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Effects of Transcutaneous Electrical Stimulation on Physiological Symptoms and Psychological Satisfaction in Women With Stress Urinary Incontinence: A Preliminary Study

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Abstract

Background: Stress urinary incontinence (SUI) is an involuntary leakage of urine from the urethra when intra-abdominal pressure increases, such as from sneezing, coughing, or physical exertion. It is caused by insufficient strength of the pelvic floor and sphincter muscles, resulting from vaginal delivery, obesity, hard physical work, or aging. The pelvic floor electrical stimulator is a conservative treatment generally used to relieve the symptoms of urinary incontinence. it recommended to applied before surgery is performed.

Objects: The purpose of this study was to determine if the transcutaneous electrical stimulation (TCES) would be effective for the physiological symptoms and psychological satisfaction of women with SUI for an 8-weeks intervention.

Methods: Easy-K is a specially designed user-friendly TCES. Five female who were diagnosed with SUI by a gynecologist but who did not require surgical intervention were included in this study. Intervention was implemented over an 8-week period. Outcome measures included vaginal ultrasonography, Levator ani muscle (LAM) contraction strength, incontinence quality of life (I-QOL), and female sexual function index (FSFI) questionnaires.

Results: The bladder neck position significantly decreased across assessment time. Funneling index and urethral width significantly decreased after 8 weeks of intervention ($p<.05$). The bladder neck-symphyseal distance and posterior rhabdosphincter thickness statistically increased and the anterior rhabdosphincter thickness showed a tendency to increase. All participants demonstrated a significant increase in the LAM contraction score across three assessment times ($p<.05$). Although the total score of the I-QOL did not show significant improvement, it steadily increased and among I-QOL subscales, only the "avoidance" subscale showed statistical improvements ($p<.05$). The total score of the FSFI statistically improved and the "desire" score significantly changed ($p<.05$).

Conclusion: The TCES is recommended for women who want to apply conservative treatments before surgery and who have suffered from SUI in aspects of sexual function and quality of life.

Key Words: Pelvic floor electrical stimulation; Pelvic floor muscle; Stress urinary incontinence.

Introduction

Stress urinary incontinence (SUI), a common women health problem, is an involuntary leakage of urine from the urethra when intra-abdominal pressure increases due to sneezing, coughing, or physical exertion (Cammu et al, 2000; Nygaard and Heit, 2004). SUI is caused by insufficient strength of the

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pelvic floor and sphincter muscles, which results from vaginal delivery, obesity, hard physical work, or aging (Dimpfl et al, 1998; Nygaard and Heit, 2004; Sievert et al, 2012).

This disorder affects women's social, physical, psychological, and sexual qualities of life (Barber et al, 2002; Jha et al, 2018; Wyman et al, 1987). Complaints about sexual activity are common in women with pelvic floor problems (Barber et al, 2002). According to a previous study, women with SUI have more sexual dysfunction than continent women, and sexual dysfunction in women is generally characterized by disorders of desire/libido, arousal, pain/discomfort, and inhibited orgasm (Rosen, 2000; Walters et al, 1990).

Pelvic floor muscles (PFM) support for the pelvic viscera under all circumstances and control of pelvic outlets (Sapsford, 2001). Levator ani muscles (LAM), the most important muscle belonging to the PFM, contain the pubococcygeus and iliococcygeus muscles (Gosling et al, 1981). Partial denervation of the pubococcygeus muscle often results from vaginal deliveries in women experienced childbirth (Allen et al, 1990). A prior study revealed that women with urinary incontinence have shorter voluntary holding times of the pubococcygeus muscle and less vaginal surface electromyography activity than continent women (Deindl et al, 1994; Gunnarsson and Mattiasson, 1999).

