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Evaluation of Electromagnetic Therapy on The Pelvic Floor as an Alternative Treatment for Stress Urinary Incontinence

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Abstract

Introduction: The aim of this study was to determine the efficacy of focused electromagnetic therapy, a minimally invasive technique, to treat stress urinary incontinence in terms of symptom resolution and to assess the impact of this technique on health-related quality of life (HRQoL).

Method: Twenty-seven women suffering from urinary incontinence (25 moderate and 2 severe cases) participated in this observational cohort study. With an average age of 52 years (22–77), a high-intensity focused electromagnetic field (HIFEM) protocol was applied in 6 sessions of 28 minutes each using BTL Emsella equipment. In addition, participants answered the International Consultation on Incontinence Questionnaire (ICIQ) and the Questionnaire on the Impact of Urinary Incontinence on the QoL of Women (Potenziani-14-CI-IO-QOL) before and after the treatment. A univariate analysis was conducted, and normal distribution of the data scores was evaluated using Kolmogorov–Smirnov and Student's t-tests. In this study, the level of statictical significance was $p<0.005$.

Results: After the HIFEM protocal, 96.3% (n=26) of the participants presented moderate servity, and 3.7% (n=1) reported severe consequences on their QoL in Potenziani-14-CI-IO-QOL-2000. The qualitative averages showed that in Potenziani-14-CI-IO-QOL-2000, most women were still classified in the moderate category after treatment. However, from a quantitative point of view, the mean exhibited a significant decrease that was closer to the minimum score in the same category.

Conclusions: Electromagnetic therapy with a HIFEM protocol using BTL Emsella equipment is a safe alternative, and the efficacy of this method was confirmed by a decrease in the indices of severity of the symptoms in ICIQ-SF and Potenziani-14-CI-IO-QOL-2000

Keywords: Stress Uniary Incontinence; Electromagnetism; Pelvic Floor Muscle; Quality of Life

Introduction

Urinary incontinence (UI) represents a public health issue; in fact, it was estimated that in 2018, the number of people with UI worldwide would be ~420 million – 300 million women and 120 million men [1]. UI is defined as any involuntary leakage of urine that can be classified into 3 types based on etiology and pathophysiology: stress UI (SUI), urge UI (UUI), and mixed UI (MUI) [2]. Menopause-associated anatomical and functional changes of the lower genitourinary tract are important contributors to all forms of UI [3]. This condition has a considerable impact on the physical and mental conditions of patients and substantially reduces patients' quality of life (QoL) [4]; therefore, it should be measured as part of a comprehensive assessment.

Incontinence can also be evaluated using questionnaires that can define the severity, facilitate follow-up, and assess patients' QoL. Evaluating the QoL of incontinent women is the best method to learn more about the impact of this condition on their daily lives and assess their own perception of the disease [5]. Patient QoL can be measured using general or specific instruments. The first type can be implemented to compare different conditions without focusing on particular effects, and specific instruments can better respond to changes and focus on particular patient subgroups [6,7]. Both are designed to assess specific states of a disease or particular functional areas [8, 9]. Currently, specific instruments are available to measure the QoL of patients suffering from urinary incontinence. The International Consultation on Incontinence Questionnaire (ICIQ) is an example of one instrument. The ICIQ is a self-administered questionnaire that characterizes patients with UI and its impact on their QoL [10,11]. Another instrument is the Questionnaire on the Impact of Urinary Incontinence on the QoL of Women (Potenziani-14-CI-IO-QOL-2000), which assesses information about the impact of UI on the daily life of female patients based on occurrences of urine leakages [12,13].

Successful treatment depends on accurate diagnosis of the type of incontinence, identification and treatment of any modifiable contributing factors and a personalized therapeutic approach [14]. As a result of the growing popularity of conservative treatments and minimally invasive therapy, new treatments have emerged in recent years to address stress urinary incontinence [15]. Magnetic stimulation (MS) was approved by the US Food and Drug Administration (FDA) in 1998, and it has demonstrated effective results in previous studies. MS has also shown encouraging response rates in the long term and minimum adverse effects, which makes it an appealing nonsurgical alternative for patients who do not wish to undergo surgery [16]. MS therapy uses high-intensity focused electromagnetism (HIFEM) technology [17] to produce changes in the electromagnetic field that generate an electric current and depolarize the motor neuron that triggers the contraction of the muscles in the pelvic floor. This produces longer supramaximal contractions, and the recruitment of more muscle fibers is equivalent to 12000 regular contractions [18,19]. MS is well accepted and well tolerated and results in high treatment satisfaction among women with SUI [20].

