

Flat Magnetic Stimulation for Anal Incontinence: A Prospective Study

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Introduction: Magnetic Stimulation (MS) works on neuromuscular tissue by creating a specific electromagnetic field capable of inducing an intense muscular contraction thereby deeply stimulating pelvic floor muscles and restoring neuromuscular function in a non-invasive manner. Flat MS (FMS) has a more homogeneous electromagnetic field which permits a greater recruitment of muscle fibers. With this study we aimed to evaluate the severity of symptoms and quality of life before and after treatment with Flat Magnetic Stimulation in women with anal incontinence.

Methods: This was a prospective observational study conducted from September 2023 to December 2023. At baseline and after the treatment, sexual function and the severity of anal incontinence were evaluated through validated St. Mark's and the Female Sexual Function Index - 19 (FSFI-19) scores respectively. The subjective improvement rate was determined through the Patient Global Impression of Improvement (PGI-I) questionnaire.

Results: We observed that there was a significant improvement in the St. Mark score both absolute and stratified according to the degree of severity, whereas there was no evidence of improvement in sexual function, assessed with the FSFI-19 score.

Conclusion: FMS represents an effective and safe non-invasive treatment for anal incontinence, resulting in patients' QOL improvement and decrease of incontinence scores.

Keywords: magnetic stimulation, anal incontinence, pelvic floor, quality of life

Introduction

Anal incontinence (AI) is defined as the involuntary loss of solid or liquid feces or flatus.¹ Globally, the median prevalence of AI is 7.7% and ranges between 2% and 20.7% depending on population,² increasing with age and decreasing when restricting the definition to only involuntary loss of solid and liquid stool (Fecal Incontinence, FI).^{2,3} However, prevalence may be underestimated as many patients appear reluctant to report it to healthcare providers.⁴ The main risk factors for AI are bowel disturbances such as diarrhea or constipation, rectal urgency, chronic illness, and anal sphincter trauma (especially due to obstetrical injury), but neurological disorders and other pelvic floor anatomical alterations such as rectal prolapse and descending perineum syndrome can contribute to the insurgence of the condition.⁵ Moreover, older age, smoking, obesity, limited physical activity, and white race have been found as additional risk factors.⁶ The pathogenesis is multifactorial as loss of anal continence can arise due to abnormal rectal compliance, dysfunction of the anal sphincter system, altered stool consistency, or alterations in rectal sensation.^{5,7} In women, the role of Obstetric Anal Sphincter Injuries (OASIS) in the development of AI has been widely discussed.^{8–11} Symptoms have a significant negative effect on the quality of life of the patients as incontinence can lead to a loss of confidence and self-respect, with severe ramifications on social life.⁵ According to international guidelines, detailed clinical history and physical examination are sufficient to exclude serious underlying pathologies and direct the first line of treatment.^{12,13} In patients unresponsive to first line treatment other diagnostic tests such as anal manometry, endoanal and transperineal ultrasound, MRI and fluorodefecography can be employed, especially in those patients with suspected anatomical

defects, whereas endoscopy and stool tests may prove useful in patients with suspected gastrointestinal underlying cause.^{7,14} Initial treatment is conservative: dietary adjustments, lifestyle changes, behavioral therapies, and pharmacological agents have been shown to reduce the frequency and severity of symptoms.^{12,13,15} Moreover, biofeedback and pelvic floor muscle training aimed at improving sensation, coordination, and strength of the pelvic floor muscles have shown some positive results.¹⁶ In unresponsive patients, surgery can be considered: sacral neuromodulation (SNM) is indicated as the first-line surgical option, but this approach can lead to complications such as infection, implementation site pain, seroma, and hematoma formation, despite the total complications' rate being limited,^{13,15,17} additionally when a sphincter defect has been clearly identified a sphincteroplasty may be undertaken although clinical effect may be transient.^{12,13,15,17} New approaches to AI still in clinical evaluation include autologous muscle cell therapy, magnetic sphincter augmentation, and sphincter bulking agents.^{18–20} Finally, if alternative therapies are not appropriate or have failed, a colostomy could allow patients to resume their normal activities, thus reducing the burden on their quality of life.²¹

