Effects of surface electrical stimulation in older women with stress urinary incontinence: A randomized controlled pilot study☆

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Abstract

Objective: The objective of this study was to evaluate the effects of surface electrical stimulation in elderly women with stress urinary incontinence (SUI) as compared to no treatment.

Materials and methods: This randomized controlled pilot study included women over the age of 60 years, with at least one episode of stress urinary leakage during the previous month. Fourteen women were allocated according to a computer generated randomization list to two groups: surface electrical stimulation (SES), and control group (CG). The women in the SES group were treated with surface electrical stimulation using four electrodes, during six weeks with two weekly sessions of 20 min each. They were evaluated before and after treatment primary outcome, urinary leakage, and secondary outcomes, King’s Health Questionnaire, pressure perineometry, and subjective satisfaction.

Results: For the urinary leakage, there was a significant decrease in SES group after treatment ($p = .017$). Significant differences were observed between the SES group and CG in the evaluation after treatment ($p < .01$; effect size: $-1.38$; 95% confidence interval from 1.18 to 14.14). No significant differences were observed in both groups for the outcome pelvic floor muscle pressure. In the evaluation of quality of life, a significant reduction of score in the gravity domain was observed for the SES group after treatment ($p = .017$).

Conclusion: The results of this study showed that surface electrical stimulation in elderly women with SUI can be an effective method for the improvement of urinary leakage.

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Efecles de la electroestimulación superficial en las mujeres mayores con incontinencia urinaria de esfuerzo: estudio piloto aleatorio controlado

Resumen

Objetivos: El objetivo de este estudio fue evaluar los efectos de la estimulación eléctrica de superficie en mujeres con incontinencia urinaria de esfuerzo (IUE) sin comparla con ningún tratamiento.

Material y métodos: Este estudio piloto, aleatorio y controlado, incluyó mujeres mayores de 60 años con al menos un episodio de fuga de orina de esfuerzo durante el mes anterior. Catorce


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mujeres fueron distribuidas aleatoriamente en 2 grupos: estimulación eléctrica de superficie (EES) y grupo control (GC). Las mujeres en el grupo EES fueron tratadas con estimulación eléctrica de superficie con 4 electrodos durante 6 semanas, con 2 sesiones semanales de 20 min. Fueron evaluadas antes y después del tratamiento para el resultado primario, la pérdida de orina, y para los secundarios, mediante el Cuestionario de Salud de King, presión de la contracción y la satisfacción subjetiva.

**Resultados:** Para el escape de orina se observó una disminución significativa en el grupo EES después del tratamiento ($p = 0.017$). Se apreciaron diferencias significativas entre el grupo EES y GC en la evaluación después del tratamiento ($p < 0.01; \text{tamaño del efecto: } \leq 1,38, \text{IC del } 95\% \text{ de 1,18 a 14,14}$). No se observaron diferencias significativas en ambos grupos para el resultado de presión de la contracción. En la calidad de vida se constató una reducción significativa de la puntuación en el dominio de la gravedad para el grupo EES después del tratamiento ($p = 0.017$).

**Conclusiones:** Los resultados demostraron que la estimulación eléctrica de superficie en mujeres con IUE puede ser un método eficaz para la mejora de las pérdidas de orina.

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**Introduction**

According to the International Continence Society (ICS), urinary incontinence (UI) is defined as any involuntary loss of urine. It is one of the most common public health problems among women of all ages, with an increase in its prevalence with aging. It is estimated that 25–45% of women of different ages have involuntary urine loss and 9–39% of women over 60 years report daily urinary leakage.

The most common type of UI in women is stress urinary incontinence (SUI). Currently, the ICS recommends physical therapy as first treatment option for SUI with the aim of improving strength and pelvic floor muscle activation. It is suggested that this alteration on the pelvic floor muscles leads to permanent elevation of the levator plate muscle to a higher resting position inside the pelvis, ‘lifting’ the pelvic viscera and restoring normal reflex activity and other protective continence mechanisms.

Different modalities of conservative treatment are proposed for the UI treatment, including electrical stimulation. The intravaginal electrical stimulation is the most common technique in clinical practice and provides good results in the treatment of SUI. However, this treatment can provide an unpleasant vaginal and perineum sensation, and promote emotional stress caused by the embarrassment with the technique, especially in elderly women. Therefore, the surface electrical stimulation may be a way to achieve the benefits of electrical stimulation, with lower cost and without discomfort or embarrassment to patients. Nevertheless, there are no studies assessing the effects of surface electrical stimulation in elderly women with SUI. Thus, the objective of this study was to evaluate the effects of surface electrical stimulation in elderly women with SUI as compared to no treatment.

