Received: 10 December 2018 | Revised: 17 April 2019 | Accepted: 27 June 2019

DOI: 10.1111/luts.12278

ORIGINAL ARTICLE

WILEY

Effects of low-frequency intravaginal electrical stimulation on female urinary incontinence, quality of life, and urinary symptoms: A pilot study

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Funding information
Ministry of Science & ICT, Grant/Award Number: 2018M3A9E8020861

Abstract

This study investigated the effects of a low-frequency home-based incontinence therapy device on quality of life (QoL) and urinary symptoms in women with urinary incontinence. From May 2017 to February 2018, 34 patients, aged ≥ 20 years, with involuntary urine leakage >2 times/week, were recruited to this study. Patients with severe pelvic organ prolapse, pregnancy, virgin status, and psychological problems were excluded. The incontinence home-care device treatments were administered in 12-minute sessions, twice daily for 8 weeks. Simultaneously, hyperthermic conditions of 35°C to 40°C and microvibrations were administered. All patients completed urinary incontinence questionnaires (King's Health Questionnaire [KHQ], Bristol Female Lower Urinary Tract Symptoms [BFLUTS] questionnaire, and the Overactive Bladder Symptom Score [OABSS]) before treatment, as well as 4 and 8 weeks into treatment. Changes in the questionnaire responses over time were compared. Two participants dropped out of the study and there was one screening failure, leaving 31 patients for analysis. After 4 weeks treatment, there were significant improvements in symptoms, such as role limitation, physical limitation, social limitation, personal relationship, emotion, sleep/energy, and severity measures. After 8 weeks treatment, almost all parameters on the KHQ revealed symptomatic improvement. On the BFLUTS, voiding times during activity, nocturia, urgency, urge incontinence, incontinence frequency, stress incontinence, volume leakage, strain to start, intermittency, reduced stream, acute retention, incomplete emptying, and stopping flow showed significant improvements. On the OABSS, almost all storage symptoms improved. Low-frequency electrical stimulation devices were effective at improving urinary incontinence, which became evident as the duration of treatment increased. Improvement of urgency and frequency was more evident after treatment.

KEYWORDS

conservative treatment, electrical stimulation, urinary incontinence

1 | INTRODUCTION

Urinary incontinence refers to a condition in which urine is inadvertently excreted from the bladder to the urethra, usually due to a disability or an incapacity to control the bladder and urethral sphincter.[1] The prevalence of urinary incontinence varies widely, but previous studies have reported life-time prevalence rates of 12.7% to 15.5%, which increases with age.[2] Incontinence is classified primarily into stress incontinence, urge incontinence, mixed incontinence, and continuous incontinence, with various causes depending on the classification.[3] Risk factors for incontinence include occupation, obstetric delivery, and previous gynecologic surgery.[4-7] Urinary incontinence may negatively affect social activity and hygiene, and have psychological effects, such as depression.[3,8]

Treatment of urinary incontinence comprises surgical and non-surgical methods. Surgical management has been the gold standard treatment for stress urinary incontinence (SUI). Sling operations under local anesthesia can be performed on an outpatient basis; however, patients may avoid this treatment option because of a fear of either surgery or recurrence after a sling operation. Non-surgical and conservative therapies include behavioral therapy, pharmacotherapy, biofeedback, physical therapy, and functional electronic stimulation (FES).[9] In the relatively early stages, conservative treatment is considered and FES can be performed rather than surgical treatment. Of the conservative options, Kegel exercises have relatively high symptom success rates of 41.2% to 68.4%.[10,11] However, the rate of accurate performance of Kegel exercises is only approximately 24%.[12] Electrical stimulation, one of the conservative methods of treatment, can be performed intravaginally or via tibial or sacral nerve stimulation. Of these options, intravaginal and tibial nerve stimulation are known to be effective in the treatment of urinary incontinence.[13] Depending on the intensity of the current and the duration of treatment, FES can be divided into two types: (a) acute maximum functional electric stimulation (AMFES), comprising a maximum current delivered for 15–30 minutes, and (b) chronic low-intensity stimulation comprising a low-frequency, low-current treatment delivered for 1.5 to 2 hours daily over 3 months.[14] The ultimate goal of FES is to improve pelvic floor muscle and sphincter strength through electrical stimulation, which makes right pelvic muscle contraction possible.

