High-Intensity Focused Electromagnetic Field (HIFEM) Technology Paves the Way for Incontinent Women to Better Quality of Life and Sexual Function

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Abstract

Objectives : The evaluation of efficacy and tolerability of flat magnetic stimulation (FMS) for pelvic floor muscle (PFM) training using the high-intensity focused electromagnetic field (HIFEM) technology for female urinary incontinence (UI).

Patients & Methods : 153 women, 60 with recurrent (Group R) and 93 with De Novo UI (Group D) were assessed at enrolment (Ass 1), at the end of sessions (Ass 2), and 6 weeks later (Ass 3) subjectively using the Pad-Usage Questionnaire (PUQ), the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), and the Female Sexual Function Index (FSFI), objectively using the International Continence Society-Uniform Cough Stress Test (ICS-UCST), and for satisfaction by the procedure outcomes. All patients received 2 sessions of 28 minutes weekly for 6 weeks. Procedure effectiveness was determined subjectively by achieving >50% reductions on the PUQ and ICIQ-SF questionnaires at Ass 3 concerning Ass 1 and objectively by a negative ICS-UCST. The frequency and severity of adverse events (AEs) were determined.

Results: At Ass 3, 99.4% and 61.4% of women achieved the procedure-effectiveness cutoff point for PUQ and ICIQ-SF scores, respectively. Objectively, 68.6%of women had negative ICS-UCST, and 60.1% of women were very satisfied-to-satisfied by the procedure outcomes. Thirty-one AEs were reported by 21 women, but all were transient and faded away in the next session. Procedure effectiveness variates were significantly better in (Group D) women, while the frequency of AEs and FSFI scores showed non-significant differences between both groups. Desire scorings were changed significantly at (Ass 3) with significantly higher scores for (Group D) women.

Conclusion: FMS of PFM using HIFEM technology is a promising efficient non-invasive therapeutic strategy for female UI with a high satisfaction rate, minimal AE, and improved sexual desire.

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Introduction

Urinary incontinence (UI) is a common global condition, which affects both genders, especially elder people [1]. UI is mostly due to disturbed physiological urination-controlling factors: such as weak pelvic floor muscles, overactive or weak bladder muscles, and pelvic muscle or nerve injury [2]. However, a national survey suggested an association between urge urinary incontinence (UUI) and household income and assured that social inequity is perhaps the greatest driver of UUI [3]. The same survey detected lower oxidative balance scores in participants who experienced UI and the prevalence of UI showed an inverted U-shaped trend with increased oxidative stress [4]. Another study found that anxiety and depression are more prevalent in UUI and mixed UI (MUI) patients than in stress UI (SUI) patients and are more with increasing severity of incontinence [5]. Also, patients with obstructive sleep apnea syndrome showed worse urinary continence recovery than patients free of obstructive airways [6].

Lower urinary tract symptoms are prevalent in the female population and are increased in both frequency and severity with age. However, urgency and incontinence are the most bothersome symptoms [7]. SUI is defined as UI that occurs concomitantly with effort as physical exercise and even with coughing and sneezing, frequently affects women after middle age and harms their quality of life (QOL) and sexual function [8].

Multiple therapeutic lines were tried for female UI, and a recent survey study found pharmacotherapy was the most common UI intervention, and the most often treated women were those with more severe and longer duration of symptoms [1]. However, about 20% of UI female patients did not receive any therapeutic line and 23% were dependent on behavioral treatments (24%), while the minority receives either neuromodulation or onabotulinumtoxin-A therapy [9]. The standard mid-urethral sling for SUI showed an acceptable success rate, and the Altis single-incision sling was also found to be effective with low adverse event rates [10].

Objectives

The assessment of the efficacy of flat magnetic stimulation (FMS) for pelvic floor muscle (PFM) training using the High-intensity focused electromagnetic field (HIFEM) technology as a non-invasive therapy for female UI.

Design

Prospective comparative clinical trial

Setting

Department of Obstetrics & Gynecology, Faculty of Medicine, Benha University in conjunction with multiple private Gynecological centers.

Study Rational

The use of non-invasive modalities for the management of female USI, whenever surgical correction is indicated, may be advantageous for these patients in terms of regaining volitional control over the micturition process with subsequent functional and psychological improvement and sparing the psychological, physical, and financial impacts of surgery, especially for women in active life.

Blindness and authors' contributions

Preparatory evaluations (Ass 1) and the conduction of questionnaires for functional, sexual, and QOL evaluation were provided by an author (Dr. Abdelzaher YMA), who is also responsible for patients' evaluations

regarding inclusion and exclusion criteria. The assignment and provision of settings were the responsibility of another author (Dr. Elshirbeny MF) who was blinded by the results of the preparatory evaluation. At the end of the sessions (Ass 2), and 6 weeks later (Ass 3), another evaluation session was provided by an author (Amer WM) who was blinded by the results of the preparatory evaluation. Following complete case collection, the results of the evaluations were interpreted to determine the outcomes.

Patients' approval of the study protocol

The study rationale and protocol of sessions were discussed with the patients before the preparatory evaluations, and patients accepted to participate in the study were evaluated for inclusion and exclusion criteria, and those fulfilling the indications for enrolment were asked to sign the written fully informed consent according to the institutional rules.

Ethical considerations

The study protocol was approved by the departmental committee in June 2019 to allow case collection. In the end, after the completion of case collection and sessions, the final approval of the protocol and its outcomes was obtained by the Local Ethical Committee. RC:3-8-2023.

Initial evaluation

During Ass 1, age and body mass index (BMI), which was calculated as weight divided by height in square meters, were determined. An obstetric history concerning several pregnancies, labors, and living offspring, mode of delivery (spontaneous or instrumental vaginal delivery) need for episiotomy and efficacy of its repair, development of tears during delivery, and the quality of its repair and operative delivery was recorded. UI data including type and severity, previous evaluation, and treatment and its results were obtained. Full gynecological examination to determine the presence of pelvic prolapse, its type, degree, and associated symptoms other than UI. Urine analysis with bacteriological examination to exclude urinary tract infection was performed. Cystoscopic examination and urodynamic studies were undertaken if indicated.

Exclusion criteria

Women who had multiple recurrences after surgical corrections of their SUI, women who had recurrences after surgical procedures other than the trans-obturator tape (TOT) procedure, and women who had moderate or severe degrees of urogenital prolapse, were maintained on hormonal therapy, refused the study rationale, or missed sessions or follow-up visits were excluded from the study.

Inclusion criteria

Women who had UI either DE Novo or recurrent after the TOT procedure for the first time, accepted the study rationale, and completed the sessions and follow-up visits were included in the study.

Evaluation tools

These tools were applied at Ass 1 for the primary evaluation of the patient's problems and at Ass 2 and Ass 3 to assess the outcomes of the applied procedure. The used tools included:

1. Two-day Voiding Dairy (2-d VD): to assess the volume and frequency of voids by daytime and nighttime, the amount leaked, the relation of leak to activity and type of the triggering activities, and the presence of urgency [11]. These points have to be fulfilled by the patient herself for three days and registered in the provided printed form (Appendix I).
2. The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) consists of three items

regarding the average frequency and amount of leakage, the impact of leakage on QOL over the past four weeks for a score range of 0-21 with a higher score indicates greater impairment secondary to incontinence [12].