Various surgical and non-surgical intervention approaches such as medications, PFM training exercises, and electrical stimulation have been applied for SUI. Pelvic floor electrical stimulation (PFES) is a conservative treatment used to relieve the symptoms of urinary incontinence and is performed before considering surgical interventions (Huffman et al, 1952; Nygaard and Heit, 2004). PFES may lead to nerve regrowth and strengthening of the external sphincter, thereby increasing bladder outlet resistance over time (Appell, 1998; Kobashi and Leach, 1999). In addition to these effects, some studies have suggested PFES for women with sexual dysfunction (Giuseppe et al, 2011; Rosenbaum, 2005).

There are two common PFES types for SUI; Transcutaneous electrical stimulation (TCES) and intravaginal electrical stimulation and the effectiveness of each type has been clinically proved (Brubaker et al, 1997; Giuseppe et al, 2011; Goode et al, 2003). The intravaginal type must be inserted into the vagina, which may cause irritation and increases the risk of infections. In contrast, TCES is more convenient to the user and safer with respect to infections compared to the intravaginal type. TCES assists women who have a hard time in identifying and feeling the PFM as well as provides electrically induced contraction of the weak PFM (Goode et al, 2003).

The purpose of this preliminary study was to investigate a specially designed user friendly TCES would be effective on the physiological symptoms and psychological satisfaction of women with SUI in an 8-weeks intervention. We hypothesized that applying TCES to women undergoing SUI will improve the physiological symptoms of SUI and their psychological satisfaction of life.

Methods

Subjects

Five female who were diagnosed with SUI by a gynecologist but did not require surgical intervention and suffered from a urinary leakage when increasing intra-abdominal pressure such as sneezing, coughing or physical exertion were included from a university hospital. The mean age of the participants was 53.8 years (range, 49-57 years). Exclusion criteria were pregnancy (Jha et al, 2018), histories of surgical correction of urinary incontinence, colporrhaphy, hysterectomy, and difficulties in understanding the questionnaires. All participants read an explanation of the experimental procedures.

Procedure

An Easy-K (Alpha medic Corp., Daegu, Korea), specially designed TCES for women with SUI, was

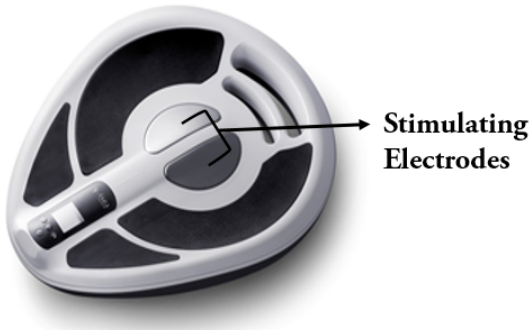

Figure 1. Easy-K, Transcutaneous electrical stimulator.

used in this study (Figure 1). The performance of the device is as follows; Maximum output frequency (㎐): 27 ± 30%, electric current (㎃): 10 ± 30%, voltage: 55 ± 30%, pulse width (㎲): 410 ± 30%. Surface electrodes of the stimulator had a pair of wide semilunar shape metal plates. The shape and position of the electrodes was designed to come in contact with the entire vulva while the user is sitting on the stimulator. A layer of wet tissue was used as conducting material between the skin and the electrodes. Before using the device, the vulva area was cleaned, and wet tissues were laid on the electrode. The participants sat on the TCES placed on the toilet seat and then self-adjusted the intensity (0-99) to the level that evoked perceivable PFM contraction. The TCES was used once a day for 20 minutes. All participants were asked to write a daily report about the use of the TCES. A researcher checked the compliance of the participants on a daily basis through the daily report and a text message. For all participants, intervention was implemented over an 8-week period and complied with the number of times. The participants were assessed 3 times at baseline, and at 4 and 8 weeks after the start of the intervention.

Outcome measurements

To investigate the effects, we asked the participants to fill out incontinence quality of life (I-QOL) and female sexual function index (FSFI) questionnaires and gynecologist measured the LAM contraction strength and an ultra-sonogram.

