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Effects of surface and intravaginal electrical stimulation in the treatment of women with stress urinary incontinence: randomized controlled trial☆

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ABSTRACT

Objective: To evaluate the effects of surface electrical stimulation (SES) and to compare them with the effects of the intravaginal electrical stimulation (IVES) in women with stress urinary incontinence (SUI).
Study design: This randomized controlled study included 48 women aged over 50 years, who complained of SUI evaluated according to two structured questions of King's Health Questionnaire (KHQ) and who had not previously undergone physical therapy for SUI. The calculation of the sample size estimated a sample of 45 volunteers with a significance level of 5% and statistical power of 90%. The women were randomized to: Surface Electrical Stimulation Group (SESG) ($n = 15$), Intravaginal Electrical Stimulation Group (IVESG) ($n = 15$) and Control Group (CG) ($n = 15$). Subjects in the intervention groups were treated with the same parameters of electrical stimulation for 12 sessions. The SESG had four silicone electrodes fixed in the suprapubic and ischial tuberosity regions. The IVES group used an intravaginal electrode. The CG did not receive any treatment during the corresponding time. They were evaluated before and after treatment by a physical therapist who was blind to group allocation. The primary outcomes were urinary leakage, pressure and strength of pelvic floor muscle (PFM) contraction. The secondary outcome was quality of life (QOL) evaluated by KHQ. Forty-five women completed the study and were included in the analysis. Statistical analysis was performed using the Wilcoxon test for intragroup analysis and Kruskal–Wallis and Mann–Whitney tests for intergroup analysis ($p < 0.05$).
Results: There was significant improvement in urinary loss and pressure of contraction in the SESG and IVESG. PFM strength increased only in the IVESG. Intergroup analysis found differences after the treatment in: urinary leakage between the SESG and CG ($p < 0.001$) and the IVESG and CG ($p < 0.001$). Regarding QOL, there was significant reduction in the incontinence impact, limitations of daily activities, physical limitation, emotion, sleep and disposition and severity domains in the SESG (all $p < 0.02$) and IVESG (all $p < 0.04$) after the treatments.
Conclusion: SES and IVES are important treatments to improve the SUI. Both improved the QOL, urinary leakage, and strength and pressure of PFM contraction.
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1. Introduction

The International Continence Society recommended physical therapy as first-line treatment for urinary incontinence (UI) [1] because it promotes good results, has low costs, is minimally invasive and has a low rate of side effects [2,3]. In a systematic review, Dumoulin and Hay-Smith [4] reported that pelvic floor muscle (PFM) training is the treatment with the best clinical results.

Bø and Sherburn [5] reported that 30% of women did not perform PFM contraction correctly during evaluation, compromising the results of PFM training, so in order to improve the proprioception of PFM the use of some equipment is indicated, such as vaginal cones, biofeedback and electrical stimulation (ES) [4,6–8], which can be performed with intravaginal, anal and superficial electrodes.

Studies have evaluated the effects of intravaginal electrical stimulation (IVES) treatment [8–10] in the treatment of stress urinary incontinence (SUI). This treatment is used more in clinical

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practice despite many disadvantages, such as discomfort, the need to sterilize the electrode and the risk of vaginal and urinary infection [8,11,12].

Another possibility for treatment is surface electrical stimulation (SES) [13–16] which can promote PFM contraction, increasing its strength and improving SUI [3,6,17,18]. This treatment is cheap, less embarrassing and does not require sterilization [16]. Nevertheless SES is a modality of therapy that still is little tackled in clinical studies. Moreover, we did not find studies that compared the effects of SES and IVES treatment, which showed the need for this present study.

The purpose of this study, therefore, was to investigate the effect of SES and compare it with IVES in women with SUI. Our hypothesis is that SES treatment will demonstrate a similar improvement of SUI, when compared to IVES treatment.

2. Materials and methods

2.1. Subjects

This was a randomized controlled study performed from January 2012 to March 2013 and conducted at the Laboratory of Research in Women's Health, Federal University of São Carlos. The local ethics committee approved the study (405/2010), which is in agreement with the Declaration of Helsinki.

The sample size was calculated considering the values of pad test (in grams) from previous data on a pilot study of SES treatment [16]. At a significance level of 5% and power of 90%, it was estimated to require a sample of at least 45 people.