Among the conservative therapies attempted in the management of patients with AI, magnetic stimulation (MS) has been proposed.²² MS works on neuromuscular tissue by creating a specific electromagnetic field capable of inducing intense muscular contraction thereby deeply stimulating pelvic floor muscles and restoring neuromuscular function in a non-invasive manner^{23–26} [Figure 1]. MS involves some advantages compared to functional electrical stimulation: endocavitary probes are not necessary, the patient is dressed and remains in a comfortable sitting position. Recent technological advances have improved magnetic stimulation equipment allowing for electromagnetic fields with a more homogenous profile: this guarantees an optimized treatment of the pelvic area because all areas can be stimulated with the same intensity thereby ensuring a more cohesive contraction of the pelvic floor and a greater recruitment of muscle fibers. Therefore FMS may be more effective than simple MS in treating neuromuscular dysfunctions.²⁷ However, the application of both techniques to anal incontinence is still vastly unexplored, while many studies exist that study its effect on urinary incontinence.

To our knowledge there are currently no studies evaluating the effectiveness of FMS in the treatment of AI. Considering the impact of the AI in the quality of life of patients, it is crucial to discover treatments that are both effective and acceptable to the patient. As a consequence, with this study, we aimed to evaluate the severity of symptoms and quality of life before and after treatment with Flat Magnetic Stimulation in women with anal incontinence.

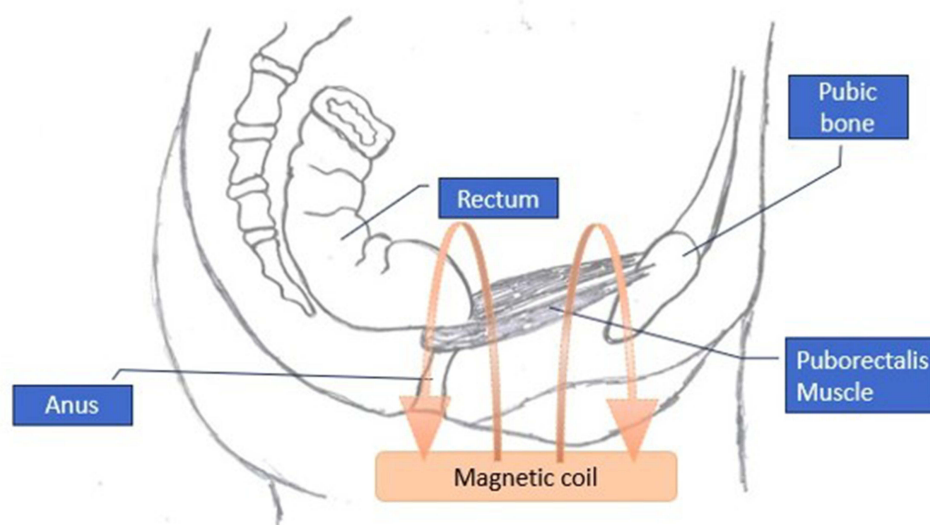


Figure 1 Magnetic stimulation works on neuromuscular tissue by creating a specific electromagnetic field which is able to optimize the effect on the entire pelvic area, in a non-invasive manner.

Materials and Methods

It is a prospective observational study conducted in a tertiary-level Urogynaecology department and included women with AI. Before starting the study we received the approval from the local Ethics Committee (protocol code: MAGCHAIR). Enrollement took place from September 2023 to December 2023 in the outpatients' group of our institution.

During the period of the study, patients suffering from anal incontinence as the main pelvic floor disorder received a clinical interview. For the purpose of this study, anal incontinence was defined as the self-reported involuntary loss of solid or liquid feces or flatus.^{2,5}

Patients were recruited among those presenting to our pelvic unit. All patients suffering from anal incontinence as the main pelvic floor disorder were evaluated by expert urogynecologists through a clinical interview which also included a pelvic exam and, if needed, an endoanal ultrasound. During the clinical interview patients who respected the criteria listed above were asked to answer, in person, a series of questionnaires to explore the impact of FI on their quality of life. At the baseline, the severity of anal incontinence was evaluated with St. Mark's score. This is a validated questionnaire that evaluates the rate of incontinence for solid/liquid stool, incontinence for gas and alteration in lifestyle on a scale ranging from 0 (never) to 4 (daily). It also evaluates the need to wear a pad or plug, the use of constipating medication, and the lack of ability to defer defecation for 15 min with a binary option of answer yes (2/4 points) or no (0 points).²⁸ The total score ranges from 0 (complete continence) to 24 (complete incontinence). We further subdivided the patients according to the degree of incontinence: 0–4 (mild), 5–8 (moderate), and more than 8 (severe). Patients were also asked to evaluate the sexual function through the Female Sexual Function Index - 19 (FSFI-19), a self-reported questionnaire with 19 items with 5-point Likert answer scales covering six domains of sexual function (sexual desire, lubrication, arousal, orgasm, pain, and satisfaction).²⁹ A cut-off of 26.5 points has been proposed to differentiate patients with and without sexual disorders. An Italian version of this questionnaire is available and can be used to evaluate sexual dysfunction in very different conditions.³⁰