I-QOL is a self-reported questionnaire to measure the incontinence-specific quality of life and a Likert-type response scale. The I-QOL contains 22 items, and the participants rated the degree of incontinence using a 5-point rating scale: 1, extreme; 2, quite a bit; 3, moderate; 4, a little; 5, not at all. The sums of the scores of the questionnaire were documented for analysis (Vakili et al, 2005). Each item belonged to one of the 3 subscales of the I-QOL: avoidance and limiting behavior, psychosocial impacts, and social embarrassment. A higher total score means that satisfaction about one's life improved with respect to incontinence.

The FSFI is a valid, reliable and brief questionnaire measuring condition-specific sexual function and satisfaction in women and was developed by Rosen (2000). The FSFI contains 19 items and is subdivided into 6 subscales as follows: desire, arousal, lubrication, orgasm, satisfaction, and pain scale. Each subscale is differently scored, and a maximum score of each domain is as follows: Desire, 10; arousal, 20; lubrication, 20; orgasm, 15; satisfaction, 15; pain, 15; with a total possible score of 95 points. A lower score indicates the severity of the dysfunctions. One of the 5 participants did not response to the FSFI because she did not have any sexual activities, and FSFI was analyzed by only 4 participants.

LAM contraction strength was assessed by a gynecologist as a vaginal insert manner and scored using the Oxford scoring system. Classification of the Oxford scoring system in an ordinal scale (0-5 scale) was as follows: 0, no contraction; 1, flicker; 2, weak contraction; 3, moderate contraction; 4, good contraction; 5, strong contraction (almost normal) (Peschers et al, 1997).

Ultra-sonography (Prosound SSD-α10; ALOKA, Tokyo, Japan) with vaginal type transducer (5.0 ㎒) was used to measure urogynecologic changes baseline, after 4 weeks and 8 weeks the intervention. Participants were asked to drink water as much as possible and not to urinate for 3-4 hours before the

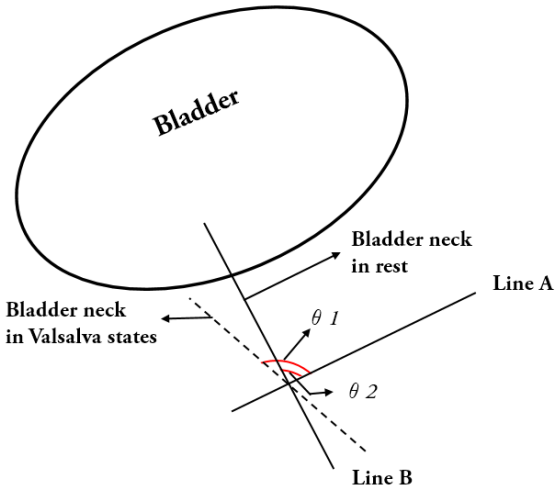

Figure 2. Schematic of an ultra-sonography view; Measurement of bladder neck position (△ bladder neck position= Θ1-Θ2).

test to fill the bladder. They were tested in a lithotomy position by a skilled gynecologist. The outcome variables obtained from the ultra-sonography included the bladder neck position, funneling index, urethral width, rhabdosphincter thickness (anterior and posterior parts), and bladder neck-symphyseal distance. The bladder neck position, funneling index, and urethral width were evaluated at both rest and Valsalva states. Changes in value from rest to the Valsalva states of these variables were calculated and statistically analyzed. The changes in value are denoted by delta(△) in the variables.

The bladder neck position (angle) is the angle between the midline of the symphysis pubis (line A) and a line between the lower margin of a symphysis pubis and the bladder neck (line B) (Yang and Huang, 2002) (Figure 2). The Bladder neck funneling is a clinical terminology to describe the shape of the urethral opening at the proximal bladder neck for diagnosis of SUI (Petri et al, 1999; Yang and Huang, 2002). The funneling is anatomically related to urethral hypermobility and decreased competence of urethral closing (Dietz and Clarke, 2001; Kuo, 1996). Funneling index is calculated by multiplying the width and height of a triangle at the bladder neck (Nishibayashi et al, 2009) (Figure 3). The greater

