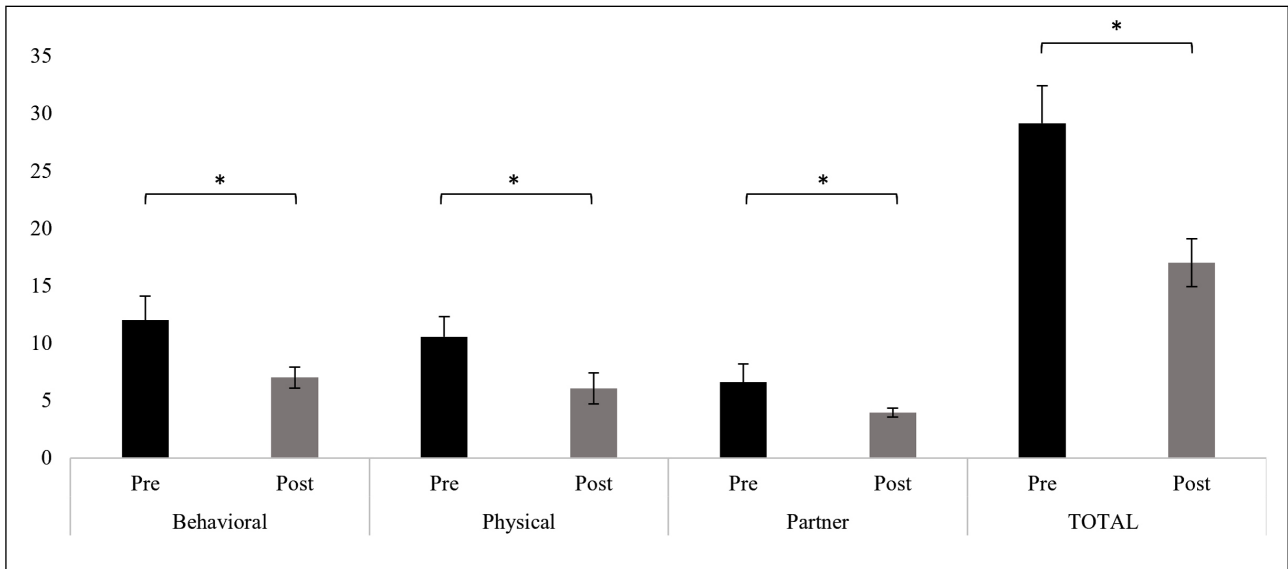


Table 2. PISQ-12 questionnaire mean results divided by different items (behavioural-emotive (items 1-4), physical (items 5-9), and partner-related (items 10-12) pre- and post-treatments.

PISQ-12 Questionnaire	Baseline Mean (± SD)	Post-treatments Mean (± SD)	Significance
Total score	29.2 (± 3.3)	17.0 (± 2.0)	p < 0.05
Behavioural-emotive Items (1-4)	12.0 (± 2.0)	7.0 (± 0.9)	p < 0.05
Physical Items (5-9)	10.6 (± 1.8)	6.0 (± 1.4)	p < 0.05
Partner related items (10-12)	6.6 (± 1.6)	3.9 (± 0.4)	p < 0.05
VAS Questionnaire	Baseline Mean (± SD)	Post-treatments Mean (± SD)	Significance
Score	8.0 (± 1.3)	3.0 (± 0.6)	p < 0.05

Moreover, most of them have had surgical events in the past. Generally, no side effects were observed during the study. When the results of the questionnaires are considered, the PISQ-12 total mean score proved to be statistically significant different (p < 0.05) and decreases from 29.2 (± 3.3) to 17 (± 2) at the end of the study. The same statistical significance is found when analysing the single items. Regarding the behavioural-emotive items (1-4), a decrease from 12 (± 2) to 7 (± 0.9) was observed. Physical items (5-9) decrease from 10.6 (± 1.8) to 6 (± 1.4) and the Partner Related items (10-12) from 6,6 (± 1.6) to 3.9 (± 0.4) (see Table 2 and Figure 2). The VAS questionnaire scores were collected by every patient at baseline (before the first treatment) and right after the last treatment. The mean score decreased from 8

Figure 2. Graphical representation of the PISQ-12 questionnaire: mean results divided by different items (behavioural-emotive (items 1-4), physical (items 5-9), and partner-related (items 10-12) at baseline (pre-first treatment) and after the last treatment.