**Materials and methods**

This is a randomized controlled pilot study, with parallel randomization (1:1), was performed from November 2010 to March 2011 and conducted at the Laboratory for Assessment and Intervention on Women’s Health, XXXXX. The local ethics committee approved the study (report #405/2010), which is in agreement with the Declaration of Helsinki.

The women were recruited through newspaper and website advertisements. This study included women over the age of 60 years, with at least one episode of urine leakage during the previous month. Two standard questions about stress and urgency UI were used to determine the patient eligibility. The questions are part of the King’s Health Questionnaire (KHQ) scale of urinary symptoms. This is one reliable instrument, validated in Portuguese/Brazil and specifically for women with UI. For SUI the question was “Do you lose urine with physical activities such as coughing, sneezing, running?”. For the urgency UI the question was “Do you have strong desire to urinate and very difficult to control?”. Only women who answered “yes” to the first question were recruited. Women who answered “yes” to the second question or to both questions were excluded. Exclusion criteria also included previous treatment for UI or hormone therapy, ongoing urinary tract infections, cognitive or neurological disorder, uncontrolled hypertension, inability to perform the proposed procedures, or use of pacemaker implantation or metal rods.

All participants signed an informed consent and were instructed about the study protocol. Twenty potential participants were screened and 14 met the criteria. They were allocated according to a computer generated randomization list in two groups: surface electrical stimulation (SES), $n = 7$; and control group (CG), $n = 7$ (Fig. 1). For the allocation, a researcher not involved in data collection or analysis developed a randomization schedule and produced 14 consecutively numbered sealed opaque envelopes containing each participant’s allocation. Immediately after collecting baseline data, the evaluator opened the allocation envelope, which contained a paper writing surface electrical stimulation or control group. Therefore all participants were allocated to one of the two groups.

**Outcome measurements**

Only one not blinded experienced physical therapist performed evaluations of the two groups. Initially, all women went through a complete physical examination and an interview regarding their thorough medical history. Women were evaluated before and after treatment completion for primary outcome (urinary leakage) and secondary outcomes
(pelvic floor muscle pressure, quality of life, and satisfaction with treatment). The primary investigator carried out a prior evaluation of the test–retest reliability. Ten women with SUI were tested on two occasions, separated by one week, to determine the intraclass correlation coefficients (ICC) and standard errors of measurement (SEM) for all variables.

The 1-h pad test was carried out to evaluate urinary leakage according to the protocol proposed by Abrams. The volunteers were instructed to place a pad previously weighed on a precision balance Denver APX200 (precision of 0.0001 g, Denver Instrument, Denver, USA) 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, reweighed and the urinary loss was calculated. The ICC and the SEM for this variable were 0.99 and 0.45 g.

To evaluate the pelvic floor muscle pressure, a Perina Stim device (Quark Medical Products, Piracicaba, Brazil) was used, graded from 0 to 60 cmH2O and supplied with a vaginal probe. Volunteers were positioned in supine, with hip and knee flexion. The vaginal probe was inserted into the vagina and the device was calibrated. Then, volunteers were asked to perform three 3-s maximum perceived effort contractions of pelvic floor muscles. The volunteers were instructed not to use abdominal, gluteal, and/or hip adductor muscles during the contractions and carry out the ‘inward and upward’ movement. The contractions were considered valid only when this pelvic floor muscle movement could be observed. The ICC and SEM were 0.97 and 0.53 cmH2O, respectively.

For the assessment of quality of life, the KHQ was used. This questionnaire consists of 30 questions, divided into nine individually scored domains. Because it is a long questionnaire, three broad domains related to UI were chosen. These domains (ICC; SEM) are: general health (0.79; 8.69), incontinence impact (0.82; 13.33), and gravity (0.91; 7.60). The total score ranges from 0 to 100, a score of 100 represents the worst possible quality of life and 0 represents the best possible quality of life.

At the end of the treatment, the women of the treated group were questioned regarding their satisfaction with the treatment. The only two response options available were ‘satisfied’ and ‘dissatisfied’. Answering ‘satisfied’ indicated that the patient did not want a different treatment. Answering ‘dissatisfied’ indicated that the patient wanted a different treatment from the initial one.