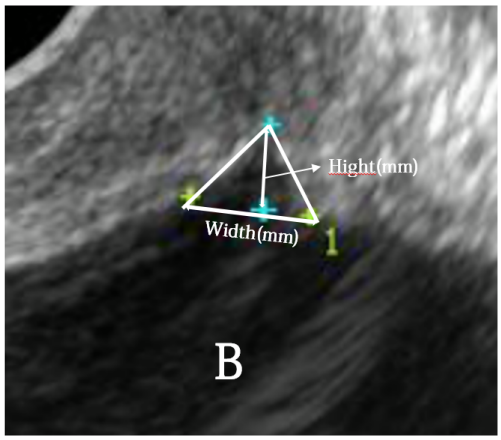

Figure 3. Funneling of bladder neck (B: urinary bladder).

positive index value represents the more severe SUI.

The spacing of the normal urethra is so narrow that it looks like a line in an ultra-sonography view. However, an increased gap between the urethral walls is frequently observed in patients with SUI. The measured spacing of the urethra is urethral width. The rhabdosphincter, a part of external urethral sphincter, is located in the middle part of the urethra (Klauser et al, 2004; Strasser et al, 1996). The thickness of the anterior and posterior rhabdosphincter muscle was measured at a distance of 5 ㎜ from the bladder neck point. The rhabdosphincter thickness were measured only in Valsalva states. The bladder neck-symphyseal distance is the distance from the bladder neck to lower margin of the symphysis pubis. This represents the urethral length indirectly. When the patients with SUI perform the Valsalva maneuver, the bladder neck funneling increases and the bladder neck-symphyseal distance decreases. A smaller bladder neck-symphyseal distance indicates high bladder neck funneling (Figure 4).

Statistical analysis

The data were analyzed using Window SPSS ver. 24.0 (IBM corp., Armork, NY, USA). The Friedman test, a nonparametric statistical test, was used to examine the differences of all outcome variables at baseline, and at 4 and 8 weeks after the intervention and the significance level was set at .05. If a sig-

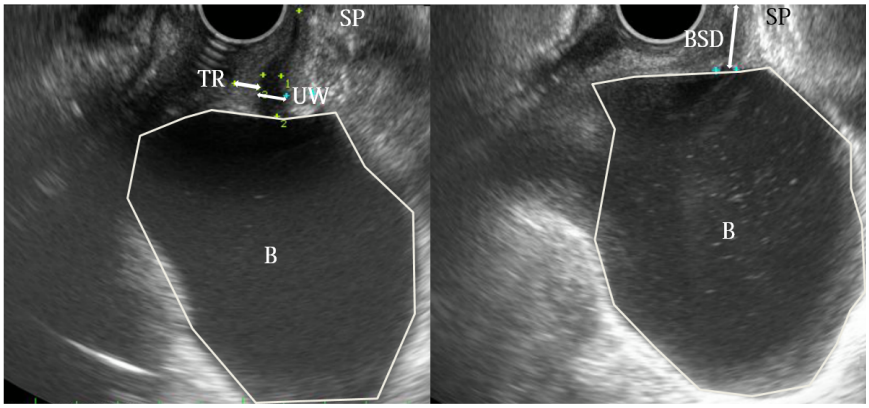

Figure 4. Ultra-sonographic capture view (B: urinary bladder, BSD: bladder neck-symphyseal distance, SP: symphysis pubis, TR: thickness of rhabdosphincter, UW: urethral width).

nificant effect was found, the Wilcoxon signed-rank test was used for the post-hoc analysis and the significance level was set at .17 determined by the Bonferroni correction.

Results

Although the total score of the I-QOL did not show significant improvement, it steadily increased from 95.4 to 94.8 at 4 weeks, and to 100 at 8 weeks. Among I-QOL subscales, only the "avoidance" subscale showed statistical improvements (from 32.4 to 33 and 35.6) ($p<.05$). The total score of the FSFI statistically improved from 44.25 to 63.75 at 4 weeks, and to 68 at 8 weeks ($p<.05$). The "desire" score changed from 7 to 10.75 at 4 weeks, and to 12.75 at 8 weeks ($p<.05$).