Recently, a study was conducted on lower urinary tract symptom treatments that introduced simple methods, including home care.[15] Continuous home-based pelvic floor muscle training was found to improve urinary incontinence symptoms.[10] This continuous treatment was as important as the outpatient-based treatment modalities.

The purpose of the present study was to investigate the effects of a low-frequency electrical pulse device for home incontinence therapy.

2 | METHODS

2.1 | Ethical considerations

Institutional ethics review was sought and the study was approved by the Catholic University of Korea, Institutional Review Board (Approval no.: XC17DEDI0007).

The Dr. Lady device (Buheung Medical, Seoul, Korea) was used to treat urinary incontinence in this study. This is a Grade 3 portable medical device for home-based treatment of urinary incontinence and pelvic disease. It delivers electrofrequency stimulation in the range 1 to 1560 Hz, a maximum of 45° of hyperthermia treatment, and emits intensity-adjustable fine vibrations. The device consists of a probe that is inserted into the vagina and generates low-frequency stimulation, heat, and fine vibration, and a body part that can generate direct heat (Figure 1).

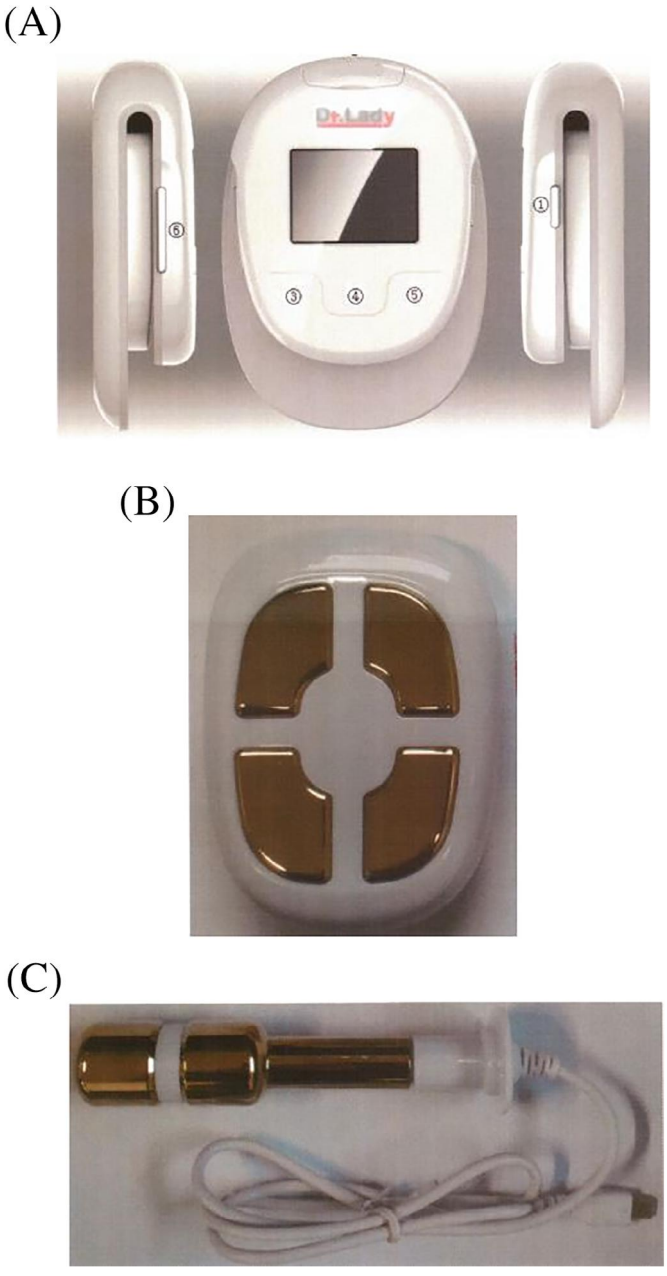


FIGURE 1 The intravaginal-type urinary incontinence therapy used at home used in this study. A, Body of the low-frequency electrical stimulation device; B, Posterior surface of the device; C, Intravaginal probe