**Treatment protocol**

The treatment protocol was carried out under the supervision of the same physical therapist who carried out the evaluation. The treatment consisted of 12 individual sessions, with two weekly sessions of 20 min each. The total time of the treatment was six weeks. The surface electrical stimulation of the pelvic floor muscles was performed using the equipment Dualpex 961 (Quark Medical Products, Piracicaba, Brazil). The women were positioned in supine, with hip and knee flexion. Four surface electrodes were used, two placed in the suprapubic region and two medial to the ischial tuberosity. Electric parameters were frequency at 50 Hz, a 4-s to 8-s work–rest cycle, and a 700-μs pulse width, with stimulation intensity gradually increasing up to the level of tolerable discomfort. The women were not instructed to perform the contraction of the pelvic floor muscles in conjunction with electrical stimulation. The CG did not receive any treatment during the corresponding treatment time. Afterwards, CG subjects were evaluated and referred to physical therapy treatment.

**Statistical analysis**

All statistical analyses were performed using the Statistica statistical software (version 7.0, StatSoft Inc., Tulsa, United States). To test the normal distribution of data in each group, the Shapiro–Wilk test was used. The Mann–Whitney test was used for intergroup analysis and to verify the homogeneity of the groups in the baseline. For intragroup
analysis, the Wilcoxon test was used. The differences were considered significant when the p value was <0.05. To measure the practical significance of the primary outcome, the effect size and the confidence interval were calculated. The effect sizes were considered mild if the values were smaller than 0.20; moderate if values were between 0.25 and 0.75, and large when values were over 0.80.15

Results

At baseline, there were no significant differences between the groups in terms of demographics and clinics characteristics (Table 1). All the women completed the treatment and were included in the analysis. For the urinary leakage measured by pad test, there was a significant decrease in the SES group after the treatment. Significant differences were observed between the SES group and the CG in the evaluation after treatment (effect size: -1.18; 95% confidence interval from 1.18 to 14.14). No significant differences were observed in both groups for the outcome of the pelvic floor muscle pressure (Table 2).

In the evaluation of quality of life, a significant reduction of score in the gravity domain was observed for the SES group after the treatment. In the intergroup analysis, significant differences for the incontinence impact and gravity domains were observed when comparing the treated group and the CG after the treatment (Table 3). Regarding satisfaction with the received treatment, all the SES group subjects reported that they were satisfied with the treatment. There were no complaints of adverse effects due to the treatment from either group.

Discussion

In the present study, we observed, after six weeks of treatment, a significant reduction of urinary leakage in women treated with surface electrical stimulation. The significant decrease in the gravity domain and the reported satisfaction with the treatment by the treated group are in agreement with the reduction of urinary leakage. However, the urinary leakage decrease was not associated with a significant increase in the pelvic floor muscles pressure. It is known that the pelvic floor muscles are essential for urinary continence since its phasic activity assists in occluding the urethral lumen by providing a firm surface against which the urethra can be compressed during increases in intra-abdominal pressure.16

It is hypothesized that electrical stimulation, applied intravaginal or superficially, is able to increase blood flow to the urethra and pelvic floor muscles, re-establish neuromuscular connections, and improve the function of muscle fibers. In this way, there could be a modification of the activation of the pelvic floor muscles, with the increase in the number of fast muscle fibers, improving the urethral closure mechanism during the increase in intra-abdominal pressure.9,17 Therefore, in this study, it is possible that electrical stimulation has reduced the onset time of the pelvic floor muscles contraction in response to increased intra-abdominal pressure, which could explain the reduction of urinary leakage in the treated women. However, the electromyographic analysis after treatment is necessary to provide this information.

Herrmann et al.18 performed the treatment with intravaginal electrical stimulation in women with SUI, with the same parameters of the present study, and he also reported a reduction in urinary leakage episodes after 8 weeks of the treatment. In agreement with this study, these authors also found no increase in pelvic floor muscle pressure, indicating that the pressure of contraction may not necessarily be a prerequisite for achieving clinical improvement of SUI18.

The effects of electrical stimulation in elderly women with UI are poorly addressed in the literature. The elderly population has a high incidence of lower urinary tract dysfunction, possibly resulting from the sum of the effects caused by the reduction of endogenous estrogen production in postmenopausal period and advanced age.19 The postmenopausal hypoestrogen status has been associated with anatomic and physiologic changes, such as thinning of the urethral mucosa, loss of urethral closure pressure, and

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Demographic and clinic characteristics of the study participants (n = 14).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SES (n = 7)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>68.57 (10.93)</td>
</tr>
<tr>
<td>BMI (kg/cm²)</td>
<td>26.6 (5.80)</td>
</tr>
<tr>
<td>Number of deliveries</td>
<td>3.71 (1.89)</td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>2.57 (1.62)</td>
</tr>
<tr>
<td>Urinary symptoms (years)</td>
<td>3.86 (1.67)</td>
</tr>
</tbody>
</table>

Data presented as mean (standard deviation).

