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Original Article

Effect of Non-invasive Transcutaneous Electrical Stimulation in Women With Stress Urinary Incontinence: A Prospective Study

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Background: Stress urinary incontinence (SUI) impacts the social, physical, and psychological well-being and quality of life of the patient. Several techniques exist for its management, including transcutaneous electrical stimulation (TES).

Objects: We aimed to demonstrate the effects of TES on ultrasonographic variables and quality of life in women with SUI.

Methods: This prospective study recruited 21 women who had been diagnosed with grade 1 or 2 SUI between July 2018 and March 2019. The exclusion criteria were pregnancy and a history of urogenital surgery. All participants were assessed at baseline and 8 weeks after intervention initiation. The bladder neck position (BNP), length of the urethra (LU), funneling index (FI), and rhabdosphincter thickness (RT) were measured. The Incontinence-Quality of Life (I-QOL) was used to assess incontinence-specific quality of life. Statistical significance level was set at $p < 0.05$.

Results: Twenty-one patients with SUI used TES for 8 weeks. BNP and FI significantly decreased after intervention ($p < 0.05$). LU, anterior and posterior RT (indicators of external sphincter hypertrophy) significantly increased post-intervention ($p < 0.05$). The total I-QOL score increased from 64.81 to 71.86 after the intervention ($p < 0.05$).

Conclusion: This intervention improved BNP, LU, FI, RT, and subjective indicators such as quality of life in women with SUI. Therefore, TES can be an effective non-surgical treatment method for improving SUI symptoms and quality of life in these patients.

INTRODUCTION

The International Continence Society defines stress urinary incontinence (SUI) as an involuntary loss of urine when the intra-abdominal pressure increases due to sneezing, coughing, or physical exertion [1,2]. A possible cause of SUI is bladder neck hypermobility due to pelvic floor muscle (PFM) weakness [3]. SUI affects the social, physical, and psychological well-being and quality of life of the patient [4,5]. However, patients with SUI often hesitate to disclose their symptoms. Various non-invasive or conservative interventions such as medications, PFM training (PFMT), and pelvic floor electrical stimulation (PFES) are available for managing SUI. Moreover, non-invasive treatment is associated with significant symptom improvement in patients with mild to moderate SUI [6].

The PFM, which supports the pelvic viscera and controls the pelvic outlets, is an active contributor to the continence mechanism [7]. During sneezing, coughing, or physical exertion, the intra-abdominal pressure increase affects the urethra by reinforcing its closure only if the urethra remains between the anterior vaginal wall, the pubic symphysis, and the PFM [8]. Assessment of bladder neck hypermobility has revealed that during functional tasks, patients with SUI show a more extensive excursion of the urethral angle than those without SUI [9,10]. Bladder neck hypermobility and reduced proximal urethral closure are associated with bladder neck funneling in SUI. With this rationale, the widening of the funnel phenomenon can be regarded as the occurrence of urinary incontinence symptoms [11,12]. Several studies have evaluated parameters related to bladder neck hypermobility, such as the bladder neck position (BNP), that are associated with PFM function [13,14]. When the BNP is above the pelvic floor, the bladder pressure is equally transmitted to the urethra, which simultaneously increases the urethral closure pressure. If the BNP is below the pelvic floor, more pressure is transmitted to the bladder compared with the urethra, resulting in urethral closure and continence. Furthermore, the length of the urethra (LU) is shorter in women with incontinence than in those without incontinence due to bladder neck descent [15]. Additionally, the external sphincter volume appears smaller on ultrasonography in women with SUI, compared with those without SUI [16]. Since BNP changes due to a decrease in LU, bladder neck funneling, and external sphincter volume, all of these variables result in urethral hypermobility. Conservative treatment of patients with SUI frequently includes PFES. This may lead to nerve regrowth and strengthen the external sphincter, increasing bladder outlet resistance over time [17,18]. Moreover, it helps the women that have trouble identifying and feeling the PFM and allows electrically induced contraction of a weak PFM [19]. Transcutaneous electrical stimulation (TES) and intravaginal electrical stimulation are the two common PFES types for SUI rehabilitation. Their effectiveness has been clinically demonstrated [19,20]. The intravaginal type uses electrodes inserted into the vagina; its application is limited by pain, intolerance of high stimulation intensity, discomfort associated with electrode insertion, hygiene management challenges, risk of infections, and bleeding. In contrast, TES is convenient and safe. The Easy-K device (Alphamedic Co., Ltd.) was recently designed to allow PFM contraction by electrical stimulation using cutaneous perivaginal electrodes with the patient in a seated position. TES effectively treats urinary incontinence and can be performed using cutaneous electrodes in the perivaginal region [21,22]. However, to the best of our knowledge, there are no studies that have evaluated ultrasound variables such as BNP, LU, bladder neck funneling, urethral external sphincter hypertrophy, and the subjective domain to compare the clinical effects after applying TES to patients with SUI.