The aim of this study was to determine the efficacy of focused electromagnetic therapy, a minimally invasive technique, to treat stress urinary incontinence in terms of symptom resolution and the impact on health-related quality of life (HRQoL).

Materials and Methods

In this observational cohort study with a longitudinal and prospective approach, the convenience sample was composed of 27 female patients between 22 and 71 years who sought consultation due to stress urinary incontinence between September 2018 and August 2020. Subjects participated voluntarily in this study, and a pelvic floor muscle training (PFMT) protocol was applied as an alternative treatment for their condition.

Inclusion and Exclusion Criteria

Patients willing to participate with a history of at least 6 months, of stress urinary incontinence confirmed with stress test upon clinical examination, no genital prolapse stage pop Q >1 ,no history of previous anti incontinence surgery or pharmacological therapy patients with BMI >35 and history of hip metal implants or cardiac pacemakers were excluded from the study ,All the patients provided written informed consent before participation and detailed personal history, age, and previous diseases.

The protocol is considered to be minimally risky in Resolution 8430 of 1993 of the Colombian Ministry of Health. Each patient was assessed using the International Consultation on Incontinence Questionnaire (ICIQ) [21] and the Questionnaire on the Impact of Urinary Incontinence on the QoL of women (Potenziani-14-CI-IO-QOL) [12] before the treatment and 4 weeks after completion. Electromagnetic therapy was applied using BTL Emsella equipment. During the application of the PFMT,

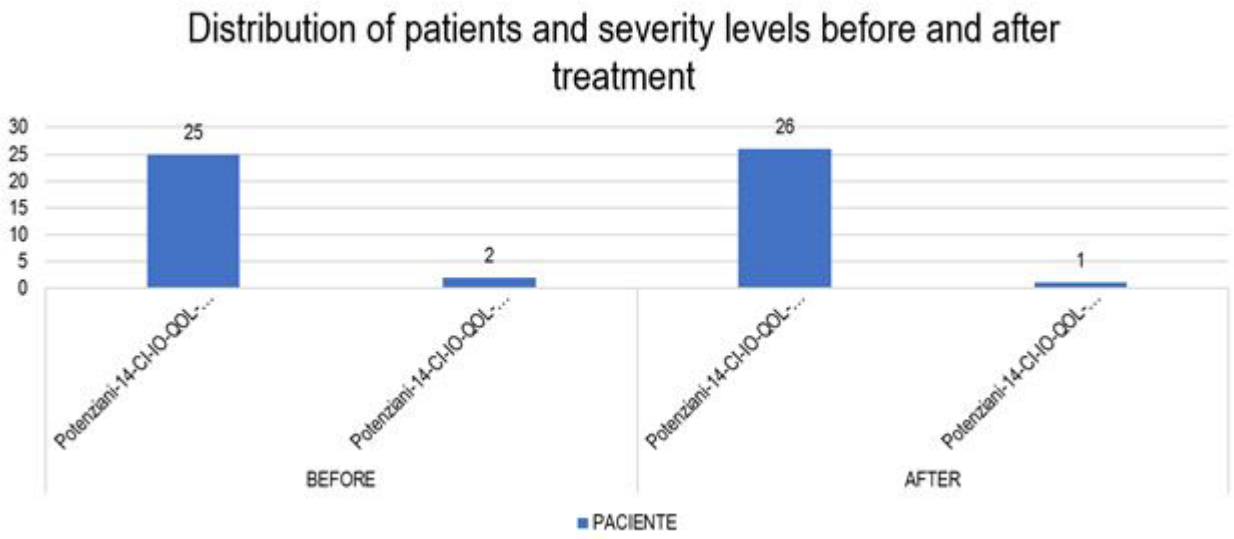
the patients were fully dressed and seated on the center of the chair while alternating magnetic fields (of intensities up to 2.5 T) penetrated the pelvic region. This procedure was repeated in 6 sessions that were performed 2 to 3 times a week for 28 minutes each session.