3. Pad usage questionnaire to evaluate the number of pads used per day [13].
4. The Female Sexual Function Index (FSFI) is a questionnaire consisting of 6 domains evaluating Desire, Arousal, Lubrication, Orgasm, Satisfaction, and Pain. Each item was rated from 1-5 with items concerning difficult function, and pain related in reverse according to its severity and the sum of points was calculated with the lower the score, the more sexual dysfunction [14].
5. The International Continence Society - Uniform Cough Stress Test (ICS-UCST) was performed at each assessment to objectively detect SUI, and its results were qualitatively evaluated as positive or negative tests. While the patient was in a lithotomy position with 200-400 ml of fluid in the bladder as judged by the US, the patient was asked to cough forcefully 1-4 times, and the examiner directly visualizes the urethral meatus for the presence of leakage coincident with/ simultaneous to the cough(s), which is considered a positive test [15].

Treatment Protocol

- The device rationale, the used device (BTL EMSELLA, BTL Medical Technologies Inc., Canada), as described by the manufacturer, depends on the generation of a rapidly changing electromagnetic field of high intensity reaching up to 2.5 T that was produced by a flat spiral-shaped coil, which is situated within a uniquely-designed seat for comfortable patient's seating position. The HIFEM interacts with motor neurons and triggers stimulation and toning of the pelvic floor area to help restoration of neuromuscular control. A single session of FMS causes thousands of supramaximal PFM contractions.
- Treatment protocol: each woman was assigned to receive 2 sessions of 28 mins weekly for 6 weeks. The patient was asked to sit straight in the center of the chair seat to ensure PFM stimulation. The author responsible for the provision of HIFEM sessions must confirm patients' posture during the session and adjust HIFEM intensity as high as tolerated by the patient

Study outcomes

- Effectiveness endpoints included subjective dryness, negative ICS-UCST, and adverse events (16).

- The primary effectiveness endpoint, as defined by the FDA, was a reduction of baseline (Ass-1) 2-d VD, ICIQ-SF, FSFI and PUQ by ≥50% at 6-w after the last session (Ass-3).
- The primary safety endpoint was the rate of related adverse events (AE) throughout the observation period. Local AE occurred locally to the treated area including muscle, joint or tendon pain, muscle spasm, local erythema or skin redness. AE was evaluated as frequency per patient, total number, and if temporary or persistent.

- The secondary effectiveness endpoint was patients' satisfaction scoring using a Likert scale of 1-5 items; very dissatisfactory, dissatisfactory, Neither dissatisfactory nor satisfactory, satisfactory or very satisfactory. Each item is given a score from 1 to 5 with a higher score indicating a higher satisfaction rate.

Results

Evaluation of patients attending the Gynecology outpatient clinic excluded 23

women; 7 were maintained on hormonal therapies for multiple indications, 5 had recurrent UI after surgical procedures than TOT, 8 had moderate-to-severe genitourinary prolapse, and three women had urolithiasis. Moreover, 11 women were missed during the study duration and were also excluded. Sixty women had recurrent UI after TOT (Group R), and 93 women had IU and did not receive any previous surgical intervention and were collected as De Novo UI group (Group D) as shown in Figure 1.

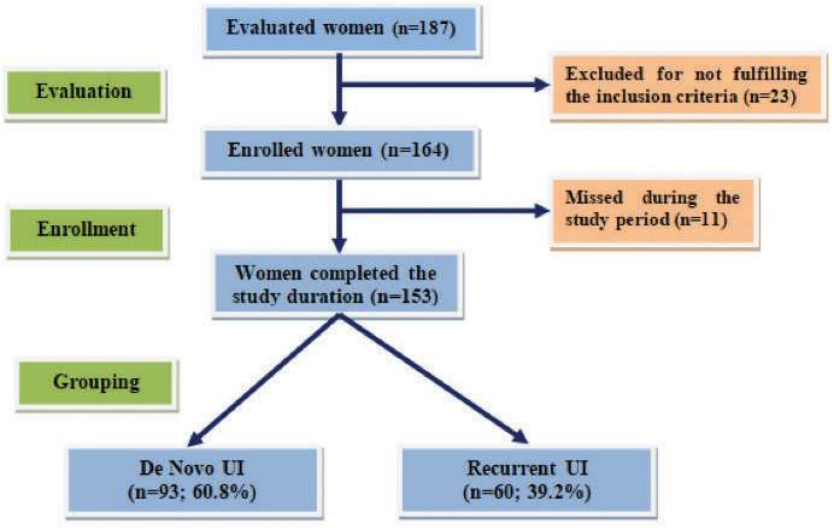

Figure 1: Study Flow Chart

Among (Group D) women, 26 patients (28%) did not receive any line treatment for their UI, while 67 patients (72%) received multiple lines of medical treatment that failed to control their UI. Duration since the start of compliance was non-significantly (P=0.056) shorter among (Group D) women, and the mean duration of recurrence of UI after TOT was 1.55 (±0.66) years. The constitutional data of the enrolled women were comparable, but (Group R) women had significantly (P=0.042) higher numbers of pregnancies and spontaneous vaginal delivery (P==0.042, 0.007, respectively). Also, the number of women who had perineal tears, and women who had badly repaired or not repaired perineal tears were significantly (P=0.024, 0.041, respectively) higher among (Group R) (Table 1).

Table 1: Constitutional and clinical data of enrolled women

Data		Group D	Group R	P
Treatment	Medical	67 (72%)	0	-
	Surgical	0	60 (100%)	-
	No	26 (28%)	0	-
Duration of UI (years)	Since the start of the complaint	3.6±1.9	4.2±1.9	**0.056**
	Since the recurrence of UI	-	1.55±0.66	-
	Average (±SD)	39.7±6.6	41±6.7	**0.251**

Age (years)	Strata	≤30	4 (4.3%)	4 (6.7%)	**0.221**
		31-35	27 (29%)	13 (21.6%)	
		36-40	20 (21.5%)	9 (15%)	
		41-45	27 (29%)	16 (26.7%)	
		46-50	15 (16.2%)	16 (26.7%)	
		>50	0	2 (3.3%)	
	Average (±SD)		30.5±2.3	30.95±2.6	**0.261**
BMI (kg/m²)	Strata	<25	1 (1%)	1 (1.6%)	**0.797**
		25-29.99	34 (36.6%)	19 (31.7%)	
		30-34.99	58 (62.4%)	40 (66.7%)	
Obstetric history	Previous pregnancies		2.6±0.95	2.9±1.08	**0.042**
	Previous labors		2.5±0.8	2.8±1.05	**0.058**
	Living offspring		2.3±0.8	2.5±0.98	**0.189**
	Mode of delivery	Spontaneous VD	55 (23.6%)	61 (36.3%)	**0.007**
		Instrumental VD	48 (20.6%)	38 (22.6%)	
		Cesarean section	130 (55.8%)	69 (41.1%)	
	Total number of deliveries		233 (100%)	168 (100%)	
Perineal examination	Vaginal delivery with	Episiotomy	72 (69.9%)	54 (54.5%)	**0.024**
		Perineal tear	31 (30.1%)	45 (44.5%)	
	Episiotomy (n=126)	Well-repaired	65 (90.3%)	44 (81.5%)	**0.153**
		Badly-repaired	7 (9.7%)	10 (18.5%)	
	Perineal tear (n=76)	Well-repaired	24 (77.4%)	22 (48.9%)	**0.041**
		Badly-repaired	4 (12.9%)	15 (33.3%)	
		Not repaired	3 (9.7%)	8 (17.8%)	