The △bladder neck position significantly decreased across assessment time from 28.8° to 14.4° and from 14.4° to 9° (Figure 5 and Table 1), showing significant differences between the three times ($p<.05$). △Funneling index and △urethral width significantly decreased after 8 weeks of intervention ($p<.05$). △Funneling index was statistically different at baseline-4 weeks and at baseline-8 weeks; △urethral width was significantly different in all comparisons. The bladder necksymphyseal distance and posterior rhabdosphincter thickness statistically increased when compared to baseline, and progressively increased by 8 weeks ($p<.05$). In the Wilcoxon signed-rank test, the posterior rhabdosphincter thickness significantly thickened at baseline-8 weeks and 4 weeks-8 weeks, and the bladder neck-symphyseal distance was significantly different at baseline-4 weeks and baseline-8 weeks. The anterior rhabdosphincter thickness showed a tendency to increase, but no statistically significant changes were observed ($p=.057$).

Table 1. The average value of ultra-sonography variables per period

	pre	4 week	8 weeks	p-value
△Bladder neck position (angle, °)	28.80	14.40	9.0	.007
△Funneling index	.16	-.07	-.008	.016
△Urethral width (㎜)	3.36	1.86	1.40	.009
Anterior Rhabdosphincter thickness in Valsalva (㎜)	4.34	5.80	6.80	.057
Posterior Rhabdosphincter thickness in Valsalva (㎜)	3.86	5.04	7.50	.029
bladder neck-symphyseal distance (㎜)	17.36	25.20	25.60	.040

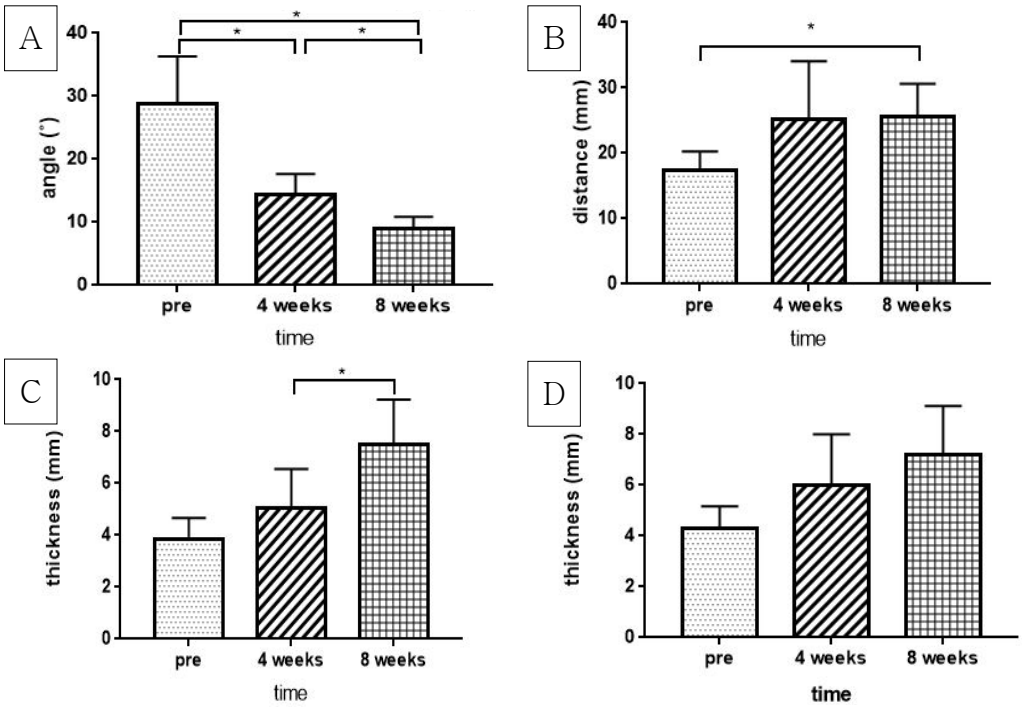

Figure 5. Graphs of ultra-sonographic variables (A: Bladder neck position (angle), B: Bladder neck-symphyseal distance, C: thickness of posterior rhabdosphincter, D: thickness of anterior rhabdosphincter).