The inclusion criteria were women aged over 50 years, who complained of urinary leakage on stress and who had not undergone physical therapy for UI. Women with symptoms of urgency UI and mixed UI were excluded. Two questions were used to determine patient eligibility. The first question was: "During the past month, have you involuntarily got wet while performing some kind of physical exertion, e.g. coughing, lifting, sneezing or laughing?" The second question was: "During the past month, have you experienced such a strong urge to urinate that it was impossible to get to the toilet in time?" Only women who answered "yes" just to the first question were recruited. The sensitivity/specificity are 0.85/0.91 and 0.90/0.90 for the first and second questions, respectively [19].

Exclusion criteria included latex allergies, vaginal or urinary infections, pelvic organ prolapse greater than grade II [20], inability to perform voluntary PFM contraction, cognitive or neurological disorder, uncontrolled hypertension, inability to carry out the evaluation or treatment, hormone therapy, use of pacemaker or metal rod implantation [8,14,21,22].

Forty-eight volunteers were recruited, signed an informed consent and were randomized following a simple randomization procedure (computerized random numbers) into three groups: Surface Electrical Stimulation Group (SESG) ($n = 15$), Intravaginal Electrical Stimulation Group (IVESG) ($n = 16$) and Control Group (CG) ($n = 17$). A researcher who was not involved in the data collection or analyses created this randomization list.

2.2. Outcome measures

Only one blinded experienced physiotherapist performed all evaluations. Initially, all women went through a physical examination and an interview about their medical history. The SESG, IVESG and CG were evaluated before and after the treatment for primary outcomes (urinary leakage and PFM function) and secondary outcomes (quality of life (QOL)).

The 1-h pad test was performed to evaluate urinary leakage according to the protocol proposed by Abrams et al. [23]. The women were instructed to wear a pad which had been previously weighed on a precision balance (Marte Shimadzu BL320, precision of 0.001 g, Marte) and then drink 500 ml of water. After 30 min, they started performing a series of provocative exercises and, at the end of 1 h, the pad was removed and reweighed, and the urinary loss calculated.

Assessment of PFM strength by digital palpation was carried out using the PERFECT scheme. The volunteers were positioned supine with 45° of hip and knee flexion, and the evaluator introduced two fingers up to one third of the vagina. The volunteer was then instructed to lift and squeeze the PFM as hard as possible. The strength measured on the 6-point Modified Oxford Scale [24]. Evaluation of the PFM contraction pressure was carried out by the perineometer Peritron 9300 (Cardio Design, Australia), graduated from 0 to 300 cmH_2O. The women were placed in the supine position, with hip and knee flexion. The vaginal probe was inserted approximately 3.5 cm into the vaginal cavity and the device was calibrated. The women were then verbally instructed to perform three PFM contractions, each of 3 s, with maximum perceived effort. The women were also instructed to avoid using the abdominal, gluteal and hip adductor muscles during the contractions. The average of three contractions' peaks was used for analysis.

For the assessment of QOL, the King's Health Questionnaire (KHQ) was used [25], as it is a reliable instrument, specific to assess QOL of women with UI and validated in Portuguese/Brazilian [26]. This questionnaire consists of 30 questions, divided into nine individually scored domains. The total score ranges from 0 to 100: a score of 100 represents the worst possible QOL, and 0 represents the best possible QOL [25,26].

2.3. Treatment protocol

The SESG and IESG performed 12 individual sessions of ES, two weekly sessions of 20 min with Dualpex 961 (Quark Medical Products) equipment. The electric parameters used in both treatments were: current type: functional electrical stimulation; frequency: 50 Hz; pulse duration: 700 μs; time: 20 min; 4-s on/8-s off cycles; rise: 2 s fall: 2 s; stimulation intensity: maximal level tolerable [7,16]. In the SESG and IESG the women were not instructed to perform the PFM contraction during the ES. The treatment of both groups was performed by another physical therapist that did not participate in the evaluations.

In the SESG the women were positioned supine, with 45° of hip and knee flexion. In this treatment, four surface electrodes of silicone (2.0 cm × 3.0 cm) were fixed with masking tape. Two electrodes were placed in the suprapubic region and the other two electrodes were crossed on the skin and fixed medial to the ischial tuberosity [16,27]. During the treatment the women used panties.

In the IESG the participants were positioned supine with 45° of hip and knee flexion for the positioning of an intravaginal electrode. The intravaginal electrode used was the Dualpex 961 (Quark Medical Products) urogynecological electrode. During the treatment the volunteers were positioned supine with hip and knee in a neutral position.

The CG did not receive any treatment during the corresponding treatment time. Afterwards, CG subjects were referred for physical therapy treatment.