P indicates significance between both groups

At (Ass 1), subjective evaluation and ICS-UCST detected SUI, UUI, and MUI in 65 (42.5%), 43 (28.1%), and 45 women (29.4%), respectively with significantly (P=0.0084) higher frequency of MUI among (Group R) women. At (Ass 2), 50 (32.7%) women, and (Ass 3) 105 women (68.6%) stopped complaining of UI and showed negative ICS-UCST with a significant difference in comparison to (Ass 1) distribution in both groups. The difference in patient distribution between both groups was insignificant at (Ass 2), but at (Ass 3), it was significant (P=0.0036) in favor of (Group D) women (Table 2).

Table 2: Patients' distribution during assessments according to type of UI

Type of UI	Group-D			Group-R		
	Ass-1	Ass-2	Ass-3	Ass-1	Ass-2	Ass-3
Continent	0	32 (34.4%)	74 (79.6%)	0	18 (30%)	31 (51.7%)
Urge UI	28 (30.1%)	20 (21.5%)	6 (6.4%)	15 (25%)	10 (16.7%)	8 (13.3%)
Stress UI	46 (49.5%)	27 (29%)	8 (8.6%)	19 (31.7%)	15 (25%)	11 (18.3%)
Mixed UI	19 (20.4%)	14 (15.1%)	5 (5.4%)	26 (43.3%)	17 (28.3%)	10 (16.7%)
P	0.0084	0.754	0.0036			
P1		<0.001	<0.001		0.00001	<0.001
P2			<0.001			0.062

P indicates significant between both groups; P1: indicates significance of difference versus Ass-1; P2: indicates significance of difference versus Ass-2

All patients showed progressively decreasing number of daily voids and concomitantly increasing volume of urine per void at the Ass-2 and Ass-3 with significant differences concerning the numbers and volumes registered at Ass-1. Despite improvements, the number of daily voids and volume of urine per void were comparable at (Ass 2) and (-3). Rec UI is more tedious, as evidenced by detecting 10 of (Group R) women (16.7%) were still complaining of the high frequency of several daily voids at (Ass 3) (Table 3).

At Ass-3, 63 (41.2%) women had no leaks and 53 patients (34.6%) denied leaks with any type of activities, while 64 patients (41.8%) still had drops, especially on activities despite the decreased frequency and number of drops. Unfortunately, 26 women (17%) were still complaining of wetting, especially on activities with significantly higher frequency among women of (Group R). The frequency of patients who got rid of UI was significantly lower among (Group R) women both at (Ass 2) and at Ass-3, but this frequency was significantly increased in both groups at (Ass 3) than at Ass-2. Interestingly, the number of activities triggering leaks before treatment was significantly higher among Group-R women with nearly double the number of activities per woman to that reported by Group-D women. However, the number of activities causing leaks per woman decreased progressively in women of both groups with treatment and the decrease showed a non-significant difference in favor of D Group (Table 3).

Table 3: Two-day Voiding Dairy (2-d VD)

Items	Time	Group-D			Group-R		
		Ass-1	Ass-2	Ass-3	Ass-1	Ass-2	Ass-3
Number of voids/ day	Mean	6.4±1.9	5±1.5	4.7±1.1	7.65±3	6.1±2.6	5.2±2.1
	P	0.002	0.0012	0.038			
	P1		<0.001	<0.001		0.0037	<0.001
	P2			0.198			0.163
Urine volume (cc)/ voiding time	Mean	250±46	290±52	301±55	211.3±48	233.3±46	259±54
	P	<0.001	<0.001	<0.001			
	P1		<0.001	<0.001		0.042	<0.001
	P2			0.309			0.014
Daily urine output (cc)	Mean	1623±644	1463±561	1430±478	1528±490	1365±522	1303±475
	P	0.332	0.284	0.104			
	P1		0.131	0.053		0.164	0.033
	P2			0.916			0.765
Amount of leaked urine	No	0	48 (51.6%)	85 (91.4%)	0	15 (25%)	41 (68.3%)
	Wet	75 (80.6%)	12 (12.9%)	2 (2.2%)	43 (71.7%)	14 (23.3%)	6 (10%)
	Drops	18 (19.4%)	33 (35.5%)	6 (6.4%)	17 (28.3%)	31 (51.7%)	13 (21.7%)
	P	0.197	0.0043	0.0012			
	P1		<0.001	<0.001		<0.001	<0.001
	P2			<0.001			<0.001

Relation of activity & leak	Yes	93 (100%)	59 (63.4%)	42 (45.2%)	60 (100%)	41 (63.4%)	29 (48.3%)
	No	0	34 (36.6%)	51 (54.8%)	0	19 (36.6%)	31 (51.7%)
	P	-	0.535	0.701			
	P1		<0.001	<0.001		<0.001	<0.001
	P2			0.012			0.026
Type of Activity	Posture change	54 (58%)	31 (33.3%)	17 (18.3%)	44 (73.3%)	26 (43.3%)	12 (20%)
	Coughing	37 (39.8%)	19 (20.4%)	10 (10.8%)	41 (68.3%)	21 (35%)	10 (16.7%)
	Laughing	41 (44.1%)	17 (18.3%)	8 (8.6%)	52 (86.7%)	16 (26.7%)	8 (13.3%)
	Lifting heavy objects	19 (20.4%)	9 (9.7%)	3 (3.2%)	50 (83.3%)	21 (35%)	11 (18.3%)
	Walking	23 (24.7%)	10 (10.8%)	6 (6.5%)	36 (60%)	19 (31.7%)	6 (10%)
	Exercise	12 (12.9%)	5 (5.4%)	2 (2.2%)	5 (8.3%)	3 (5%)	3 (5%)
	Activities/ patient	2	1.5	1.1	3.8	2.6	1.7
	P	0.0028	0.182	0.361			
	P1		0.958	0.848		0.599	0.567
	P2			0.982			0.885

P indicates significant between both groups; P1: indicates significance of difference versus Ass 1; P2: indicates significance of difference versus Ass 2

The calculated ICIQ-SF score at Ass 1 was significantly (P=0.0082) lower in Group D than in Group R women. All women showed progressive decreases in their ICIQ-SF scores at Ass 2 and Ass 3 in comparison to Ass 1 scores with significantly lower scores determined at Ass 3 than Ass 2 scores. Further, Ass 2 and Ass 3 ICIQ-SF were significantly lower in Group D than in Group R women as shown in Table 4 and Figure 2. The determined ICIQ-SF score at Ass-3 had decreased by 61.2 (±12%) and 72 women (77.4%) had decreased their score by >50% in Group-D women. At Ass 3 of Group R women, the mean percentage of decrease in ICIQ0SF was 48.2 (±10.8%), and 22 women (36.7%) had decreased score by >50. ICIQ-SF score of Group D women showed a significantly (P<0.001) higher percentage of decrease with a significantly (P<0.001) higher number of women decrease by >50% than scores of Group R women.