Statistical analysis

The statistical analysis was performed with SPSS (IBM Corp., New York, USA). Specifically, the Student t-test (p < 0.05 for significance) was conducted (means and ± SDs).

RESULTS

In total, 40 women presenting secondary chronic pelvic pain were considered. Some general demographic information is reported in Table 1. The population median age was 34.7± 8.1 year (from the youngest, 19 years old, to the eldest, 45 years old). The great majority of the subjects were married (82.5%) and with a higher education (77.5%).

Table 3. VAS questionnaire mean results at baseline (before the first treatment) and after the last treatment are reported.

VAS Questionnaire	Baseline Mean (± SD)	Post-treatments Mean (± SD)	Significance
Score	8.0 (± 1.3)	3.0 (± 0.6)	p < 0.05

(± 1.3) to 3 (± 0.6) with statistical significance (p < 0.05) (see Table 3 and Figure 3).

Figure 3. Graphical representation of the VAS questionnaire for the pain intensity evaluation. The mean results pre- and post-treatment are shown.

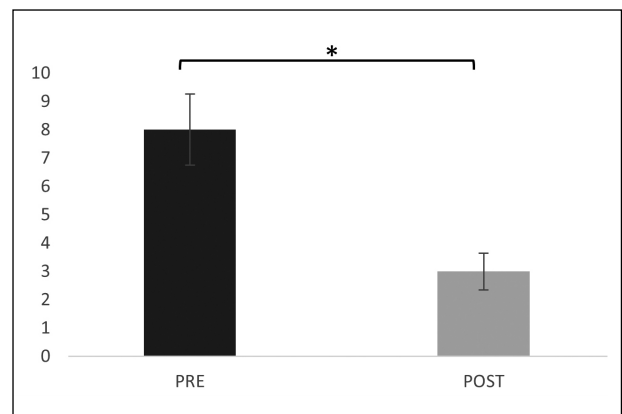
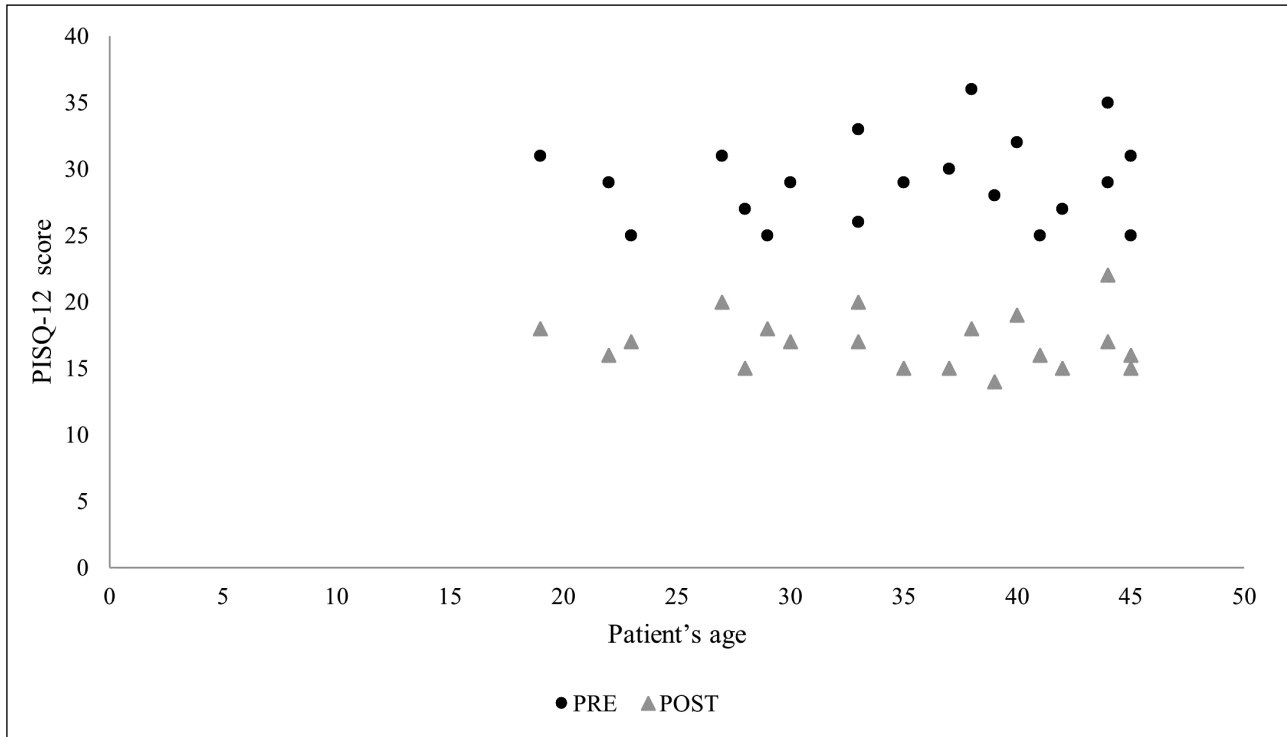