2.4. Statistical analysis

All statistical analyses were performed using Statistica Statistical Software 7.0 (StatSoft Inc.). The Shapiro–Wilk test was used to evaluate the normal distribution, Kruskal–Wallis test to verify the homogeneity, Wilcoxon nonparametric test for intragroup analysis, Kruskal–Wallis test for intergroup analysis, and

Table 1
Demographic and clinics characteristics of the study participants ($n = 45$).

	SESG ($n = 15$)	IVESG ($n = 15$)	CG ($n = 15$)
Age (years)	64.46 ± 8.83	59.86 ± 4.82	60.13 ± 9.35
BMI (kg/m^2)	28.28 ± 4.383	28.26 ± 4.26	29.88 ± 3.75
Number of deliveries	2.73 ± 1.66	2.80 ± 0.94	2.66 ± 1.04
Vaginal deliveries	0.86 ± 1.12	1.20 ± 1.14	1.06 ± 0.96

Data presented as mean ± standard deviation.
SESG, Surface Electrical Stimulation Group; IVESG, Intravaginal Electrical Stimulation Group; CG, Control Group.

Mann–Whitney test for pairwise comparison. The level of significance used was <0.05 and to measure the clinical significance of the data, the effect size and confidence interval (CI) were calculated. The effect sizes were considered: mild: values <0.20; moderate: 0.25 and 0.75; large: >0.80 [28].

3. Results

Among the 48 women who started the treatment, two from the CG (13.33%) did not perform the final evaluation due to a health problem and were excluded and substituted by two other patients. One participant in the IVESG (6.66%) reported dysmenorrhea and was excluded from this treatment and substituted by another participant. Forty-five volunteers completed the study and were included in the analysis (Fig. 1). No important difference in any characteristic was found at baseline between the groups (Table 1).

There was a significant reduction in urinary leakage measured by the 1-h pad test in the SESG ($p = 0.01$; effect size: 0.21) and IVESG ($p = 0.01$; effect size: 0.41) after the treatment. In the CG there was no significant difference in this variable ($p = 0.61$, effect size: 0.02). In the intergroup analysis, there was a significant reduction, after the treatment, in the SESG and CG ($p = 0.009$; effect size −0.31; 95% CI from −14.61 to 5.99) as well as between IVESG and CG ($p < 0.001$; effect size: −0.67: 95% CI from −15.30 to 0.88) after the treatment (Table 2).

There was a significant improvement in muscle strength after the treatment in the IVESG. The intergroup analysis did not find statistical differences between SESG, IVESG and CG (Table 2). There was a significant increase in perineometry of the PFM in the SESG and IVESG after treatment. The intergroup analysis did not show statistical differences between SESG, IVESG and CG (Table 2).

In the evaluation of QOL, there was a significant reduction of scores in different domains, such as: incontinence impact, limitations of daily activities, physical limitation, emotion, sleep and disposition and severity in SESG (all $p < 0.02$; effect size −2.73; 95% CI from −75.46 to 6.96) and IVESG (all $p < 0.04$; effect size −3.07; 95% CI from −77.27 to 6.40) after the treatments. In relation to the social limitation there was significant improvement after the treatment only in the IVESG. The intergroup analysis presented significant differences in incontinence impact, limitations of daily

Table 2
Values and intragroup and intergroup analysis of urinary leakage and pelvic floor muscle strength for the three groups before and after treatment.

		Pre-treatment	Post-treatment	Intragroup p value
One hour pad test (g)	SESG	6.28 ± 15.19	3.31 ± 12.10[b]	0.010[a]
	IVESG	2.20 ± 4.65	0.41 ± 0.78[b]	0.010[a]
	CG	7.33 ± 16.02	7.62 ± 15.27	0.61
	Intergroup p value	0.18	0.0005	
Strength	SESG	2.06 ± 0.80	2.53 ± 0.83	0.07
	IVESG	2.00 ± 1.00	2.66 ± 0.81	0.007[a]
	CG	2.16 ± 0.83	2.25 ± 0.86	0.99
	Intergroup p value	0.95	0.29	
Pressure (cmH_2O)	SESG	39.41 ± 17.65	47.37 ± 19.16	0.004[a]
	IVESG	37.42 ± 22.89	44.23 ± 20.10	0.04[a]
	CG	37.92 ± 22.95	37.65 ± 19.16	0.58
	Intergroup p value	0.74	0.52	

Data presented as mean ± standard deviation.
SESG, Surface Electrical Stimulation Group; IVESG, Intravaginal Electrical Stimulation Group; CG, Control Group.
[a] Significant differences intragroup between pre-treatment and post-treatment.
[b] Significant differences versus Control Group (Mann–Whitney tests).