According to the PUQ, women using <5 pads/day were significantly higher among Group D than Group R at Ass 1, while at Ass 2 and Ass 3, the number of women using no pads was significantly higher among Group D than Group R. In both groups, the frequency of women using no pads at Ass 3 was significantly higher than at Ass 2. Similarly, the mean number of daily used pads was significantly decreased with time-course assessments in both groups and was significantly lower in Group D than Group R. About 63 women (41.2%) stopped using pads at the time of Ass 2 and 130 women (85%) at the time of Ass 3 with a significantly higher number of women stopping pads usage among Group D women. The mean number

of pads used decreased progressively with assessments with a significant difference between the number defined at each assessment and a significantly lower mean number for Group D women than Group R women. The mean percentage of decrease in the number of used pads was significantly (P=0.014) higher among Group D than Group R women, and only one woman (0.65%) showed a decrease in number of the used pads by ≤50% (Table 4, Fig. 3).

Table 4: The calculated mean value of the total ICIQ-SF score and Pads Usage Questionnaire determined at the three assessments

Score			Group-D			Group-R		
			Ass-1	**Ass-2**	**Ass-3**	**Ass-1**	**Ass-2**	**Ass-3**
ICIQ-SF	Mean		13±4.2	7.7±2.9	4.9±2.2	14.6±2.6	10.4±1.7	7.6±1.9
	P		0.0082	<0.001	<0.001			
	P1			<0.001	<0.001		<0.001	<0.001
	P2				<0.001			<0.001
	Mean % of ↓			61.5±12			48.2±10.8	
	P		<0.001					
	↓ by <50%			21 (22.6%)			38 (63.3%)	
	↓ by >50%			72 (77.4%)			22 (36.7%)	
	P		<0.001					
PUQ	The number of pads used	0	0	48 (51.6%)	84 (90.3%)	0	15 (25%)	46 (76.7%)
		<5	48 (51.6%)	34 (36.6%)	8 (8.6%)	13 (21.7%)	29 (48.3%)	14 (23.3%)
		6-10	42 (45.2%)	11 (11.8%)	1 (1.1%)	37 (61.7%)	16 (26.7%)	0
		>10	3 (3.2%)	0	0	10 (16.6%)	0	0
		P	0.0001	0.0024	0.031			
		P1		<0.001	<0.001		<0.001	<0.001
		P2			<0.001			<0.001
	The mean number of pads used		6±2.5	2.3±2.6	0.3±1	8.05±2.3	3.9±2.4	0.85±1.6
			<0.001	0.0002	0.01			
				<0.001	<0.001		<0.001	<0.001
					<0.001			<0.001
	Mean% of ↓			96.9±10.5			91.7±15.5	
	P		0.014					
	↓ by <50%			1 (1.1%)			0	
	↓ by >50%			92 (98.9%)			60 (100%)	
	P		0.421					

Ass: Assessment; ICIQ-SF: The International Consultation on Incontinence Questionnaire-Short Form; PUQ: Pads Usage Questionnaire; P indicates significant between both groups; P1: indicates significance of difference versus Ass-1; P2: indicates significance of difference versus Ass-2

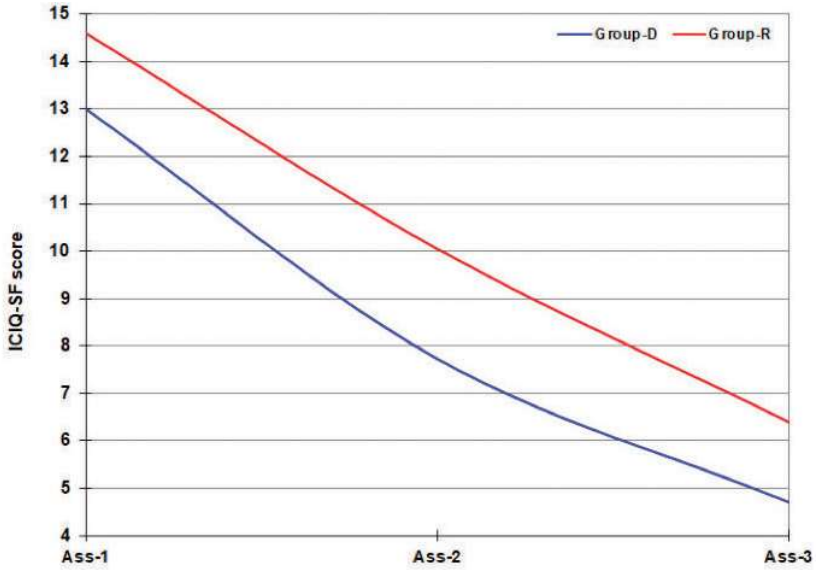

Fig. (2): Mean ICIQ-SF of women of both groups

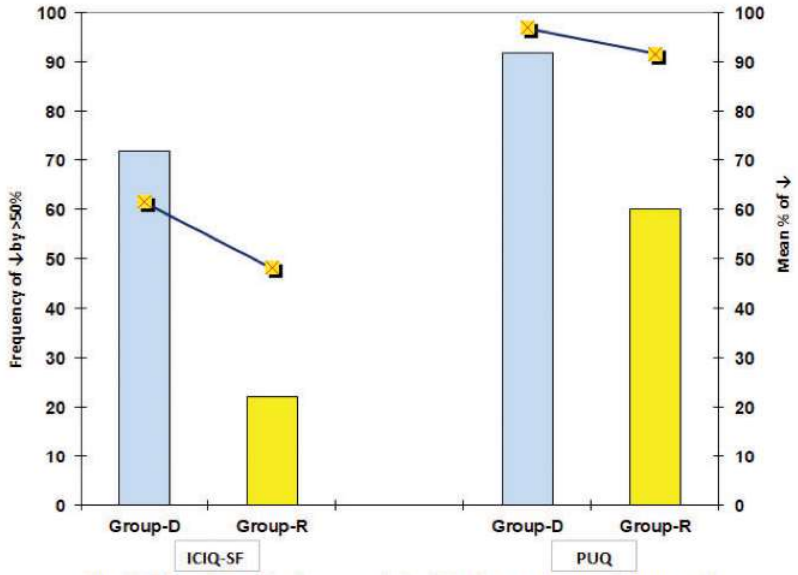

Fig. (3): Procedure effectivness as judged by the percentage of change at Ass-3 in relation to at Ass-1 for ICIQ-SF and PUQ

The mean scores of five domains of FSFI score determined at Ass 2 and Ass 3 of women of both groups were comparable to scores determined at Ass 1 with insignificant differences between Ass 2 and 3. However, desire was the only domain that significantly changed at both Ass 2 (P=0.011) and Ass 3 (P<0.001) for Group D patients concerning Ass 1 scores with significantly (P=0.0001) higher desire score at Ass 3 than at Ass 2. Moreover, Ass 3 desire scorings of Group R women were significantly (P=0.030) higher than Ass 1 scores and were non-significantly (P=0.113) higher than Ass 2 scores which were non-significantly (P=0.518) higher than Ass 1 scores. The differences between the three assessments of women of both groups were non-significant (Table 5, Fig. 4).