Figure 4.

Graphical representation of the correlation between the patient's age and different PISQ-12 item score results.



No correlation between the patient's age and different PISQ-12 item score results was remarkable (see Figure 4). Magnetic stimulation appears to be effective in the observed improvement of sexual function and health regardless of patient age as shown by the consistent reduction of the PISQ-12 questionnaire scores.

DISCUSSION

In women, when the pelvic floor muscles show an increased hypertonicity or activity, it can lead to CPP. The magnetic stimulation technique deeply interests the muscles of the pelvic floor, restoring neuromuscular control (22). The interaction with the tissue can result in muscle contraction or relaxation, depolarization of neuronal cells, and changes to the blood circulation system. According to the scientific literature (23-27), this technology may have an impact on the sexuality and health of a large patient population. Based on the subjective assessment, patients also reported additional therapeutic advantages, such as improved urine control (28-30) and higher sexual satisfaction (31). In fact, the overtone/pain protocol for hypertonic management may use lower frequencies (around 10 Hz) to produce an electromagnetic field distribution that is homogeneous and does not produce regions of different stimulation intensity, preventing overstimulation of the already hypersensitive receptors and sensory nerves typical of chronic pelvic pain. Because no probe is placed into the vaginal channel during muscle stimulation, the device we employed is considered non-invasive. Thanks to the steady emission of energy that is progressively given, patients can continue to be fully clothed in a comfortable and supportive chair and resume their daily activities straight immediately following sessions.

The DR ARNOLD system can also be seen as an "educator" system because it enables the patient to sense the relaxation of the treated muscles, allowing them more autonomy and awareness to choose when to repeat the next treatment session. Furthermore, the use of this novel technology can be combined with existing pharmacological or physical methods (32). The etiopathology of CPP is not fully understood. Indeed, genito-pelvic pain/penetration disorders, vulvodynia, interstitial cystitis/bladder pain syndrome and endometriosis, are just a few of the illnesses that can produce CPP. However, it's possible that women with any of these diseases have identical pelvic floor muscle tone and functionality. Studying the correlation between personal and social characteristics such as the marital status or the education level and the presence of CPP, was not matter of this research study. But, according to other investigation in literature, *pelvic floor muscle strength* (PFMS) declines with age and ageing increases the likelihood of incontinence and genital organ prolapses and also CPP development (33, 34). Furthermore, a number of studies have demonstrated a strong correlation between pelvic floor diseases and educational attainment [34-36]. Similar findings were made by Gümüşsoy *et al.* (2021) [37], where it was discovered that as women's educational levels rose, so did their PFMS values. This finding implies that women's awareness of PFMS is raised by education. According to the results of this study, women with lower income levels or without employment had lower PFMS values.