Patients with a suspected defect of the anal sphincter system were evaluated through endoanal ultrasound (EAUS). EAUS has been proven as the most reliable method to diagnose an anatomical lesion of the muscle of anal sphincter, particularly in the case of internal sphincter's lesions.^{31,32} During EAUS the proximal, middle and distal segments of the anal canal are studied, thus allowing for a complete evaluation of the whole structure of both the external (EAS) and internal anal sphincters (IAS). An intact IAS normally appears as a hypoechogenic ring in the proximal and middle anal canal, with a thickness of 2–3 mm, while the EAS presents as a hyperechoic ring surrounding the IAS in the middle anal canal and the anal mucosa distally, varying between 7–9 mm in thickness. In contrast, defects are seen as irregularities in the echogenicity or as thinning of either the IAS and the EAS, usually involving the anterior (obstetric) portion of the sphincter complex especially in the case of a previous OASIs. All 3D-EAUS were performed by an expert urogynecologist (MF) using a Flex Focus 400 (BK Medical) equipped with an anorectal 3D 2052 probe. This is a mechanical multi-frequency transducer with a built-in 3D mover to provide a 360° field of view of the anal canal. Any defect of either sphincter was reported. We considered as significant any full-thickness deficit in IAS and/or EAS greater than a 30° angle in circumferential extension and more than 50% in longitudinal extension.^{33,34}

After proper counseling, patients were asked to choose between different pelvic floor rehabilitation techniques available in our Institution, such as pelvic floor muscle training, endoanal biofeedback and electrostimulation or magnetic stimulation, according to their preference, compliance to follow the treatment, distance from the Hospital or job's commitments. Exclusion criteria for magnetic stimulation were pregnancy, age less than 18 years, history of neoplasia, arrhythmia, congestive heart failure, recent deep venous thrombosis, fever, acute inflammatory diseases, or fractures in the area of treatment. Moreover, women with insufficient Italian language proficiency, weight more than 160 kg, or with neurostimulators, pacemakers, defibrillators, or ferromagnetic prostheses were excluded.

Patients who choose magnetic stimulation, in the absence of exclusion criteria, were recruited. The FMS protocol was aimed to induce and optimize muscular hypertrophy. The FMS program included 8 sessions of 25 min each, spread over one month (twice a week), with Dr. Arnold (DEKA, Calenzano, Italy). Sessions 1 to 4 followed the Hypotonus/Weakness 1 protocol. Sessions 5 to 8 followed the Hypotonus/Weakness 2 protocol. They consist of a warm-up and muscle

activation phase, with the aim of recovering tropism (volume) and muscle tone phase (protocol 1, 20–30Hz) and muscle strength phase (protocol 2, 40–50Hz) in a Trapezoidal shape.

Immediately at the end of the treatment, patients were asked again to score sexual function and the severity of anal incontinence with the St. Mark’s score and the FSFI-19 as previously stated. At the end of the treatment we also asked patients to complete the Patient Global Impression of Improvement (PGI-I) questionnaire.

The PGI-I questionnaire is a 7-point scale that allows a self-evaluation about how much the patient’s disease has improved or worsened compared to a baseline state collected at the beginning of the treatment. This scale rated as 1, very much improved; 2, much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; or 7, very much worse.³⁵ An improvement compared to baseline (PGI-I score ≤ 3) was considered as a success. All questionnaires were collected and analyzed by the clinicians responsible for the first recruitment.