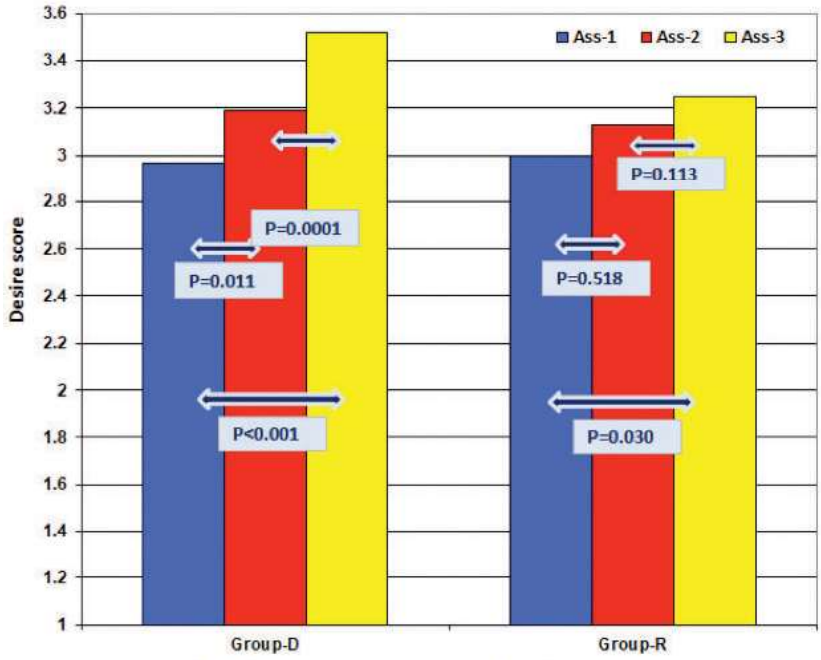

Fig. (4): Desire score of women of both groups

The calculated total FSFI scores at the three assessments showed non-significant differences between patients of both groups. Among Group D women, the total Ass-2 FSFI score was non-significantly higher than the Ass 1 score, while was significantly (P=0.027) higher than the Ass 3 score, which also was significantly (P=0.071) higher than the Ass 1 score. Regarding Group R, Ass 2 total FSFI score showed insignificant differences between Ass 1 and Ass 3 scores, while Ass 3 score was significantly (P=0.013) higher than Ass 1 score, (Table 5, Fig. 5).

Table 5: Scores of individual domains and total FSFI score determined at the three assessments

		Group-D			Group-R		
Domain Time		Ass-1	Ass-2	Ass-3	Ass-1	Ass-2	Ass-3
Desire	Mean	2.99±0.71	3.25±0.65	3.66±0.74	3.07±0.84	3.17±0.85	3.44±0.99
	P	0.541	0.527	0.129			
	P1		0.011	<0.001		0.518	0.030
	P2			0.0001			0.113
Arousal	Mean	2.82±1	2.89±0.95	2.9±0.9	2.81±0.95	2.86±0.97	2.93±0.89
	P	0.906	0.882	0.721			
	P1		0.871	0.786		0.965	0.976
	P2			0.986			0.982
Lubri-cation	Mean	2.57±0.9	2.59±0.91	2.69±0.75	2.6±0.85	2.56±0.8	2.69±0.85
	P	0.402	0.353	0.845			
	P1		0.898	0.545		0.818	0.907
	P2			0.815			0.981

Orgasm	Mean	2.78±0.53	2.81±0.89	2.92±0.92	2.9±1	3.1±0.94	2.98±1.1
	P	0.355	0.053	0.729			
	P1		0.835	0.430		0.527	0.894
	P2			0.667			0.804
Satis-faction	Mean	2.65±1.04	2.5±1.02	2.61±1.22	2.37±1	2.51±0.6	2.53±0.86
	P	0.112	0.938	0.631			
	P1	-	0.355	0.846		0.652	0.583
	P2			0.514			0.993
Pain	Mean	2.17±0.58	2.06±0.79	2.11±0.77	2.1±0.9	2.2±0.55	2.25±0.44
	P	0.561	0.242	0.186			
	P1		0.568	0.913		0.682	0.424
	P2			0.815			0.909
Total score	Mean	13.41±1.88	13.52±2.12	14.2±2.1	13.25±2.1	13.85±1.54	14.1±1.7
	P	0.638	0.301	0.833			
	P1		0.715	0.0071		0.082	0.013
	P2			0.027			0.336

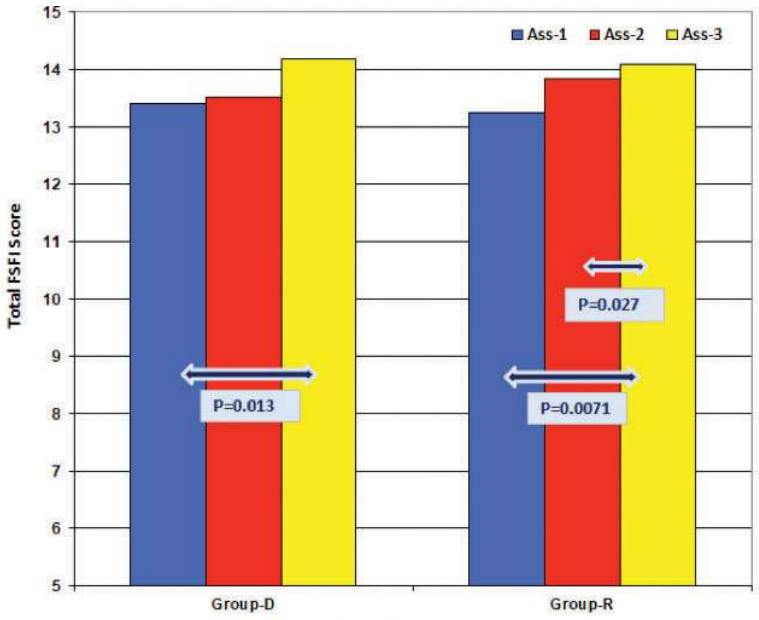

Fig. (5): Total FSFI score of women of both groups

Only 13 patients (8.5%) achieved the cutoff point for procedure effectiveness as regards sexual desire; 11 of Group D (14%) and two of Group R (3.3%) patients with non-significantly (P=0.065) higher frequency among Group D. However, the mean percentage of change of desire score among Group D patients (27.5±36.3; range: 0-150%) was significantly (P=0.024) higher than the mean percentage of change among Group R patients (13.8±22.8; range: 0-100%) as shown in figure 6. Unfortunately, no women achieved the cutoff point for procedure effectiveness as regards the total FSFI score. Moreover, 34 women (22.2%) had decreased total FSFI scores and another 35 women (22.9%) showed no change in their score, while 84 women (54.9%) had increased scores but to ≤50% with insignificant differences

between both groups as regards women's distribution according to the change in total FSFI score. On the contrary, the mean percentage of change of total FSFI score of Group-D women (6.4±12.67; range: [-25]-40) was significantly (P<0.001) higher than the mean percentage of change in scores of Group-R women (-8.26±14.9; range: [-57.14]-18.75) as shown in figure 6