Overholt *et al.* (2019) (38) described a clinical case providing support to evaluate the efficacy of pulsed electromagnetic field therapy for the management of chronic pelvic pain in interstitial cystitis/bladder pain syndrome. Indeed, for urinary incontinence higher frequencies (fre-

quencies ≥ 20 Hz) are needed to target the muscles and improve muscular tone. In this study, device protocols with a low-frequency (10Hz) emission were used. By using the Top FMS technology, the distribution of the magnetic vibrations is homogeneous in the treated area. Indeed, these low frequencies are able to create a homogeneous distribution of the electromagnetic field that does not create regions of different stimulation intensity avoiding an overstimulation/overactivation of the pelvic floor muscles. In this way, no energy-peak can be produced. This is important because, in patients presenting CCP, these energy-peaks can cause opposite outcomes, resulting in the worsening of the pain feeling due to an overactivation of the pelvic floor muscles.

With this study we wanted to evaluate with validated questionnaires the efficacy and the safeness of a new device that uses Top flat Magnetic Stimulation for the management of muscular hypertonia in women with CCP. Our results indicated that the patient's symptoms of muscular hypertonia and chronic pelvic pain were improved. As support, the PISQ-12 questionnaire was used because of its internal consistency, test-retest reliability, and validity. After the final therapy, we have seen a considerable decrease in the PISQ-12 mean score. When the single items are considered, the trend is comparable. Also, results from the VAS questionnaires revealed a statistically significant reduction of the patient pain perception after the conclusion of the treatment cycle. No correlation between the patient's age and different PISQ-12 item score results was remarkable probably indicating the wide efficacy of the magnetic stimulation regardless the age of the patient.

Study limitations

Our long-term objective is to register additional patients to further examine this novel, non-invasive approach to treating complex illnesses such as chronic pelvic pain without sex distinction. Moreover, the number of patients enrolled should be increased and a control group should be included for better completeness. Lastly, it would be interesting to evaluate the short-term and long-term improvement of the symptoms following the patients after the conclusion of the treatment cycle.

CONCLUSIONS

The device we used in this research demonstrated to be a valid tool for the treatment of chronic pelvic pain in female patients. Further studies are needed to have a deeper knowledge about the electromagnetic stimulation activity in reducing the hypertonia of the muscles since it could be the right strategy to improve the quality of life of the patients affected.

REFERENCES

1. Grimes WR, Stratton M. *Pelvic Floor Dysfunction*, in *StatPearls, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Dec. 14, 2023. [Online]. Available: <http://www.ncbi.nlm.nih.gov/books/NBK559246/>*
2. World Health Organization (WHO), *ICD-11 for Mortality and Morbidity Statistics. Accessed: Sept 23, 2023. [Online]. Available: <https://icd.who.int/browse11/l-m/en>*.