All participants demonstrated a significant increase in the LAM contraction score across three assessment times ($p<.05$).

Discussion

The purpose of this study was to determine if the TCES for 8 weeks would be effective in improving the physiological symptoms and psychological satisfaction of the women with SUI. The main findings of this study indicated that TCES improved physiological aspects such as mechanical urogynecologic structures, muscle thickness (anterior and posterior rhabdosphincter), strength (LAM score), the subjective opinions on urinary incontinence, and aspects of the sexual functions in women with SUI.

Disturbance of pudendal nerve conduction, weakness and delayed reflexive response of the PFM are contributing factors for SUI (Appell, 1998). Therefore, facilitating the pudendal nerve and strengthening the PFM and external urethral sphincter have been regarded as effective treatment strategies for SUI.

As PFES guides PFM contraction by direct stimulation, it may be effective to restore normal neuromuscular activities and to strengthen the PFM as an alternative to surgery (Goode et al, 2003; Yamanishi et al, 1997). The PFES stimulates a pudendal nerve afferent, which activate the pudendal and hypogastric nerve efferent and subsequent innervated muscle contractions of the smooth and striated periurethral muscle and striated PFM (Eriksen and Mjølnerød, 1987). According to Appell (1998) and Kobashi and Leach (1999), the PFES targeting the nerves may lead to nerve regrowth and strengthening of the external sphincter. Since the PFES contributed to nerve regrowth and strengthened the muscles, it may have also increased the resistance of the bladder neck outlet and the urethra closure function.

Also, previous studies described that PFES had a similar positive effect as PFM training. However, some individuals performing the PFM training some-

times misidentified the PFM contraction, and in this case, it is difficult to expect the correct training effect. On the contrary, when using PFES, it is rare for the PFM to be contracted inappropriately due to the influence of direct stimulation (Fall and Lindström, 1994; Hahn et al, 1991).

The shape and location of the surface electrodes of the TCES were designed to fit the dermatome of the pudendal nerve and the base of the pubococcygeus and iliococcygeus muscles. The equipment effectively stimulates the muscles and pudendal nerve to generate a muscle-strengthening effect and guide the user to identify. This experiment showed that 8-week intervention with TCES significantly improved the strength of the LAM and the rhabdosphincter thickness. The △funneling index showed negative values after use of the TCES, and the difference in bladder neck position between Valsalva and the rest state decreased. These findings are clinically meaningful because they partially reflect faster and stronger control of PFM and external sphincters to prevent leakage of urine under increased intra-abdominal pressure such as caused by sneezing, coughing, or physical exertion (Goode et al, 2003).

This preliminary study has verified the positive effects of the TCES that were hypothesized, but there are some limitations that are difficulty to generalize our result because this experiment has not been tested on many sample and control group. Further controlled experimental research with a large sample size and control group is necessary to confirm the effectiveness of TCES on SUI.

Conclusion

We examined the effects of TCES on the physiological symptoms and psychological satisfaction of women with SUI in an 8-weeks intervention. We found that the mechanical urogynecologic structures, muscle thickness (anterior and posterior rhabdosphincter), strength (LAM score), I-QOL and FSFI score in the participants are significantly improved after 8-weeks intervention. The TCES is recommended for women who suffered from SUI with respect to sexual function and quality of life as a conservative treatment before surgical intervention. Improvements in SUI symptoms can improve a women's self-esteem, both socially and psychologically, and can be beneficial for sexual activities.

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