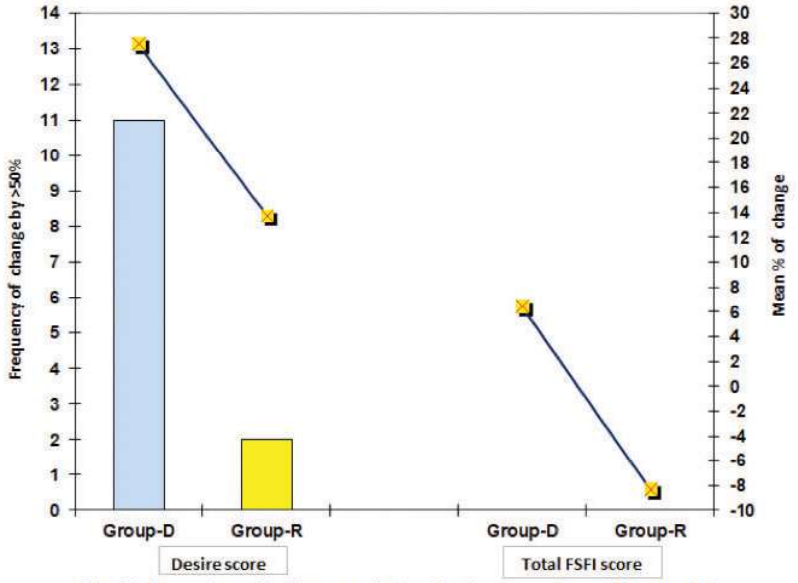

Fig. (6): Procedure effectivness as judged by the percentage of change at Ass-3 in relation to at Ass-1 for Desire and Total FSFI scores

Concerning satisfaction grading of procedural outcomes, 53 women (34.6%) were very satisfied, 39 women (25.5%) were satisfied, 35 women were neither dissatisfied nor satisfied (22.9%), 17 women (11.1%) were dissatisfied and only 9 women (5.9%). The frequency of women having very satisfactory and satisfactory outcomes was significantly (P=0.028) higher among Group-D women (Fig. 7).

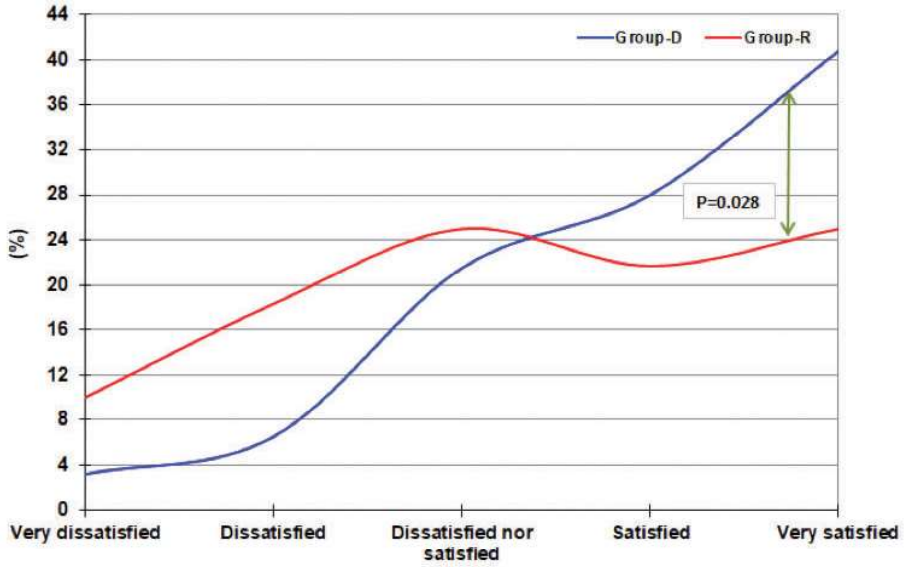

Fig. (7): Women's distribution according to satisfaction by procedure outcomes

Among the studied women, 21 women (13.7%) developed AE with non-significant (P=0.713) difference between both groups and all the reported AE were temporary and disappeared on the next day of the session. The total number of the reported AE was 31 events; 18 and 13 events affecting women of Group-D and Group-R, respectively with non-significant (P=0.874) difference between both groups. Regarding the type of AE, muscle spasm and local skin erythema were the most common AE (22.2%), respectively, and were followed by muscle pain (19.4%) and skin redness (16.1%), while pelvic and tendon pain were the least frequent and represent 9.7% each. The frequency of ported adverse events was 1.5 and 1.4 event/patient for both groups, respectively with insignificant differences between both groups (Table 6).

Table 6: Patients' distribution according to procedure-induced AE

Frequency of adverse events		
	Group D	Group R
No	81 (87.1%)	51 (85%)
Yes	12 (12.9%)	9 (15%)
P=	0.713	
Prognosis of adverse events		
	Group D	Group R
Temporary	12 (100%)	9 (100%)
Permanent	0	0
Total	12 (100%)	9 (100%)
P=	-	

Frequency of adverse events			
Events		Group D	Group R
Pain	Muscular	3 (25%)	3 (33.3%)
	Pelvic joints	2 (16.7%)	1 (11.1%)
	Tendons	2 (16.7%)	1 (11.1%)
Muscle spasm		4 (33.3%)	3 (33.3%)
Local erythema		4 (33.3%)	3 (33.3%)
Skin redness		3 (12%)	2 (22.2%)
Total		18	13
Adverse event/ Patient		1.5	1.4
P=		0.874	

Discussion

The current study depended on a tripod evaluation approach to assess the procedure effectiveness; subjectively using ICIQ-SF and pad-usage questionnaires (PUQ), objectively using the ICS-UCST and lastly the extent of patients' satisfaction. Similarly, **Barba et al.** [17] applied the same rationale and detected a statistically significant reduction in the subjective UI evaluation at the end of FMS sessions with significant objective improvement and stable subjective satisfaction scorings.

According to the FDA recommendations, the procedure effectiveness was defined as a reduction of the number of the used pads on PUQ and the ICIQ-SF score by >50% concerning pre-procedure data, the FMS therapy provided marvelous outcomes and nearly all the studied (99.4%) women achieved the cutoff point for the PUQ and 61.4% of women had reduced ICIQ-SF score by >50%. Objectively, 105 women (68.6%) had negative ICS-UCST at the end of 6-w after the last FMS session. Moreover, 92 women (60.1%) were very satisfied-to-satisfied by the procedure outcomes. In line with these results, **Samuels et al.** [18] using HIFEM technology for female UI detected its ability to safely and effectively treat a wide range of UI patients with ICIQ-SF improvement and reduction in pad usage. Thereafter, **González-Isaza et al.** [19] reported reduced scores of UI evaluation questionnaires after FMS sessions and at 14-w of follow-up and assured the favorable impacts of the procedure on clinical outcomes and QOL of women who had SUI who prefer non-surgical treatments. Also, **Filippini et al.** [20] using the "chair" device for pelvic floor muscle (PFM) stimulation detected a significant and consistent improvement in patients with UI and pelvic floor disorders

as judged by ultrasound measurements and validated questionnaires without discomfort or side effects and concluded that the used device represents valuable and effective modality for women affected by different urogenital pathologies.