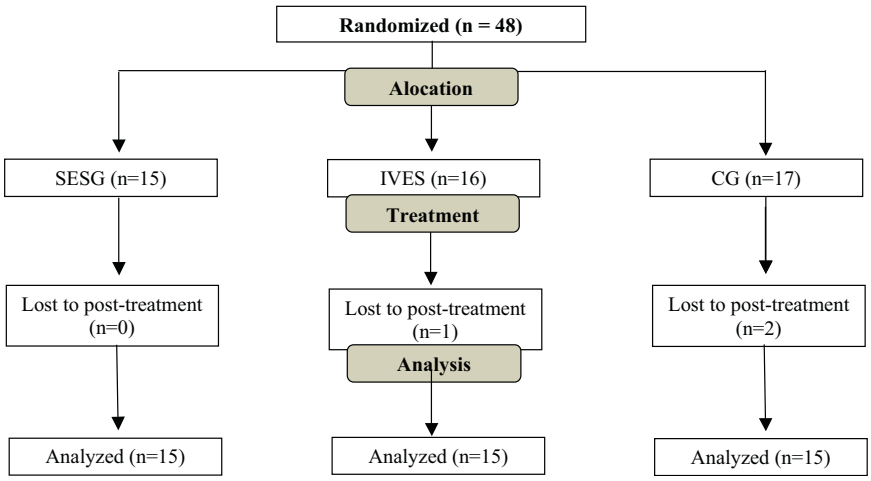

Fig. 1. Participants flow diagram.

Table 3
Values of the King's Health Questionnaire domains for the groups.

		Pre-treatment	Post-treatment	Intragroup *p* value
General health	SESG	40.00 ± 26.39	33.33 ± 32.27	0.68
	IVESG	38.33 ± 18.58	26.66 ± 17.59	0.07
	CG	37.50 ± 25.00	43.75 ± 21.65	0.61
	Intergroup *p* value	0.74	0.17	
Incontinence impact	SESG	57.78 ± 32.04	6.66 ± 13.80[b]	0.0005[a]
	IVESG	64.44 ± 32.03	4.44 ± 11.73[b]	0.0005[a]
	CG	58.33 ± 37.94	61.11 ± 37.15	0.44
	Intergroup *p* value	0.80	<0.0001	
Limitations of daily activities	SESG	34.44 ± 42.00	0.00 ± 0.00[b]	0.01[a]
	IVESG	36.66 ± 26.12	0.00 ± 0.00[b]	0.001[a]
	CG	56.94 ± 39.85	54.16 ± 40.27	1.00
	Intergroup *p* value	0.39	<0.0001	
Physical limitations	SESG	43.33 ± 31.37	1.11 ± 4.30[b]	0.0003[a]
	IVESG	43.33 ± 39.74	1.11 ± 4.30[b]	0.004[a]
	CG	54.16 ± 44.45	51.38 ± 42.91	0.68
	Intergroup *p* value	0.52	<0.0001	
Social limitations	SESG	18.52 ± 32.71	1.85 ± 5.00	0.22
	IVESG	21.48 ± 31.83	0.00 ± 0.00[b]	0.02[a]
	CG	33.79 ± 34.85	31.01 ± 36.19	0.68
	Intergroup *p* value	23	0.0007	
Personal relationships	SESG	4.44 ± 11.73	0.00 ± 0.00[b]	0.47
	IVESG	13.33 ± 35.74	0.00 ± 14.08	0.22
	CG	13.88 ± 23.39	22.22 ± 33.58	1.00
	Intergroup *p* value	0.35	0.04	
Emotions	SESG	28.15 ± 38.23	2.96 ± 8.88[b]	0.01[a]
	IVESG	48.15 ± 33.77	2.96 ± 7.82[b]	0.0008[a]
	CG	49.07 ± 32.29	56.48 ± 33.65	0.75
	Intergroup *p* value	0.1548	<0.0001	
Sleep and disposition	SESG	27.77 ± 41.62	0.00 ± 0.00[c]	0.02[a]
	IVESG	14.44 ± 28.08	0.00 ± 0.00[c]	0.07
	CG	30.55 ± 43.13	30.55 ± 43.13	0.68
	Intergroup *p* value	0.8140	0.003	
Severity measures	SESG	37.77 ± 29.67	8.09 ± 14.60[b]	0.0005[a]
	IVESG	38.66 ± 21.56	1.77 ± 4.69[b]	0.0003[a]
	CG	47.22 ± 26.12	58.33 ± 25.60	0.75
	Intergroup *p* value	0.7605	<0.0001	

Data presented as mean ± standard deviation.
SESG, Surface Electrical Stimulation Group; IVESG, Intravaginal Electrical Stimulation Group; CG, Control Group.
[a] Significant differences between pre-treatment and post-treatment.
[b] Significant difference versus Control Group ((Mann–Whitney tests).
[c] Significant differences Surface Electrical Stimulation Group versus Intravaginal Electrical Stimulation Group (Mann–Whitney tests).

activities, physical limitation, social limitation, emotion, sleep and disposition and severity domains when comparing the SESG and CG, and the IVESG and CG ($p < 0.04$). In the social relation and sleep domains there were significant differences intergroup analysis, after the treatment, between the SESG and CG ($p = 0.04$), and the SESG and IVESG (<0.001) (Table 3).