This study aimed to demonstrate the effects of TES on BNP, LU, bladder neck funneling, urethral external sphincter hypertrophy, and quality of life in women with SUI. We hypothesized that 8 weeks of TES in women with SUI would result in the improvement of bladder neck hypermobility (BNP, LU, bladder neck funneling, urethral external sphincter hypertrophy) and a consequential increase in the Incontinence-Quality of Life (I-QOL) scores.

MATERIALS AND METHODS

1. Participants and Study Design

G* Power software version 3.1.2 (Franz Faul, University of Kiel) was used for power analysis based on a pilot study of five participants [23]. We performed sample size calculations with a power of 0.80, an alpha level of 0.05, and an effect size of 0.95; the required sample size was 10 participants. We recruited 21 women who had been diagnosed with grade 1 or 2 SUI by a gynecologist according to the Stamey grading system, through a social networking site between July 2018 and March 2019. The exclusion criteria were pregnancy and a history of urogenital surgery, such as urinary incontinence surgery, colporrhaphy, and hysterectomy. All the participants signed an informed consent form. This study was approved by the Institutional Review Board of the Yonsei University Mirae campus (IRB no. 1041849-201808-BM-077-02). The trial has been approved for clinical trial registration by the Clinical Research Information System (CRIS) of the South Korea Institute (CRIS registration number: KCT0005030).

This was a single-group clinical trial using a pre- and post-design over 8 weeks. All participants were assessed at two timepoints: baseline and 8 weeks after intervention initiation. During treatment, they were required to write a daily report on TES usage; the researcher regularly evaluated participant compliance through their reports and text messages. The intervention and data collection were conducted between December 2018 and August 2019.

2. Intervention

Easy-K is a TES device that uses cutaneous electrodes in the perivaginal region to stimulate the PFMs and surrounding structures (35 × 41 × 4.5 cm). The shape and position of the electrodes were adapted to contact the entire vulva while the participant was sitting on the stimulator (Figure 1). The conducting material between the skin and the electrodes was a layer of wet tissue. Before using the device, the vulva was cleaned, and wet tissues were applied to the electrode. Consequently, the generated electrical stimulus could directly contact

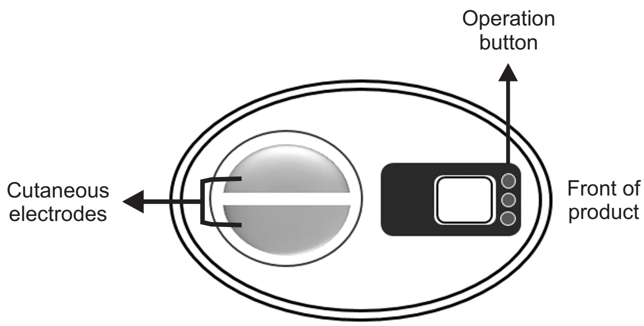

Figure 1. Transcutaneous electrical stimulation device.

the perivaginal regions and extensively stimulate the PFM while the participants sat on the Easy-K machine. The participants sat on a device placed on the toilet seat, and the cutaneous electrodes contacted the perivaginal regions. Subsequently, the physical therapist set the stimulation amplitude to evoke perceivable and comfortable stimulation levels in initial stage. The intervention was conducted so that participants could perceive and learn the feeling of muscle contraction kinesthetically as well as sensory perception of PFM contraction. Easy-K delivered biphasic asymmetric impulses of 21–27 Hz and provided control sessions for the pulse (5 seconds) and resting (4 seconds) durations. The participants used the device once a day in a 20-minuite session, 5–6 days a week for 8 weeks. Furthermore, they underwent Easy-K sessions where the stimulation amplitude could be increased to a pain-free range.

3. Outcome Measures

The participants were requested not to urinate for 3–4 hours before the examination. The objective variables, including BNP, LU, funneling index (FI), and rhabdosphincter thickness (RT) were measured using an ultrasound scanner (SSD-α10, ALOKA) with a 5.0 MHz vaginal-type transducer. Researchers who did not participate in the patient evaluation process performed the data collection process under the supervision of qualified persons to avoid potential bias. A skilled gynecologist examined the patients in the lithotomy position and Valsalva conditions. Their morphological characteristics were evaluated and analyzed using frozen images. The BNP (°) was quantified by calculating the pubourethral angle between the two axes. A line drawn from the lower margin of the pubic symphysis to the bladder neck was defined as the x-axis, while the midline of the pubic symphysis served as the y-axis (Figure 2) [24].