2.2 | Treatment protocol

From May 2017 to March 2018, patients aged ≥20 years with involuntary urine leakage more than twice weekly were recruited to the study (Figure 2). Patients with SUI, urge, and mixed urinary incontinence were included in the study, but those with incontinence caused by neurogenic diseases were excluded. Data on previous urological therapy, gynecologic surgery or disease, parity, and accompanying diseases were obtained for all subjects. All subjects underwent physical examination, uroflowmetry, and post-voiding residual (PVR) bladder scans, and kept voiding diaries for 3 days to assess their characteristics and urination status. Previous treatment methods, treatment termination points, and treatment periods were also recorded. Patients with cardiac pacemakers, pelvic organ prolapse, psychiatric illnesses, allergic or infectious diseases, continuous incontinence without urgency or elevated abdominal pressure, large PVR (>150 mL), inadequate intellectual ability (eg, dementia, psychosis), those who were pregnant and patients without sexual experience were excluded from the study.

Before the devices were distributed, patients were instructed on their use. Patient guides were distributed with information on the modes (intensity, time, and amplitude of the current) used for each patient. In the treatment modules, the electrical frequency (or pulse) was set to 40 Hz for 12 minutes, during which the action time maintained specified cycles, comprising 3-second resting cycles with increasing intensity, 4-second intensity maintenance, 3-second decreasing intensity, and 5-second rest periods. The maximum amplitude peaked at 22 V (±30%) and the maximum current was 6 mA (±30%). Simultaneously, hyperthermia of 35°C to 40°C and microvibrations were administered. Prior to delivery of electrical stimulation, the probe began to vibrate. Patients were treated twice daily, in 12-minute sessions, for 8 weeks. At the time of probe insertion, a small amount of lubricant gel was applied over the probe surface. All subjects performed routine activities during the treatment process after probe insertion.

All patients completed the King's Health Questionnaire (KHQ), the Bristol Female Lower Urinary Tract Symptom (BFLUTS) questionnaire, and the Overactive Bladder Symptom Score (OABSS) questionnaire. The subjects had a washout period of 4 weeks after confirming their history of drug therapy, such as anticholinergics or β_3-adrenoceptor agonists or other incontinence-related treatment. After the washout period, the questionnaires were repeated to identify lower urinary tract symptoms and confirm urinary incontinence status. Subsequently, treatments were started.

2.3 | Sample sizes

The number of subjects was similar to other similar studies.[16] A minimum of 29 subjects were identified. It was 33 people considering 10% dropout rate. Finally, 34 patients were selected to match the number of subjects in both hospitals.

2.4 | Evaluation of incontinence symptoms

The KHQ, BFLUTS, and OABSS were used to compare patients' symptoms.

2.4.1 | King's Health Questionnaire

The validated Korean version of the KHQ was used in this study.[17] Subjects completed the questionnaire before treatment and after