3. Dydyk AM, Gupta N. *Chronic Pelvic Pain. in StatPearls, Treasure Island (FL): StatPearls Publishing, 2023. Accessed: Dec. 13, 2023. [Online]. Available: <http://www.ncbi.nlm.nih.gov/books/NBK554585/>*
4. Reavey J, Vincent K. *Chronic pelvic pain. Obstetrics, Gynaecology & Reproductive Medicine. 2022; 32:8-13.*
5. Faubion SS, Shuster LT, Bharucha AE. *Recognition and management of nonrelaxing pelvic floor dysfunction. Mayo Clin Proc. 2012; 87:187-193.*
6. Kadah S, Soh S-E, Morin M, et al. *Is there a difference in pelvic floor muscle tone between women with and without pelvic pain? A systematic review and meta-analysis. J Sex Med. 2023; 20:65-96.*
7. Demetriou L, Krassowski M, Mendes AP, et al. *Clinical profiling of specific diagnostic subgroups of women with chronic pelvic pain. Frontiers in Reproductive Health. 2023; 5:1140857.*
8. Franco JV, Turk T, Jung JH, et al. *Non-pharmacological interventions for treating chronic prostatitis/chronic pelvic pain syndrome. Cochrane Database Syst Rev. 2018; 5:CD012551.*
9. Meister MR, Shivakumar N, Sutcliffe S, et al. *Physical examination techniques for the assessment of pelvic floor myofascial pain: a systematic review. Am J Obstet Gynecol. 2018; 219:497.e1-497.e13.*
10. Spitznagle TM, Robinson CM. *Myofascial pelvic pain. Obstet Gynecol Clin North Am. 2014; 41:409-432.*
11. Kuner R. *Central mechanisms of pathological pain. Nat Med. 2010; 16:1258-1266.*
12. Apte G, Nelson P, Brismée J-M, et al. *Chronic female pelvic pain-part 1: clinical pathoanatomy and examination of the pelvic region. Pain Pract. 2012; 12:88-110.*
13. Bo K, Frawley HC, Haylen BT, et al. *An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. Neurourol Urodyn. 2017; 36:221-244.*
14. Pastore EA, Katzman WB. *Recognizing myofascial pelvic pain in the female patient with chronic pelvic pain. J Obstet Gynecol Neonatal Nurs. 2012; 41:680-691.*
15. Dionisi B, Senatori R. *Effect of transcutaneous electrical nerve stimulation on the postpartum dyspareunia treatment. J Obstet Gynaecol Res. 2011; 37:750-753.*
16. Ghisu G-P. *Vulvodinia - Diagnostics and Management Strategies. Praxis (Bern 1994), 2019; 108:685-691.*
17. Dionisi B, Anglana F, Inghirami P, et al. *Use of transcutaneous electrical stimulation and biofeedback for the treatment of vulvodinia (vulvar vestibular syndrome): result of 3 years of experience. Minerva Ginecol. 2008; 60:485-491.*
18. Meister MR, Sutcliffe S, Badu A. *Pelvic floor myofascial pain severity and pelvic floor disorder symptom bother: is there a correlation? Am J Obstet Gynecol. 2019; 221:235.e1-235.e15.*
19. Salsi B, Ganassi G, Lopopolo G, et al. *Approach of Chronic Pelvic Pain with Top Flat Magnetic Stimulation. Advances in Urology. 2023; 2023:9983301.*
20. Rogers RG, Coates KW, Kammerer-Doak D, et al. *A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Int Urogynecol J Pelvic Floor Dysfunct. 2003; 14:164-168.*
21. Rogers RG, Kammerer-Doak D, Villarreal AK, et al. *A new instrument to measure sexual function in women with urinary incontinence or pelvic organ prolapse. Am J Obstet Gynecol. 2001; 184:552-558.*