To analyze the information, we used a systematized database in SPSS software (version 22) for Apple macOS licensed to Universidad de Caldas. In such software, we analyzed the differences between averages before and after treatment; in addition, we applied the Kolmogorov–Smirnov statistical test to determine the normality of the distribution and Student's t-test for related samples. The statistical significance level considered in this paper was $p<0.005$.

Results

The study population was composed of 27 women (n=27) with an average age of 52 years. Before the treatment, 22.2% (n=6) of the patients presented severe urinary incontinence on the ICIQ scale, which is defined as a score greater than 12, and 78.8% (n=21) suffered from moderate urinary incontinence, i.e., an ICIQ score under 12. Their answers in the Potenziani-14-CI-IO-QOL-2000 indicated that 92.4% (n=25) experienced moderate negative effects on their QoL, and 7.4% (n=2) suffered severe negative consequences. The application of the Kolmogorov–Smirnov and Student's t-test showed that the scores on the scales had a normal distribution.

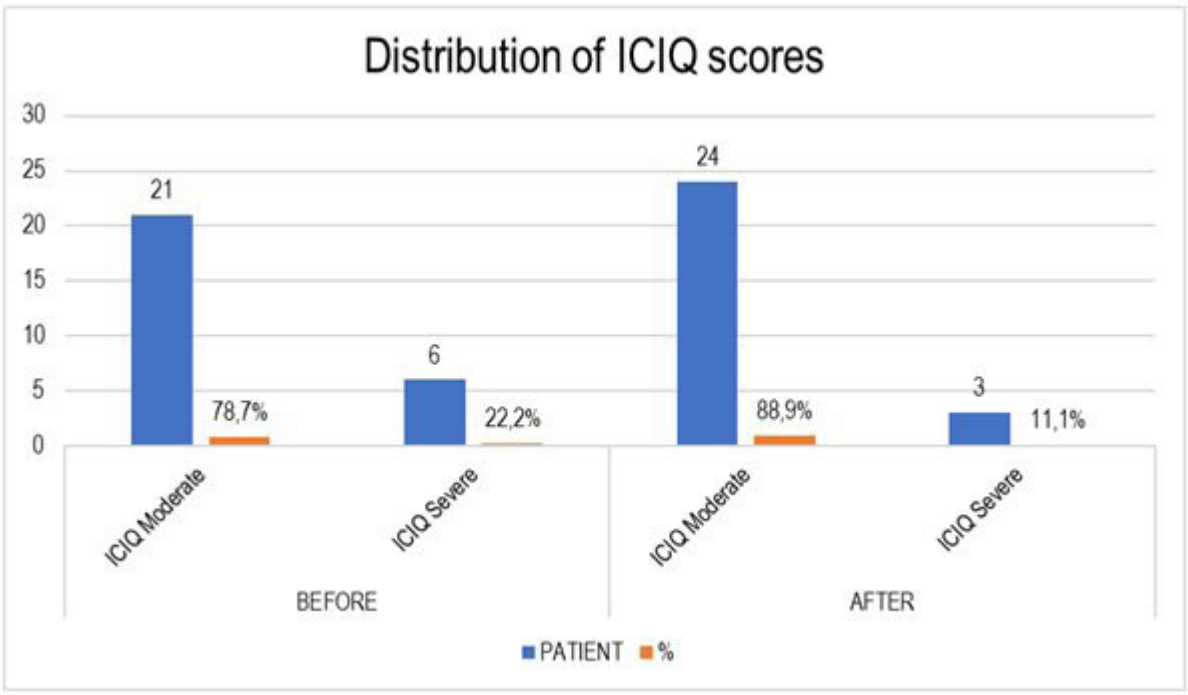
After the EM protocol, 11.1% (n=3) reported severe urinary incontinence on the ICIQ scale, i.e., a score greater than 12, and 88.9% (n=24) reported moderate urinary incontinence, i.e., a score less than 12. Therefore, the group with severe incontinence was divided in half.