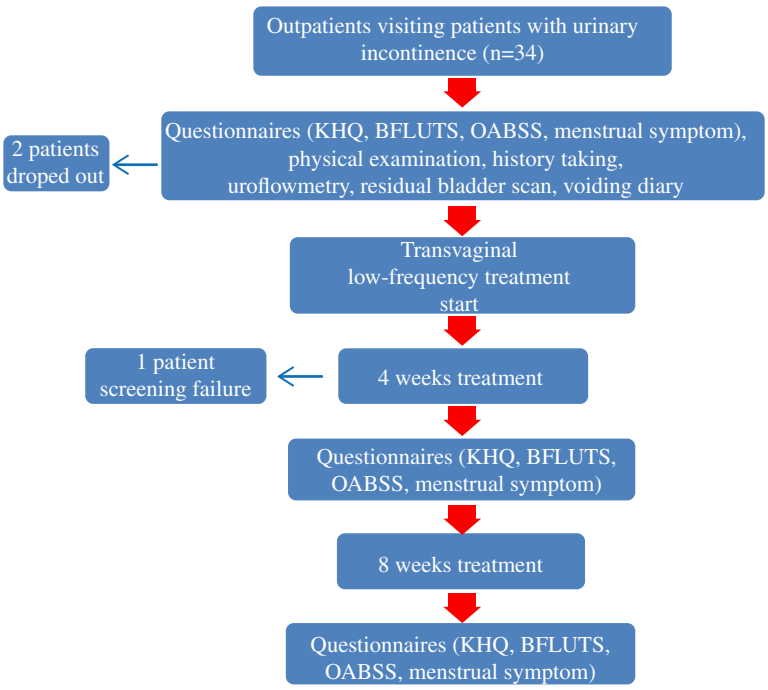


FIGURE 2 Study flow diagram. KHQ, King's Health Questionnaire; BFLUTS, Bristol Female Lower Urinary Tract Symptoms questionnaire; OABSS, Overactive Bladder Symptom Score

4 and 8 weeks treatment. Of the 32 items in the KHQ questionnaire, 31 were scored by referring to other articles[18] (the 32nd item required narrative answers). Scores of for Questions 1 to 9 and the last 10 questions were compared. In addition, a paired *t* test was used to confirm symptom improvement according to treatment duration.

2.4.2 | Bristol Female Lower Urinary Tract Symptom questionnaire

As for the KHQ, the Korean version of the BFLUTS[19] was used in this study to evaluate symptom changes. The questionnaire was scored using the method of Brookes et al.,[20] with most questions based on lower urinary tract symptoms and their resulting problems, symptoms related to sexual function, and the recognition of these symptoms. The BFLUTS comprises questions on QoL and recognition of the problem. Not all questions involve problem recognition, and each classification was analyzed individually according to the answers and problem recognition.

2.4.3 | Overactive Bladder Symptom Score

To confirm the symptoms of overactive bladder, such as urgency and urge incontinence, the OABSS was administered before treatment, at 4 weeks, and after completing the treatment and all four questions and five points were compared.

All patients underwent uroflowmetry and PVR scans to assess bladder function. Voiding diaries maintained over 3 days were also assessed to identify urinary frequency, severity of urge incontinence, functional bladder capacity, and nocturia characteristics.

2.5 | Statistical analysis

Statistical analyses were performed using SPSS 18.0 (SPSS Inc., Chicago, Illinois). Patient data before treatment, after 4 weeks treatment, and at the end of treatment were compared using one-way analysis of variance (ANOVA). Significance was defined as $P < 0.05$.

3 | RESULTS

3.1 | Participant characteristics

In all, 34 women with urinary incontinence symptoms were included in the study; however, two patients withdrew their consent and there was one screening failure. This left, 31 patients for analysis. Of those, 15 had SUI, 10 had urge urinary incontinence, and 6 had mixed urinary incontinence. The mean age was 54.79 years. Two of the patients had previously undergone sling operations for incontinence, but their symptoms recurred, leading to their participation in the study. Three patients had undergone cesarean sections, whereas the remaining 28 patients had experienced spontaneous labor. The mean number of deliveries per subject was 2.03. The mean duration of incontinence symptoms was ~47.3 months. Three patients were treated with anticholinergics or β_3-adrenoceptor agonists before the study and were treated for an average of 8 months. The mean maximal flow rate was 21.52 mL/s, mean voiding volume was 186.1 mL, mean PVR volume was 32.83 mL, mean functional bladder capacity was 478.57 mL, mean number of daytime voids (daytime frequency) was 7.57, and mean night-time voids (nocturia) was 1.01.