22. Gilling PJ, Wilson LC, Westenberget AM, et al. A double-blind randomized controlled trial of electromagnetic stimulation of the pelvic floor vs sham therapy in the treatment of women with stress urinary incontinence. *BJU Int.* 2009; 103:1386-1390.
23. Vadalà M, Palmieri B, Malagoli A, Laurino C. High-power Magnetotherapy: A New Weapon in Urinary Incontinence? *Low Urin Tract Symptoms.* 2018; 10:266-270.
24. González-Isaza P, Sánchez-Borrego R, Lugo Salcedo F, et al. Pulsed Magnetic Stimulation for Stress Urinary Incontinence and Its Impact on Sexuality and Health. *Medicina (Kaunas).* 2022; 58:1721.
25. Lopopolo G, Salsi B, Banfi A, et al. Is It Possible to Improve Urinary Incontinence and Quality of Life in Female Patients? A Clinical Evaluation of the Efficacy of Top Flat Magnetic Stimulation Technology. *Bioengineering (Basel).* 2022; 9:140.
26. Isaza PG, Borrego RS, Fusco I. A case of stress urinary incontinence after radical prostatectomy successfully treated with an innovative device based on top flat magnetic stimulation. *World J Urol.* 2022; 40:1887-1889.
27. Dominguez AP, Isaza PG, Pantoja SN, Fusco I. Role of top flat magnetic stimulation for urinary incontinence as a debilitating condition of pelvic floor dysfunction: an observational evaluation of Latin American population. *World J Urol.* 2023; 41:173-177.
28. Filippini M, Biordi N, Curcio A et al. A Qualitative and Quantitative Study to Evaluate the Effectiveness and Safety of Magnetic Stimulation in Women with Urinary Incontinence Symptoms and Pelvic Floor Disorders. *Medicina (Kaunas).* 2023; 59:879.
29. Frigerio M, Barba M, Cola A, et al. Flat Magnetic Stimulation for Stress Urinary Incontinence: A Prospective Comparison Study. *Bioengineering (Basel).* 2023; 10:295.
30. Biondo A, Isaza PG, Fusco I. Efficacy of Top Flat Magnetic Stimulation Technology for Female Stress and Urge Urinary Incontinence: A Clinical Evaluation. *World Journal of Nephrology and Urology.* 2022; 1118-23.
31. Biondo A, Murina F, Fusco I. Treatment of Pelvic Floor Hypertonic Disorders with top Flat Magnetic Stimulation in Women with Vestibulodynia: A Pilot Study. 2023. *J Women's Health Dev.* 2022; 5:175-184.
32. Rosen NO, Dawson SJ, Brooks M, Kellogg-Spadt S. Treatment of Vulvodynia: Pharmacological and Non-Pharmacological Approaches. *Drugs.* 2019; 79:483-493.
33. Li H, Wu RF, Qi F, et al. Postpartum pelvic floor function performance after two different modes of delivery. *Genet Mol Res.* 2015; 14:2994-3001.
34. Özdemir ÖÇ, Bakar Y, Özen N, Duran B. The effect of parity on pelvic floor muscle strength and quality of life in women with urinary incontinence: a cross sectional study. *J Phys Ther Sci.* 2015; 27:2133-2137.
35. Braekken IH, Majida M, Engh ME, Bø K. Are pelvic floor muscle thickness and size of levator hiatus associated with pelvic floor muscle strength, endurance and vaginal resting pressure in women with pelvic organ prolapse stages I-III? A cross sectional 3D ultrasound study. *Neurourol Urodyn.* 2014; 33:115-120.
36. Nygaard I, Barber MD, Burgio KL, et al. Prevalence of symptomatic pelvic floor disorders in US women. *JAMA.* 2008; 300:1311-1316.
37. Gümüşsoy S, Öztürk R, Kavlak O, et al. Investigating Pelvic Floor Muscle Strength in Women of Reproductive Age and Factors Affecting It. *Clin Nurs Res.* 2021; 30:1047-1058.
38. Overholt TL, Ross C, Evans RJ, Walker SJ. Pulsed Electromagnetic Field Therapy as a Complementary Alternative for Chronic Pelvic Pain Management in an Interstitial Cystitis/Bladder Pain Syndrome Patient. *Case Rep Urol.* 2019; 2019:5767568.

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Conflict of interest: BMP, IF and AC are employed at El. En. Group. The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Institutional Review Board Statement: All the authors declare that the procedures followed were in accordance with the Declaration of Helsinki. **Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.