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Values of urinary leakage and pelvic floor muscle pressure for the groups before and after treatment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable groups</td>
<td>Pre</td>
</tr>
<tr>
<td>Urinary leakage (g)</td>
<td>SES</td>
</tr>
<tr>
<td></td>
<td>CG</td>
</tr>
<tr>
<td></td>
<td>Intergroup p value</td>
</tr>
<tr>
<td>Pressure (cmH₂O)</td>
<td>SES</td>
</tr>
<tr>
<td></td>
<td>CG</td>
</tr>
<tr>
<td></td>
<td>Intergroup p value</td>
</tr>
</tbody>
</table>

Data presented as mean (standard deviation).

* Statistical difference (p < 0.05).
Table 3  Values of the KHQ domains for the groups.

<table>
<thead>
<tr>
<th>Domains</th>
<th>Groups</th>
<th>Pre</th>
<th>Post</th>
<th>Intragroup p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Health</td>
<td>SES</td>
<td>42.86 (18.91)</td>
<td>35.71 (13.36)</td>
<td>0.42</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>42.86 (12.22)</td>
<td>32.14 (12.23)</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>Intergroup p value</td>
<td>0.89</td>
<td>0.65</td>
<td></td>
</tr>
<tr>
<td>Incontinence impact</td>
<td>SES</td>
<td>66.57 (33.52)</td>
<td>23.76 (25.81)</td>
<td>0.062</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>71.43 (29.95)</td>
<td>66.71 (27.22)</td>
<td>0.98</td>
</tr>
<tr>
<td></td>
<td>Intergroup p value</td>
<td>0.61</td>
<td>0.013^</td>
<td></td>
</tr>
<tr>
<td>Gravity measures</td>
<td>SES</td>
<td>49.57 (27.77)</td>
<td>12.43 (15.18)</td>
<td>0.017^</td>
</tr>
<tr>
<td></td>
<td>CG</td>
<td>37.19 (18.02)</td>
<td>38.1 (18.74)</td>
<td>0.97</td>
</tr>
<tr>
<td></td>
<td>Intergroup p value</td>
<td>0.37</td>
<td>0.02^</td>
<td></td>
</tr>
</tbody>
</table>

Data presented as mean (standard deviation).

^Statistical difference (p < 0.05).

Alteration of the urethrovaginal angle. It is also known that advanced age is associated with decline in muscle function throughout the body, including the pelvic floor muscles. These alterations are caused among other factors by decreased muscle mass, with preferential atrophy of type II fibers. The fast twitch type II fibers in the pelvic floor muscles play an important role in continence, because they are activated during increased intra-abdominal pressure in order to occlude the urethra and prevent urine leakage.

Spruitt et al. treated a group of incontinent elderly women with supervised intravaginal electrical stimulation and a second group was instructed to perform pelvic floor muscle training at home. The authors found no significant differences between the groups for urinary leakage and pelvic floor muscle pressure. These authors concluded that the intravaginal electrical stimulation results in high levels of physical and emotional stress to elderly patients, indicating that perhaps the most efficient and acceptable way of electrical stimulation in this population has yet to be determined. Thus, with the results of the present study, the surface electrical stimulation could be an option for the urinary incontinence treatment in older women and also in children and men.

Few studies have evaluated the effects of surface electrical stimulation as a treatment option for incontinent women. Demirturk et al. evaluated the effects of interferential current applied to electrodes positioned similar to the present study in women with SUI. The women were treated for five weeks, with three weekly sessions of 15 min. In comparison with a second group treated with biofeedback, superficial electrical stimulation showed similar results for urinary leakage, pelvic floor muscle pressure, and quality of life. The results demonstrated that surface electrical stimulation may be effective for the treatment of incontinent women without side effects, however, the absence of a control group prevents any conclusion about the effectiveness compared with no treatment.

The sample size is the main limitation of this initial study. Also, it cannot be ignored that a larger sample size could have altered some of the results of the study. However, despite the small sample size, the calculation of effect size showed that the treatment had a large effect on clinical variables. Another limitation is that the therapist who carried out the evaluation and treatment was not blinded. Furthermore, the electromyographic evaluation could provide additional information about the possible modifications of muscle recruitment in response to treatment with the use of surface electrical stimulation. Therefore, further research is required before definite conclusions about this topic can be drawn.

Conclusions

The results of this study showed that surface electrical stimulation in elderly women with SUI can be an effective method for the improvement of urinary leakage. Therefore, this technique can be used as an alternative to intravaginal application in clinical practice without offering discomfort or embarrassment. However, further studies should be performed to reach definite conclusions about this intervention in elderly women.

Conflict of interest

The authors declare no conflict of interest.

References