3.2 | King's Health Questionnaire

After 4 weeks treatment, there were significant improvements in symptoms, including role limitation, physical limitation, social limitation, personal relationship, emotion, sleep/energy, and severity measures (Table 1). Mean symptom improvements after 4 weeks treatment were 5% role limitation, 14% for physical limitation, 14% for social limitation, 13% for personal relationship, 10% for emotions, 5% for sleep/energy, and 9% for severity measures. After 8 weeks treatment, significant improvements were observed in all items compared with before treatment (general health perception improved by 20%, incontinence impaction improved by 15%, role limitation improved by ~13%, physical limitation improved by 18%, social limitation improved by 17%, personal relationships improved by 18%, emotions improved by 27%, sleep/energy improved by 13%, and severity measures improved by 22%). Comparing Weeks 4 and 8 of treatment, except for the personal relationship domain ($P = 0.185$), all domains showed proportional improvements as treatment continued.

Comparing severity measures and lower urinary tract symptom severity, 26 of 31 patients showed symptomatic improvement (83.9%), 3 patients reported no change (9.7%), and 2 patients experienced mild deterioration (6.4%). When the degree of improvement after treatment was compared with before treatment for each voiding symptom, the improvements were 45.2% in frequency, 54.8% in nocturia, 71.0% in urgency, 64.5% in urge incontinence, 87.1% stress incontinence, 29% in enuresis, 80.6% in intercourse incontinence, 71% in recurrent infection, and 61.3% in bladder pain and voiding difficulty (Table 1).

3.3 | Bristol Female Lower Urinary Tract Symptom questionnaire

Voiding symptoms, sexual function, and QoL sections of the BFLUTS were compared. After 4 weeks treatment, voiding symptoms, nocturia, frequency of incontinence, stress incontinence, volume leakage, and incomplete emptying were significantly improved ($P = 0.032$, $P = 0.020$, $P < 0.001$, $P = 0.001$, and $P = 0.003$, respectively). At the end of treatment, the number of voids during activity, nocturia, urgency, urge incontinence, frequency of incontinence (some leakage), stress incontinence, volume leakage, straining to start urination, intermittency, reduced stream, acute retention, incomplete emptying, and stopping flow had improved significantly compared with before treatment ($P < 0.001$, $P < 0.001$, $P < 0.001$, $P = 0.003$, $P < 0.001$, $P < 0.001$, $P < 0.001$, $P = 0.010$, $P = 0.003$, $P < 0.001$, $P = 0.031$, $P < 0.001$, and $P < 0.001$, respectively). Nocturia, frequency of incontinence (some leakage), stress incontinence, volume leakage, and incomplete emptying showed continuous improvement throughout the treatment period (Figure 3A).

TABLE 1 Domain scores on the King's Health Questionnaire before treatment and after 4 and 8 weeks treatment

	Pretreatment	4 weeks treatment	*P*-value (4 weeks treatment vs pretreatment)	8 weeks treatment	*P*-value (8 weeks treatment vs pretreatment)	*P*-value (4 vs 8 weeks treatment)
General health perceptions	49.14	46.55	0.083	29.31	0.000	0.000
Incontinence impactions	62.07	55.17	0.083	47.13	0.000	0.032
Role limitation	45.4	40.23	0.017	32.76	0.000	0.001
Physical limitation	57.47	43.68	0.000	39.08	0.000	0.030
Social limitation	43.87	33.33	0.000	26.63	0.000	0.006
Personal relationship	34.52	22.02	0.007	19.14	0.003	0.185
Emotions	58.24	48.66	0.004	31.8	0.000	0.000
Sleep and energy	36.78	31.61	0.017	23.56	0.000	0.000
Severity measures	54.31	45.68	0.011	32.76	0.000	0.000
LUTS						
Frequency	2.03	1.9	0.255	1.72	0.477	0.787
Nocturia	1.93	1.76	0.023	1.55	0.010	0.169
Urgency	2.24	1.97	0.003	1.79	0.000	0.030
Urge incontinence	2.21	1.76	0.001	1.59	0.030	1.000
Stress incontinence	2.83	2.38	0.003	1.9	0.000	0.002
Nocturnal enuresis	1.24	1.17	0.326	1.17	0.004	0.001
Intercourse incontinence	1.24	1.24	1.000	1.03	0.057	0.023
Waterworks infection	1.21	1.24	1.000	1.1	0.134	0.057
Bladder pain	1.1	1.07	0.663	1	0.161	0.573
Voiding difficulty	1.07	1	0.161	1	0.161	0.021

Abbreviation: LUTS, lower urinary tract symptoms.