Source: Created by the authors. Distribution of total values and percentages of the cumulative averages in the two questionnaires: Potenziani-14-CI-IO-QOL-2000 and ICIQ

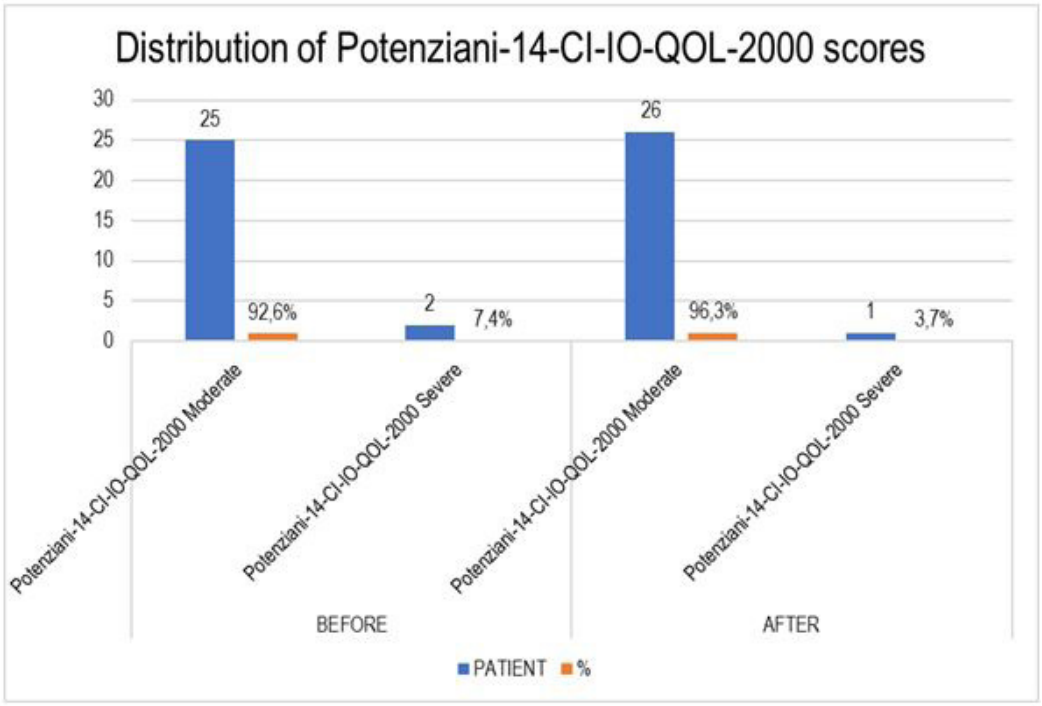
Figure 1: Distribution of patients and severity levels before and after treatment

In addition, the ICIQ score presented a mean reduction of 3.8 points, and the average score on the questionnaire after treatment was 5.7 with a p-value of 0.000. The means in Table 1, which ranged from 1 to 18, were used to make the comparison before and after the protocol was applied.



Source: Created by the authors. Distribution of total values and percentages of the cumulative averages in the ICIQ. Distribution of Potenziani-14-CI-IO-QOL-2000 scores. Distribution of ICIQ scores.

Figure 2: Distribution of ICIQ scores



Source: Created by the authors. Distribution of total values and percentages of the cumulative averages in the Potenziani-14-CI-IO-QOL-2000.

Figure 3: Distribustion of Potenziani-14-CI-IO-QOL-2000 Scores

Table 1: The distribution of scores in the ICIQ-SF before and after the application of the protocol as well as the numerical differences between the two