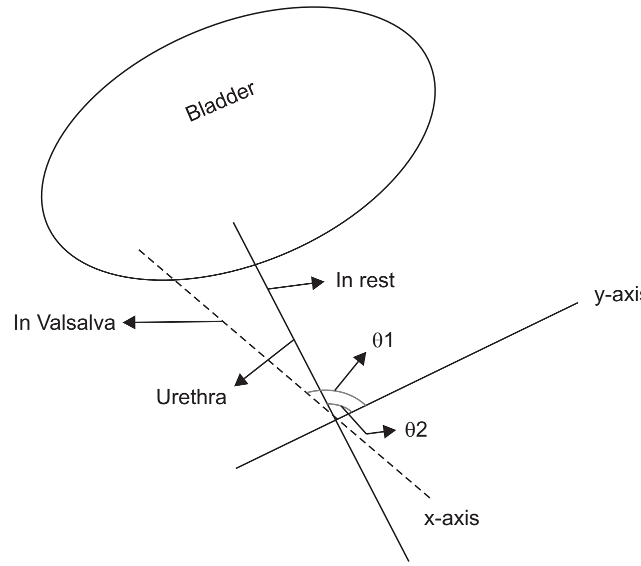

Figure 2. Schematic of an ultrasonographic view; measurement of the bladder neck position.

The LU (mm) was the distance from the bladder neck to the lower margin of the pubic symphysis; longer LU corresponds to higher bladder positions. We measured the FI (mm^2) by multiplying the width of the bladder neck by its height [25]. The rhabdosphincters, part of the external urethral sphincter, are in the middle of the urethra [16]. The RT (mm) was measured at a distance of 5 mm from the bladder neck point towards the bladder in the sagittal plane [23]. The anterior RT (ART) and posterior RT (PRT) were measured from the anterior and posterior urethral walls, respectively.

The subjective variables were self-reported using the Korean version of the I-QOL questionnaire. The I-QOL is used to assess incontinence-specific quality of life. It resembles a Likert-type response scale and contains 22 items. The participants performed self-evaluations using 5-point scale questions on daily life related to SUI with the following score categories: 1 (extreme), 2 (quite a bit), 3 (moderate), 4 (a little), or 5 (not at all). The sum of these scores was used in the analysis. This score had three subscales: avoidance and limiting behavior (AL), psychosocial impact (PI), and social embarrassment (SE). Higher total scores indicated higher self-satisfaction and better SUI-related quality of life.

4. Statistical Analysis

Data were analyzed using IBM SPSS for Windows (version 24.0; IBM Co.). The Kolmogorov–Smirnov test was used to confirm the normal distribution of the data. Paired t-test was used to analyze the BNP, LU, FI, ART, PRT, and I-QOL scores before and after the intervention. The level of significance was set at 0.05.

RESULTS

Sixty-four women with urinary incontinence were screened and recruited. A total of 21 women met the inclusion criteria. Their mean age was 51.3 years, and mean body mass index was 24.12 kg/m^2. Table 1 summarizes the demographic characteristics of the participants.

Table 2 presents the ultrasonographic findings. BNP and FI significantly decreased after 8 weeks of intervention ($p < 0.05$). LU, ART and PRT (indicators of external sphincter hypertrophy), and ART significantly increased post-intervention ($p < 0.05$).

The total I-QOL score increased from 64.81 to 71.86 after the intervention ($p < 0.05$). Among the three subscale scores, the AL and PI scores significantly improved ($p < 0.05$). Although the SE score did not significantly improve ($p > 0.05$), it steadily increased from 14.33 to 14.9 over the 8-week treatment period.

DISCUSSION

This study aimed to demonstrate the effects of TES on bladder neck hypermobility (BNP, LU, bladder neck funneling, urethral external sphincter hypertrophy) and quality of life in women with SUI. To the best of our knowledge, this study is the first to evaluate BNP, LU, FI, ART, and PRT using ultrasonography 8 weeks after TES in women with SUI. Previous studies have suggested that PFMT may decrease bladder neck hypermobility in SUI [3,26]. However, there is no evidence regarding the improvement in bladder neck hypermobility after TES of the PFM. The main finding of the present study was that TES improved bladder neck hypermobility and SUI symptoms.

We found an increase in LU after the 8-week treatment period. Kim et al. [23] reported that women with UI have a shorter LU than those without SUI, especially during the Valsalva maneuver, because LU decreases as bladder neck funneling increases. Moreover, 8 weeks of TES resulted in LU increase and symptom improvement in women with SUI [23]. We confirmed the increase in ART and PRT. Rhabdosphincters are directly connected to the PFM and function as urine flow regulators. Additionally, the ultrasound variable FI exhibited a significant change; higher FI in women corresponded to increased urine pressure from the bladder to the urethra. This finding could indicate an improvement in urethral pressure against load after 8 weeks of TES. In conclusion, ultrasonographic variables may serve as important clinical indicators for determining the mechanism leading to SUI symptom improvement after TES. For instance, an increased LU with bladder neck ascent may be interpreted as an improvement of SUI symptoms through hypermobility-related mechanisms.