After 8 weeks treatment, there was a significant improvement in nocturia, urge incontinence, bladder pain, frequency of incontinence (some leakage), stress incontinence, unpredictable incontinence, and strain to start compared with before treatment. Urge incontinence and unpredictable incontinence were improved after 8 weeks treatment ($P = 0.001$ and $P = 0.018$, respectively).

Dyspareunia pain was relieved from 4 weeks to the end of treatment. However, vaginal dryness and sex life quality worsened after treatment ($P = 0.016$ and $P = 0.019$). In sexual function problem recognition, there was no significant difference between pretreatment and 4 weeks after treatment (Figure 3B).

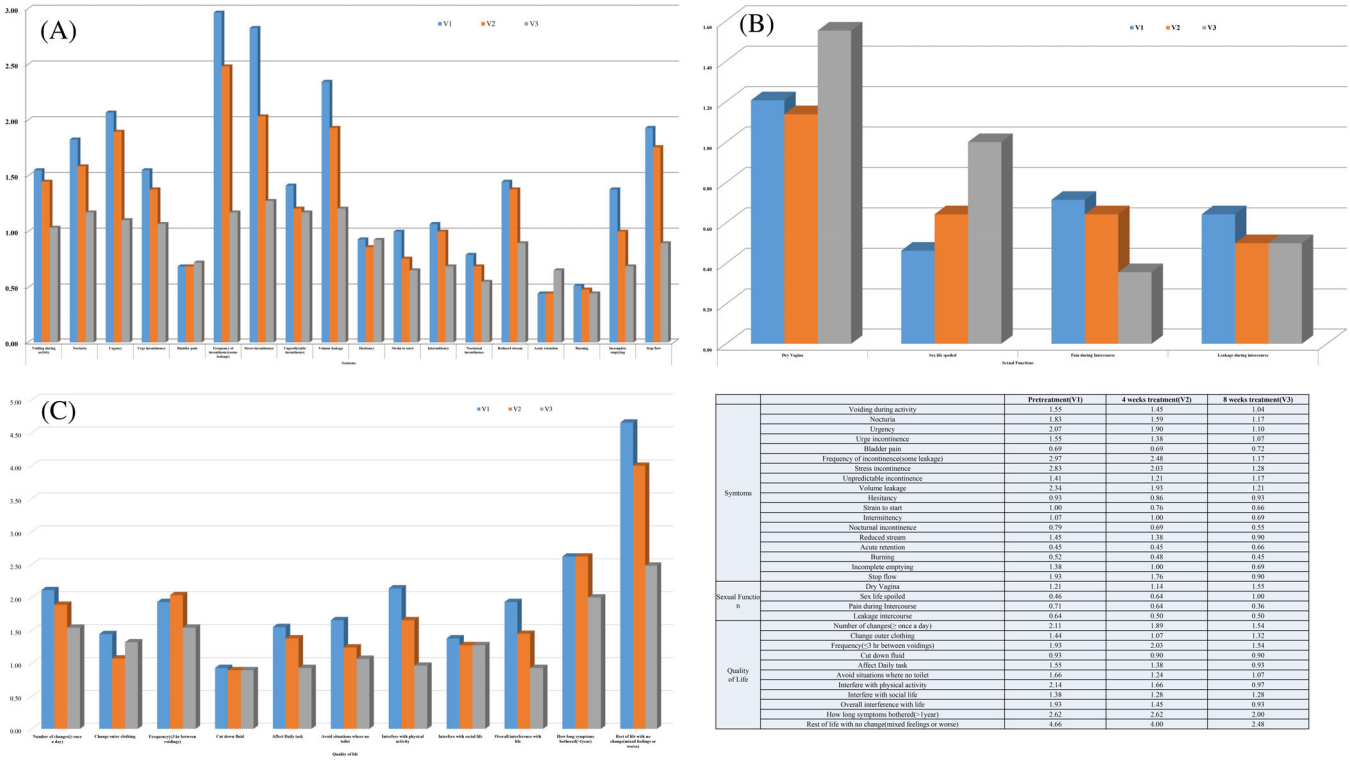
Regarding QoL, items such as changes of outer clothing, avoiding situations where toilets are not available, interference with physical activity, and overall interference with life, symptoms improved after 4 weeks treatment ($P = 0.030$, $P = 0.001$, $P = 0.001$, and $P = 0.001$, respectively). Compared with before treatment, the number of clothing changes (≥1 per day), frequency of urination (≤3 hours between voids), effects on daily tasks, avoiding situations of toilet unavailability, overall interference with life, length of problematic symptoms (≥1 year), and rest of life with no change (mixed feelings or worse) were improved at the end of treatment ($P = 0.002$, $P = 0.025$, $P = 0.000$, $P = 0.000$, $P = 0.000$, $P = 0.000$, $P = 0.003$, and $P = 0.000$, respectively). Interference with physical activity and overall interference with life were improved throughout the course of treatment. For QoL, urinary frequency (≤3 hours between voids), avoiding situations of toilet unavailability, interference with physical activity, and interference with social life, subjects were less aware of their problems after the treatment ($P = 0.045$, $P = 0.003$, $P = 0.000$, and $P = 0.023$, respectively; Figure 3C).