Patient number assigned in this study	**ICIQ-SF score before treatment**	Level of urinary incontinence before treatment	**ICIQ-SF score after treatment**	Level of urinary incontinence after treatment	Difference
1	18	Severe	15	Severe	3
2	14	Severe	8	Moderate	6
3	7	Moderate	8	Moderate	-1
4	7	Moderate	3	Moderate	4
5	10	Moderate	3	Moderate	7
6	6	Moderate	4	Moderate	2
7	8	Moderate	1	Moderate	7
8	7	Moderate	4	Moderate	3
9	12	Moderate	7	Moderate	5
10	9	Moderate	4	Moderate	5
11	1	Moderate	1	Moderate	0
12	9	Moderate	7	Moderate	2
13	8	Moderate	4	Moderate	4
14	18	Severe	5	Moderate	13
15	6	Moderate	4	Moderate	2
16	6	Moderate	1	Moderate	5
17	9	Moderate	6	Moderate	3
18	4	Moderate	1	Moderate	3
19	7	Moderate	1	Moderate	6
20	10	Moderate	4	Moderate	6
21	10	Moderate	9	Moderate	1
22	1	Moderate	1	Moderate	0
23	14	Moderate	10	Moderate	4
24	17	Severe	16	Severe	1
25	16	Severe	16	Severe	0
26	9	Moderate	5	Moderate	4
27	15	Severe	6	Moderate	9

Source: Created by the authors. Average scores on the ICIQ-SF before and after the protocol.

After the electromagnetic protocol, in the Potenziani-14-CI-IO-QOL-2000, 96.3% (n=26) of the participants presented moderate severity, and 3.7% (n=1) reported severe effects on their QoL. This finding indicates that the index of severity of the condition was improved in 1 patient. Thus, in Table 2, the average score in the Potenziani-14-CI-IO-QOL-2000 after treatment was 6.9 with a p-value of 0.000, which was used to compare means before and after the protocol.

Table 2: Presents the distribution of scores in the Potenziani-14-CI-IO-QOL-2000 before and after the application of the protocol as well as the difference between the two

Patient number assigned in this study	**Potenziani-14-CI-IO-QOL score before treatment**	Severity level before treatment	**Potenziani-14-CI-IO-QOL score after treatment**	Severity level after treatment	Difference
1	16	Severe	15	Severe	-1
2	13	Moderate	13	Moderate	0
3	9	Moderate	7	Moderate	-2
4	9	Moderate	6	Moderate	-3
5	10	Moderate	5	Moderate	-5
6	4	Moderate	3	Moderate	-1
7	10	Moderate	5	Moderate	-5
8	5	Moderate	6	Moderate	1
9	11	Moderate	8	Moderate	-3
10	3	Moderate	5	Moderate	2
11	4	Moderate	4	Moderate	0
12	9	Moderate	11	Moderate	2
13	6	Moderate	3	Moderate	-3
14	12	Moderate	11	Moderate	-1
15	7	Moderate	6	Moderate	-1
16	10	Moderate	10	Moderate	0
17	10	Moderate	8	Moderate	-2
18	6	Moderate	4	Moderate	-2
19	8	Moderate	4	Moderate	-4
20	12	Moderate	6	Moderate	-6
21	9	Moderate	6	Moderate	-3
22	4	Moderate	4	Moderate	0
23	14	Moderate	8	Moderate	-6
24	19	Severe	10	Moderate	-9
25	10	Moderate	6	Moderate	-4
26	8	Moderate	6	Moderate	-2
27	7	Moderate	6	Moderate	-1

Source: Created by the authors. Average Potenziani-14-CI-IO-QOL-2000 scores before and after the protocol.

The qualitative averages show that in Potenziani-14-CI-IO-QOL-2000, most women were classified in the moderate category; however, when the evaluation was quantitative, the mean exhibited a significant decrease and was closer to the minimum score in this category.

No adverse effects were reported during the application of the PFMT protocol to treat urinary incontinence.

Discussion

Electromagnetic therapy is considered a feasible and safe alternative to approach for stress urinary incontinence and has been employed as a successful adjuvant therapy in many cases [16,18]. Nevertheless, in this study, it was used as monotherapy and demonstrated a statistically significant decrease (6.9 points) in the indices of severity of urinary incontinence. These results are consistent with Silantyeva, *et al.* [17], who found that HIFEM therapy offers positive results, improving the QoL of patients.

In our experience, pelvic floor rehabilitation is an effective therapeutic weapon in the treatment of SUI, which helps to improve the QoL of patients. According to a recent meta-analysis of studies with short-term follow-up, MS leads to an improvement in SUI without any reported safety concerns and an improvement in patient quality of life [22]. However, the long-term outcome of this technique remains unclear and is the subject of ongoing research.