In support of the efficacy of FMS as a non-invasive therapeutic modality for female UI, a systemic review concluded that FMS is an effective and non-invasive therapy for UUI treatment (21) and prospectively, **Dominguez et al.** [22] reported subjective improvement at 3-m after FMS sessions for elderly women with the debilitating condition of pelvic floor dysfunction and concluded that the noninvasiveness and safety of device allowed it to be an interesting approach for these patients. Another prospective study compared the effectiveness of FMS versus PFM training for women with SUI but ineligible for surgery and observed significantly improved urinary-related QOL scores with FMS [23].

Physiologically, the myotatic reflex, which is an inducible action, is outplayed through the Golgi tendon organs and mediated via the 1β and γ afferents to relay to the spinal cord with subsequent inhibition of the inhibitory and summations of the excitatory postsynaptic potentials resulting in shortening of the refractory period of the action potential, thus rapidly successive stimuli will affect the muscle which is in the excitatory state leading to super-threshold stimulation and development of tonic contractile status (24, 25). Similarly, exposure of PFM to a rapidly changing high-intensity electromagnetic field will induce intense muscular contractions with the regulation of the neuromuscular control and enhanced muscular blood supply resulting in muscle fiber hypertrophy and hyperplasia secondary to the more efficient stimulation. In support of this assumption, recent clinical studies using electromagnetic stimulation of upper arm muscles reported increased muscle mass and reduction of fat as judged by MRI (26) with increased muscle strength measurements, using the dynamometer that was sustained at 30 and 90 days (27).

Thus, the reported improved UI with FMS therapy could be attributed to the improved PFM contractility with subsequent improvement of urethral hypermobility and intrinsic urethral deficiency, the two pathognomonic pathological changes causing UI (28). In support of this assumption, **Frigerio et al.** [23] detected an increased volume of urethral rhabdosphincter after FMS concerning baseline assessment in women with SUI

The 2nd procedure effectiveness target was the frequency and severity of AE; only 21 of the studied women developed 31 AEs for a frequency of 1.47 AE/ affected woman and 0.2 AE/studied woman. Fortunately, these AE were transient and completely fade away before the next session, thus indicating the safety and tolerability of the procedure and go in hand with a recent study documenting that side effects of FMS procedure are minimal and transient in comparison to other active treatments and FMS could be considered as one of the safest methods for UI patient and as a suitable first step in treating UI (29). Further, one survey study detected the preference of patients with mild-to-moderate pelvic floor disorders for procedures with the greatest safety profile and quickest recovery time as FSM over procedures of the highest efficacy (30).

Unfortunately, the total FSFI score did not indicate improved sexual functions of the treated women and desire scorings were the only significantly improved scores. Similarly, a recent meta-analysis did not confirm the improved sexual function of women with UI using energy equipment as FMS (31).

The reported insignificant improvement of FSFI even with improved UI scorings and especially in women who had RUI could be attributed to the fear of UI on excitation as previously noted before treatment and to the

history of disappointed partner by history of leaks during abdominopelvic muscular contractions that occur simultaneously with excitation and orgasm. In line with this attribution, an earlier study found women with UI have poorer sexual functioning, and are more likely to restrict sexual activity for fear of incontinence (32).

Another point of view was that about 50% of the studied women were peri-menopausal, an age category that is vulnerable to PFM weakness and disorders including UI and had dry vaginas secondary to hormonal imbalance leading to sexual dysfunction (33). As long as the mechanism of action of FMS is excessive muscular stimulation, it could improve the PFM disorders but could not improve lubrication of the vagina as did hormonal therapy (34) and subsequently could not interrupt the circle of inability, fear of UI and loss of interest leading to less satisfaction and failure to approach the orgasm.

Moreover, the majority of the studied women were mostly obese or overweight, a finding pointing to a possible relation between obesity and UI. In support of this suggestion women who had recurrent UI were more obese than women who had De Novo UI and **Chen et al.** [35] detected a significant positive relationship between both BMI and percentage of trunk fat and the prevalence and severity of female UI. Further, **Nosrati et al.** [36] assured that obesity is an independent risk factor for UI and sexual dysfunction and **Infante et al.** [37] detected a high sexual dysfunction rate in obese women and considered obesity as a risk factor for female sexual dysfunctions. Considering, the applied FMS did not affect women's weight, the maintained obesity may explain the persistent sexual dysfunction.

Conclusion

The use of flat magnetic stimulation (FMS) of pelvic floor muscle using HIFEM technology could be considered a promising efficient therapeutic strategy for female UI. FMS/HIFEM strategy provided effective non-invasive control of patients' complaints with a high satisfaction rate, minimal or no adverse events and improved sexual desire. However, such effects were hampered by being costly and the frequent session may cause dropped-off sessions.

Limitation

The short duration of follow-up, small sample size, single-center study, and dependence on subjective evaluation questionnaires are the study limitations

Recommendations

Trials to reduce the costs of sessions might help to use the FMS/HIFEM strategy as frequently repeated therapy, especially for cases with incomplete symptom resolution, recurrence of manifestations after successful sessions and the application of such strategy on a wider scale patients population, especially the low-outcome strata.

References

1. Lane GI, Erekson E, Austin A, Carmichael D, Minassian V, Grodstein F, Bynum JP: Treatment for Urinary Incontinence in Women Older Than 65 Years. Urogynecology (Phila). 2023; 29(8):687-695.
2. Palmer SJ: Overview of Urinary Incontinence. Br J Community Nurs. 2023; 28(8):410-412.
3. Okada C, Kim J, Roselli N, Halani P, Melamed M, Abraham N: Food Insecurity Is Associated With Urge Urinary Incontinence: An Analysis of the 2005-2010 National Health and Nutrition Examination Survey. J Urol. 2023; 210(3):481-491.
4. Yuan Y, Tan W, Huang Y, Huang H, Li Y, Gou Y, Zeng S, Hu Z: Association

between oxidative balance score and urinary incontinence in females: results from the national health and nutrition examination survey in 2005-2018. Int Urol Nephrol. 2023; 55(9):2145-2154.