We used JMP software version 17 (SAS Institute, Cary, NC, USA) for the statistics. Outcomes were reported as mean \pm standard deviation for continuous variables and as number (percentage) for noncontinuous variables. Pre and post-treatment comparisons were performed for objective and subjective outcomes and tested for statistical significance. Differences were tested using a paired *T*-test for continuous data and Chi-square test for noncontinuous data. Since there were no previous studies on FMS for AI, data on expected outcomes were not available and thus power calculation was not performed. A *p*-value <0.05 was considered statistically significant.

Results

Forty women were screened. After counseling, 21 female patients were enrolled. Population characteristics are shown in Table 1. None have significant ($>$ stage I) pelvic organ prolapse nor previously underwent hysterectomy. All patients underwent 8 sessions of Flat Magnetic Stimulation according to the described protocol. Baseline and post-treatment symptoms and quality of life are reported in Table 2. Specifically, we observed that there was a significant improvement in the St.Mark score both absolute (T0: 10.3 vs T1: 6.8, $p<0.0001$) and stratified according to the degree of severity ($p < 0.0001$), whereas there was no evidence of improvement in sexual function, accessed with the FSFI score (T0: 14.1 ± 12.2 ; T1: 16.1 ± 12.7 ; p 0.0545). During the treatment there were no adverse events. What’s more, according to the PGI-I score 76% of patients experienced an improvement of their condition. No side effects were reported.

Table 1 Population Baseline (T0) Characteristics

Variable	Mean \pm SD or Absolute (Relative) Frequency
Age [years], mean \pm SD	53.3 \pm 21.2
Menopause, n (%)	10 (47.6%)
Parity [n], median [interquartile range]	1 [1–2]
Previous OASIS, n (%)	8 (38.1%)
Sonographic defect, n (%)	10 (47.6%)
Previous functional electrical stimulation, n (%)	4 (19%)
Previous hysterectomy	0 (0%)
Significant pelvic organ prolapse	0 (0%)

Notes: Continuous data are reported as mean \pm standard deviation (SD) with the exception of parity (median [interquartile range]). Non-continuous data are reported as absolute (relative) frequency.
Abbreviation: OASIS, Obstetric anal sphincter injuries.

Table 2 Pre- (T0) and Post- (T1) Treatment Comparisons

Questionnaire	T0	T1	p value
St.Mark score (absolute), mean \pm SD	10.3 \pm 4.3	6.8 \pm 5	< 0.0001
St.Mark mild, n (%)	1 (4.8%)	8 (38.2%)	< 0.0001
St.Mark score moderate, n (%)	7 (33.3%)	6 (28.6%)	
St.Mark score severe, n (%)	13 (61.9%)	7 (33.3%)	
FSFI-19 score, mean \pm SD	14.1 \pm 12.2	16.1 \pm 12.7	0.0545
PGI-I \leq 3, n (%)	–	16 (76.2%)	n/A

Note: P-value in bold are statistically significant.

Abbreviations: FSFI-19, Female Sexual Function Index; PGI-I, Patient Global Impression Improvement; n/A, not applicable.

Discussion

Anal incontinence is a multifactorial disease.^{5,7} Retention of gas and feces is guaranteed by many continence processes. Anal incontinence arises from a variety of factors such as muscle competence, appropriate innervation, and the intricate working of all these structures collectively.³⁶ As such, treatment is multifaceted ranging from lifestyle changes to surgical options.^{12,13,15,17} Rehabilitation can be used as a viable conservative alternative: pelvic floor muscle training and endoanal biofeedback have been used with some success in treating AI.¹⁶ Compared to electrical stimulation and biofeedback, MS is a type of passive rehabilitation that is performed passively and with no need for vaginal or anal probes, which may cause discomfort among patients: in fact, patients need to be undressed and have an endocavitary plug inserted leading to feelings of shame and discomfort and therefore to poor compliance.²⁶

FMS is a relatively recent method that combines the benefits of electrostimulation with increased compliance. As a new application of a well-known physics principle, FMS implies that a fluctuating magnetic field will cause an electron flow within the field. The magnetic field's precise pulsation causes tiny currents to flow through the tissue, which in turn causes the nerve axons to depolarize. This results in a nerve impulse that travels in both proximal and distal directions. The acetylcholine relapse that follows will cause the depolarization and contraction of the corresponding muscle fibers; this process of nerve fiber depolarization, which results in muscular strengthening, is essential to the effectiveness of focal muscle stimulation. The pelvic floor muscle groups' activity is modified by the FMS clinical effect.²³

Muscle strength and endurance are increased by the repetitive activation of a muscle's activity brought on by nerve depolarization, which has a hypertrophic and hyperplastic effect on muscle tissue.²⁴ Compared to functional electrical stimulation, less electrical current is needed to modulate the nerves because of the minor impedance of the tissues than demanded by electrical stimulation.