Different questionnaires are used to assess the impact of SUI on the QoL of patients, although we agree with other authors [23] in recommending the use of the Potenziani-14- CI-IO-QOL-2000 questionnaire, which favors the collaboration of the patient for its completion, given its simplicity. Currently, some of the most important parameters to be evaluated in lower urinary tract symptoms (LUTS) are changes in the QoL of patients due to the presence or absence of a disease, which can be measured using tools, such as the Potenziani-14-CI-IO-QOL-2000 questionnaire. In this study, a statistically significant reduction in the mean of the values was noted after electromagnetic therapy (3.8 points). This finding is consistent with the paper by Lim, *et al.* [16], who showed that electromagnetic interventions produce positive changes in the questionnaire results on QoL.

The instruments used in this protocol evidenced an improvement in the QoL of the patients who underwent the protocol, which has been reported by He Q, *et al.* [24]. This improvement could reduce the incidence of depression, anxiety, and social isolation and affect personal relationships caused by UI, thus enabling patients to perform their daily activities without major inconveniences. As indicated by Suarez, *et al.* [25], the QoL of incontinent women can be greatly affected by the presence of even mild symptoms (no matter how severe) given their own perception of their role in society.

This study had two limitations: a small sample size and the use of monotherapy without other associated factors.

Conclusion

Electromagnetic therapy with a PFMT protocol using BTL Emsella equipment is a safe treatment method, and its efficacy was confirmed by a decrease in the indices of severity of the symptoms in two questionnaires, i.e., the ICIQ-SF and Potenziani-14-CI-IO-QOL-2000, which are tailored for female patients.

The selection of treatments for SUI should always consider a balance between risks and benefits as well as patient preferences, despite a short follow up period,this promising PFMT protocol, offers high acceptance, and adherence. This is an attractive noninvasive option for patients who cannot or do not wish to undergo surgical procedures.limitations to this study are related to a small sample size and the use of monotherapy. Therefore, future research in this field should adopt a more comprehensive approach including other variables of interest a control group against placebo or guided pelvic floor muscle training and a longer follow-up.

Conflict of Interest

Disclosure

The authors report no conflicts of interest in this work. The authors are solely responsible for the article, and BTL has not participated in data analysis or article preparation. This paper did not receive any specific grant from funding agencies in the public, commercial or not-for-profit sectors.

Author contributions

All authors contributed to data analysis, drafted and critically revised the paper, gave final approval of the version to be published, and agreed to be accountable for all aspects of the work.

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References

1. Abrams P, Cardozo L, Wagg A, Wein A (2017) Incontinence 6th edition ICI-ICS. International Continence Society, 2017. Bristol UK.

2. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B , *et al.* (2010) An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J 21: 5-26.

3. Lugo Salcedo F, Sánchez Borrego R; G.U.I.A.S Group (2013) Assessment of female prevalence of overactive bladder (OAB) in Barcelona using a self-administered screening questionnaire: the Cuestionario de Autoevaluación del Control de la Vejiga (CACV). Int Urogynecol J 24: 1559-66.

4. Cheng S, Lin D, Hu T (2020) Association of urinary incontinence and depression or anxiety: a meta-analysis. J Int Med Res 48: 300060520931348.

5. National Guideline Alliance (UK) (2019) Urinary incontinence and pelvic organ prolapse in women: management. London: National Institute for Health and Care Excellence (UK). 6. Monz B, Espuña M, Hampel C, Hunskaar S, Quail D , *et al.* (2005) Patient-reported impact of urinary incontinence--results from treatment seeking women in 14 European countries. Maturitas. 30: S24-34.

7. Lauffer A, Solé L, Bernstein S, Lopes MH, Francisconi CF (2013) Practical aspects for minimizing errors in the cross-cultural adaptation and validation of quality of life questionnaires. Rev Gastroenterol Mex 78: 159-76.