The afferent pudendal nerve transmits the stimulus to the efferent pudendal nerve, and the hypogastric nerve induces the contraction of the periurethral muscle and PFM [27]. In patients with SUI, pudendal nerve conduction is disturbed, which along with sphincter and PFM weakness, delays the PFM reflexive response [17]. The TES device electrodes are positioned to fit the dermatome of the pudendal nerve and the base of the pubococcygeus and iliococcygeus muscles of the PFM. As TES directly stimulates the muscle, it may be effective in muscle strengthening and imparting the ability to identify and recognize the location and contraction of the PFM to women who cannot voluntarily contract this muscle. These ef-

Table 1. Demographic characteristics of the participants

Characteristic	Total (N = 21)
Age (y)	52.24 ± 8.11
Weight (kg)	61.57 ± 8.89
Height (cm)	159.00 ± 5.69
Body mass index (kg/m^2)	24.24 ± 3.21
Childbirth experience (n)	18
Vaginal delivery (n)	13
Menopausal status (n)	13
Hormone drug therapy (n)	0
Onset time (y)	7.26

Values are presented as mean ± standard deviation or number only.

Table 2. Ultrasonographic variables before and after the intervention (N = 21)

	Before the intervention	After the intervention	p-value
BNP (°)	24.38 ± 11.32	16.38 ± 7.17	0.002*
LU (mm)	22.88 ± 7.40	27.43 ± 5.64	0.013*
FI (mm^2)	0.83 ± 0.45	0.54 ± 0.45	0.019*
ART (mm)	2.40 ± 0.72	3.62 ± 1.23	0.002*
PRT (mm)	2.16 ± 0.68	3.29 ± 0.84	0.001*

Values are presented as mean ± standard deviation. BNP, bladder neck position; LU, length of the urethra; FI, funneling index; ART, anterior rhabdosphincter thickness; PRT, posterior rhabdosphincter thickness. *$p < 0.05$.

fects can restore normal neuromuscular activities [19]. Restoring neuromuscular control and PFM function increases bladder neck stability and urethral closure [17,18]. TES-induced muscle contraction provides an involuntary exercise for improving the urethral closure mechanism [19]. According to Hahn et al. [28], although TES and PFMT have similar positive effects, achieving accurate training effects is difficult due to insufficient PFM force and the poor perception of PFM contraction in patients with SUI. Therefore, electrical stimulation can help patients perceive PFM contractions through direct stimulation [28,29].

Our study provided evidence of the positive effects of TES on the ability to maintain urinary continence through the development of strong and rapid voluntary control of the PFM and sphincters in women with SUI. TES is beneficial in improving the stability of the PFM and sphincter support system as it provides an adequate resistive force against increased intra-abdominal pressure [30]. In this study, we believe that the improvement of the quality of life in women with SUI may significantly affect their anticipatory and reactive abilities. Therefore, our findings may be useful for developing SUI treatment guidelines.

This study had some limitations. First, it can be difficult to generalize our results because the experiment included a relatively small sample size with no control group. Second, we did not measure parameters such as electromyographic data, strength, power, and endurance of the PFM.

Based on the study results, future studies with larger sample sizes and control groups are required to provide evidence for the usefulness of TES in SUI intervention and evaluation. The results of this study could help provide advanced guidelines for SUI treatment.

CONCLUSIONS

TES was helpful in improving symptoms and quality of life in patients with SUI. Additionally, it is essential to improve the muscular function and quality of life in women with SUI. The results of this study provided insights that could be beneficial for planning intervention and evaluation strategies for SUI.

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CONFLICTS OF INTEREST

No potential conflicts of interest relevant to this article are reported.

AUTHOR CONTRIBUTION

Conceptualization: JHK, HSJ, OYK, UJH, EYP, SJK. Data curation: JHK, EYP, SJK. Formal analysis: JHK, HSJ, OYK, UJH. Funding acquisition: OYK, UJH. Investigation: JHK, EYP, SJK. Methodology: JHK, HSJ, OYK, UJH. Project administration: JHK, UJH. Resources: EYP, SJK. Software: JHK, HSJ, UJH. Supervision: HSJ. Validation: OYK, UJH. Visualization: JHK. Writing - original draft: JHK, HSJ. Writing - review & editing: JHK, HSJ, OYK, UJH, EYP, SJK.

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