FMS has been successfully used to treat urinary incontinence. Biondo et al analyzed 81 female patients reporting both SUI and UI. Before starting and after 3 months of follow-up, two questionnaires were administered, IIQ-7 and ICIQ-OAB. The result was a decrease in both urge and stress incontinence complaints, improving patients' QoL without risk.²⁴ Other two studies conducted in our center demonstrated that FMS is a safe and effective conservative option for SUI and UI management both from an objective and a subjective point of view. Moreover, we observed a substantial rhabdosphincter muscle hypertrophy, consisting of a 15.4% augmentation in muscular total volume.²⁵

While there is currently little research on the subject, the previously outlined concepts related to urine incontinence also apply to anal incontinence. An earlier study assessed the impact of conventional magnetic stimulation on AI. This study enrolled 30 patients who underwent an FMS treatment once weekly for 8 weeks. After this period the number of solid and liquid stool leakage per week was significantly reduced ($p < 0.05$) with a significant improvement of the Cleveland Clinic Fecal Incontinence Score (CCFIS) and fecal incontinence QOL questionnaire (FIQL) ($p < 0.05$).²²

However, the current study is the first to report the effectiveness of FMS in the treatment of AI. Our results look promising since 76% of our patients reported an improvement on quality of life after the treatment, which was particularly evident when analyzing specifically the severity of the symptoms. In fact, the St.Mark's score was

significantly reduced after treatment suggesting a quantifiable effect of FMS on the severity of AI. Moreover, the absence of side effects is particularly significant considering that AI often affects older patients who are already burdened by severe comorbidities. We did not find any improvements in sexual function. However, this may be due to the high proportion of sexually inactive women (42.8%).

Therefore our study demonstrated an objective and subjective improvement of anal incontinence and quality of life. This outcome attests to the decline in psychological distress associated with the patients' clinical state as well as the decline in the pathology-imposed forced modifications to daily living. Therefore, because FMS is non-invasive, painless, and does not need undressing, it significantly improves patient compliance when compared to other means of pelvic floor rehabilitation, such as anal electrostimulation. Because FMS produces neural stimulation, which is capable of penetrating all types of tissue without attenuation and has a lower energy intensity than anal electrostimulation, also discomfort is expected to be significantly reduced.

Limitations

The principal limitation of the study is the small sample size, which precluded any analysis of the effect of covariates and other potential influencing factors (eg diet, physical activity). Furthermore, the long-term recurrence of symptoms following the cessation of magnetic stimulation treatment remains a key point. Long-term follow-up data following stimulation are currently unavailable, given the current study was prospective and centered on evaluating the efficacy of FMS; therefore, research on the ideal duration of stimulation, combination treatments, and randomized controlled studies with a sham-stimulation group are required.

Conclusion

FMS represents a promising non-invasive treatment for anal incontinence, resulting in patients' QOL improvement and decrease of incontinence scores.

Data Sharing Statement

The data presented in this study are available on request from the corresponding author.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board of ASST Monza (protocol code MAGCHAIR), date: 7th July 2022.

Author Contributions

Conceptualization, M.B.; A.C.; D.D.V.; C.C.; M.F.; formal analysis, M.B.; A.C.; D.D.V.; I.R.; C.C.; B. d.P.; S.M.; M.F.; investigation, M.B.; A.C.; D.D.V.; C.C.; M.F.; data curation, M.B.; A.C.; D.D.V.; C.C.; I.R.; B. d.P.; S.M.; M.F.; writing—original draft preparation, M.B.; A.C.; D.D.V.; C.C.; I.R.; B. d.P.; A.V.; S.M.; M.F.; writing—review and editing, M.B.; A.C.; D. D.V.; C.C.; I.R.; B. d.P.; A.V.; M.F.; S.M. project administration M.B.; A.C.; D.D.V.; C.C.; I.R.; B. d.P.; M.F. All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflicts of interest in this work.

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