8. Bakali E, Johnson E, Buckley BS, Hilton P, Walker B , *et al.* (2019) Interventions for treating recurrent stress urinary incontinence after failed minimally invasive synthetic midurethral tape surgery in women. Cochrane Database Syst Rev 4: CD009407.

9. Badia Llach X, Castro Díaz D, Conejero Sugrañes J (2000) Validity of the King's Health questionnaire in the assessment of quality of life of patients with urinary incontinence. The King's Group]. Med Clin (Barc). 114: 647-52.

10. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M , *et al.* (2004) ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn 23: 322-30.

11. Nyström E, Sjöström M, Stenlund H, Samuelsson E (2014) ICIQ symptom and quality of life instruments measure clinically relevant improvements in women with stress urinary incontinence. Neurourol Urodyn 34: 747-51.

12. Questionnaire on the impact of urinary incontinence on the quality of life of women (Potenziani- 14-CI-IO-QOL-2000). Madrid: Spanish Association of Urology.

13. Amesty MV, Chocarro G, Lobato R, Monsalve S, Martinez-Urrutia MJ , *et al.* (2016) Quality of Life in Female Epispadias. Eur J Pediatr Surg 26: 277-81.

14. Russo E, Caretto M, Giannini A, Bitzer J, Cano A , *et al.* (2021) Management of urinary incontinence in postmenopausal women: An EMAS clinical guide. Maturitas 143: 223-30.

15. Mazur-Bialy AI, Kołomańska-Bogucka D, Nowakowski C, Tim S (2020) Urinary Incontinence in Women: Modern Methods of Physiotherapy as a Support for Surgical Treatment or Independent Therapy. J Clin Med 9: 1211.

16. Lim R, Lee SW, Tan PY, Liong ML, Yuen KH (2015) Efficacy of electromagnetic therapy for urinary incontinence: A systematic review. Neurourol Urodyn 34: 713-22.

17. Silantyeva E, Zarkovic D, Astafeva E, Soldatskaia R, Orazov M , *et al.* (2020) Academician of the Russian Academy of Sciences. A Comparative Study on the Effects of High-Intensity Focused Electromagnetic Technology and Electrostimulation for the Treatment of Pelvic Floor Muscles and Urinary Incontinence in Parous Women: Analysis of Posttreatment Data. Female Pelvic Med Reconstr Surg.

18. Lim R, Liong ML, Leong WS, Khan NAK, Yuen KH (2017) Effect of pulsed magnetic stimulation on quality of life of female patients with stress urinary incontinence: an IDEAL-D stage 2b study. Int Urogynecol J 29: 547-54.

19. Samuels JB, Pezzella A, Berenholz J, Alinsod R (2019) Safety and Efficacy of a Non-Invasive High-Intensity Focused

Electromagnetic Field (HIFEM) Device for Treatment of Urinary Incontinence and Enhancement of Quality of Life. Lasers Surg Med 51: 760-6.

20. Lim R, Liong ML, Leong WS, Khan NAK, Yuen KH (2018) Patients' perception and satisfaction with pulsed magnetic stimulation for treatment of female stress urinary incontinence. Int Urogynecol J 29: 997-1004.

21. Espuña M, Rebollo P, Puig M (2004) Validation of the Spanish version of the International Consultation on Incontinence Questionnaire-Short Form. A questionnaire for assessing the urinary Incontinence. Med Clin 122: 288-92.

22. Peng L, Zeng X, Shen H, Luo DY (2019) Magnetic stimulation for female patients with stress urinary incontinence, a meta-analysis of studies with short-term follow-up. Medicine (Baltimore) 98: e15572.

23. Aranda Lozano J, Sierra Labarta R (2018) Stress Urinary Incontinence in Women: Impact in the Quality of Life after Pelvic Floor Rehabilitation. Rev Arg de Urol 83: 60-67.

24. He Q, Xiao K, Peng L (2019) An Effective Meta-analysis of Magnetic Stimulation Therapy for Urinary Incontinence. Sci Rep 9: 9077.

25. Suárez Serrano CM, Medrano Sánchez E, Díaz Mohedo E, de la Casa Almeida M, Chillón Martínez R, (2013) Affection of the quality of life in women with urinary incontinence. Physiotherapy 35: 18-23.