5. Sarkar D, Tandon M, Pal DK: Comprehensive study of anxiety and depression in females with urinary incontinence. Urologia. 2023; 45(3):166-170.
6. Shahait M, Nguyen T, Asmar J, Dobbs R, Walker J, Kim J, El-Fahmawi A, Lee DI: Impact of Obstructive Sleep Apnea Syndrome on Time to Complete Recovery of Continence After Robot-Assisted Radical Prostatectomy: A Propensity Score Matching Analysis. J Endourol. 2023; 37(8):882-888.
7. Bharti V, Tiwari R, Gupta S, Upadhyay R, Singh M, Singh D: The spectrum and etiologies of lower urinary tract symptoms in postmenopausal women. Curr Urol. 2023; 17(3):179-183.
8. Biyikoglu M, Kettas E, Sesli M, Senel S, Cayan S, Akbay E: The effect of duloxetine on female sexual functions in the treatment of stress incontinence. Arch Gynecol Obstet. 2023; 308(3):1037-1042.
9. Bretschneider CE, Liu Q, Smith A, Mansfield S, Kirkali Z, Amundsen C, Lai H, Geynisman-Tan J, Kirby A, Jelovsek J: Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) Study Group: Development and validation of models predicting treatment patterns in women with urinary urgency and/or urgency incontinence: A Symptoms of Lower Urinary Tract Dysfunction Research Network observational cohort study. Neurourol Urodyn. 2023; 42(6):1214-1226.
10. Tu L, Gheiler E, Hanson C, Jalkut M, McCrery R, Parekh M, Parva M, Erickson T: Management of female stress urinary incontinence with single-incision mini-sling (Altis®): 36 month multicenter outcomes. Neurourol Urodyn. 2023;67(2):284-298
11. Nambiar A, Bosch R, Cruz F, Lemack G, Thiruchelvam N, Tubaro A, Bedretdinova D, Ambühl D, Farag F, Lombardo R, Schneider M, Burkhard F: EAU Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence. Eur Urol. 2018; 73(4):596-609.
12. Avery K, Donovan J, Peters T, Shaw C, Gotoh M, Abrams P: ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol.Urodyn. 2004; 23(4):322-30.
13. Kretschmer A, Hübner W, Sandhu JS, Bauer RM. Evaluation and management of postprostatectomy incontinence: a systematic review of current literature. Eur Urol Focus. 2016;2:245–59
14. Rosen R, Brown C, Heiman J, Leiblum S, Meston C, Shabsigh R, Ferguson D, D'Agostino R (2000): The Female Sexual Function Index (FSFI): A Multidimensional Self-Report Instrument for the Assessment of Female Sexual Function, Journal of Sex & Marital Therapy, 26:2, 191-208,
15. Guralnick ML, Fritel X, Tarcan T, Espuna-Pons M, Rosier PFWM: ICS Educational Module: Cough stress test in the evaluation of female urinary incontinence: Introducing the ICS-Uniform Cough Stress Test Neurourol Urodyn. 2018 Jun; 37(5):1849-1855.
16. Sherburn M, Bird M, Carey M, Bø K, Galea MP. Incontinence improves in older women after intensive pelvic floor muscle training: An assessor-blinded randomized controlled trial. Neurourol Urodyn 2011; 30(3):317–324.
17. Barba M, Cola A, Rezzan G, Costa

C, Melocchi T, De Vicari D, Terzoni S, Frigerio M, Maruccia S: Flat Magnetic Stimulation for Stress Urinary Incontinence: A 3-Month Follow-Up Study. Healthcare (Basel). 2023; 11(12):1730-41.

18. Samuels JB, Pezzella A, Berenholz J, Alinsod R: 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. 2019; 51(9):760-766.
19. González-Isaza P, Sánchez-Borrego R, Salcedo F, Rodríguez N, Rizo D, Fusco I, Callarelli S: Pulsed Magnetic Stimulation for Stress Urinary Incontinence and Its Impact on Sexuality and Health. Medicina (Kaunas). 2022; 58(12):1721-1734.
20. Filippini M, Biordi N, Curcio A, Comito A, Pennati B, Farinelli M: 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(5):879-891.
21. Antić A, Pavčnik M, Lukanović A, Matjašič M, Lukanović D: Magnetic stimulation in the treatment of female urgency urinary incontinence: a systematic review. Int Urogynecol J. 2023; 34(8):1669-1676.
22. Dominguez AP, Isaza P, Pantoja S, 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(1):173-177.
23. Frigerio M, Barba M, Cola A, Marino G, Volontè S, Melocchi T, De Vicari D, Maruccia S: Flat Magnetic Stimulation for Stress Urinary Incontinence: A Prospective Comparison Study. Bioengineering (Basel). 2023; 10(3):295-307.
24. Palmieri RM, Ingersoll CD, Hoffman MA: The hoffmann reflex: methodologic considerations and applications for use in sports medicine and athletic training research. J Athl Train. 2004; 39(3):268-77.
25. Héroux ME: Tap, tap, who's there? It's localized muscle activity elicited by the human stretch reflex. J Physiol. 2017; 595(14):4575- 4598.
26. Jacob C, Weiss RA: Simultaneous HIFEM and Synchronized RF Procedure Can Be Effectively Used for Increasing Muscle Mass and Decreasing Fat in the Upper Arm. J Clin Aesthet Dermatol. 2023; 16(2):50-54.
27. Ugonabo N, Rambhia P, You J, Ibrahimi O, Chapas A: Prospective study to assess the efficacy and safety of a noninvasive electro-muscular stimulation for improvement of muscle strength and muscle toning of the extremities. Lasers Surg Med. 2023 8(4):252-264.
28. D'Alessandro G, Palmieri S, Cola A, Barba M, Manodoro S, Frigerio M: Clinical and urodynamic predictors of Q-tip test urethral hypermobility. Minerva Obstet. Gynecol. 2022; 74:155–160.
29. Pavčnik M, Antić A, Lukanović A, Krpan Ž, Lukanović D: Evaluation of Possible Side Effects in the Treatment of Urinary Incontinence with Magnetic Stimulation. Medicina (Kaunas). 2023; 59(7):1286-1296 .
30. Shah GS, Phillips C: What women want now! Eur J Obstet Gynecol Reprod Biol. 2023; 286:118-120.
31. Pavarini N, Valadares A, Varella G, Brito L, Juliato C, Costa-Paiva L: Sexual function after energy-based treatments of women with urinary incontinence. A systematic review and meta-analysis. Int Urogynecol J. 2023; 34(6):1139-1152.

32. Rogers GR, Villarreal A, Kammerer-Doak D, C Qualls: Sexual function in women with and without urinary incontinence and/or pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12(6):361-5.

33. Ozaki Y, Tomoe H, Shimomura M, Ninomiya N, Sekiguchi Y, Sato Y, Nagao K, Takahashi Y, Takahashi S: Female sexual dysfunction and lower urinary tract symptoms associated with vulvovaginal atrophy symptoms: Results of the GENJA study. Int J Urol. 2023 83(2)583-594.

34. Christmas MM, Iyer S, Daisy C, Maristany S, Letko J, Hickey M: Menopause hormone therapy and urinary symptoms: a systematic review. Menopause. 2023; 30(6):672-685.

35. Chen J, Peng L, Xiang L, Li B, Shen H, Luo D: Association between body mass index, trunk and total body fat percentage with urinary incontinence in adult US population. Int Urogynecol J. 2023; 34(5):1075-1082.

36. Nosrati F, Nikoobakht M, Oskouie I, Rahimdoost N, Inanloo H, Abolhassani M, Mousavi S, Nazarpour M, Dialameh H: Does Significant Weight Loss After Bariatric Surgery Affect Sexual Function and Urinary Symptoms? An Iranian Study. Obes Surg. 2023; 33(8):2509-2516.

37. Infante A, Arribas B, Khan K, Zamora J, López A, Pasero M, Fernández C: Obesity and female sexual dysfunctions: A systematic review of prevalence with meta-analysis. Semergen. 2023; 49(7):1020-1031.