4. Comment

In this study, 12 sessions of treatment with SES and IVES were effective for SUI, demonstrating these to be a good option for treatment. We observed improvement after IVES treatment in urinary leakage, strength and pressure of PFM contraction, while the SESG presented improvement only in urinary leakage and PFM pressure.

The improvement in the urinary leakage in women treated with IVES was verified in other studies [7,29] agreeing with the result of the present study. In relation to SES treatment, only one study has verified the improvement of urinary leakage evaluated by the 1-h pad test [16].

In relation to the PFM contraction pressure, Dumoulin et al. [14] also found an increase in the pressure with SES. In the study of Pereira et al. [16], however, there was no improvement in contraction pressure with the SES treatment, disagreeing with this study.

In intergroup analysis, there was significant difference between the CG and both the SESG and IVESG in the 1-h pad test after treatment. There are no studies that compared SES and IVES, only those that evaluated the difference between an IVESG and a CG [10,30]. Bø et al. [10] did not find intergroup difference in contraction pressure and pad test, agreeing partially with this study. Castro et al. [30] verified a significant difference in the 20-min pad test, agreeing with the present study.

Currently QOL evaluation is considered to be more relevant than quantitative measurement, because it reflects the patients' satisfaction with the treatment [36,37]. This study found improvement in many domains of KHQ in both treatment groups. Two studies verified improvement in QOL after IVES, but those studies used another questionnaire, the I-QOL. Only Pereira et al. [16] evaluated the QOL after SES treatment and found improvement in some domains of KHQ, agreeing with the present study.

In this study the women who underwent treatment with SES or IVES presented a significant decrease in pad test value and reported an improvement in QOL after the treatment. A possible explanation for the improvement of SUI is that the ES causes the pudendal nerve stimulation [6,8]. This stimulus promotes

contractions of the PFM, thus strengthening its muscle fibers [8,31–33]. Another important role of ES is an improvement in the electric activation, improving the proprioception and coordination in pelvic floor contraction during the situations that cause SUI [34].

Moreover the pudendal nerve is an efferent nerve for the external urethral sphincter [35], so this treatment is capable of increasing the pressure of urethral closure, improving the SUI. Another important factor is that the ES increases the blood flow to the urethra and PFM, improving the neuromuscular connections, muscular fiber function and genital atrophy. So, with these changes in the PFM there is improvement of the mechanism of urethral closure and SUI [6,33]. These are two possible explanations for the result of this study in that it improved the urinary leakage and QOL without a significant difference between the three groups in the PFM strength and pressure after the treatment.

The position used in this study was described in 1995 by Dumoulin et al. [14], who compared it with another positioning and concluded that in this position the current penetrates deeper within the pelvis. After, Kajbafzadeh et al. [27] used this same position of electrodes in children with myelomeningocele and found a good result. In the last study with this position, Pereira et al. [16] concluded that this treatment improved the SUI and QOL of women. So, interest in this less invasive treatment seems to be increasing because it is effective, but it needs more studies.

According to Green et al., IVES is a very invasive treatment in the patient's perception, decreasing the acceptance and adherence to use of this treatment. The use of SES can be more acceptable to the patients and comfortable for physical therapist [9].

The main limitation of this study was the absence of an electromyographic evaluation to verify if modification in PFM activation occurs. Another limitation is that we did not utilize ultrasonography to evaluate if hypertrophy of PFM happens after the ES treatment.

The clinical application of this study is that SES is an option for SUI treatment, with good results and many advantages, such as: it is not necessary sterilize the equipment, it is a cheap treatment, it is not necessary to use specific equipment and this treatment can be used in women, men and children, because it is not invasive.

In conclusion, SES and IVES are important treatments to improve SUI. Both treatments improved QOL, urinary leakage, strength and pressure of PFM contraction. Although this is a preliminary study that compares the SES with the IVES, it opens a new line of possibilities for further studies. Future research should include a follow-up period, urodynamic examination and the use of electromyography.

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