3.4 | Overactive Bladder Symptom Score

The results of the OABSS questionnaire showed symptomatic improvements in almost all the storage symptoms, including nocturia, urgency, urge incontinence, and the total score (except for daytime frequency) after 4 weeks treatment ($P = 0.003$, $P = 0.000$, $P = 0.000$, and $P = 0.000$, respectively); after completing treatment, significant improvements were seen for all symptoms ($P = 0.000$ for all). These effects persisted over the course of treatment, and symptoms improved significantly as the duration of treatment increased (Figure 4).

3.5 | End of treatment

After 8 weeks of treatment, all patients remained treated effect for more than 2 weeks after treatment was terminated. Only one patient underwent transobturator tape surgery under general anesthesia with recurrence of symptoms 1 month after discontinuation of treatment. Fifteen patients (52%) requested continued use of the device. Study



		Pretreatment(V1)	4 weeks treatment(V2)	8 weeks treatment(V3)
Symtoms	Voiding during activity	1.55	1.45	1.04
	Nocturia	1.83	1.59	1.17
	Urgency	2.07	1.90	1.10
	Urge incontinence	1.55	1.38	1.07
	Bladder pain	0.69	0.69	0.72
	Frequency of incontinence(some leakage)	2.97	2.48	1.17
	Stress incontinence	2.83	2.03	1.28
	Unpredictable incontinence	1.41	1.21	1.17
	Volume leakage	2.34	1.93	1.21
	Hesitancy	0.93	0.86	0.93
	Strain to start	1.00	0.76	0.66
	Intermittency	1.07	1.00	0.69
	Nocturnal incontinence	0.79	0.69	0.55
	Reduced stream	1.45	1.38	0.90
	Acute retention	0.45	0.45	0.66
	Burning	0.52	0.48	0.45
	Incomplete emptying	1.38	1.00	0.69
	Stop flow	1.93	1.76	0.90
Sexual Function	Dry Vagina	1.21	1.14	1.55
	Sex life spoiled	0.46	0.64	1.00
	Pain during Intercourse	0.71	0.64	0.36
	Leakage intercourse	0.64	0.50	0.50
Quality of Life	Number of changes(≥ once a day)	2.11	1.89	1.54
	Change outer clothing	1.44	1.07	1.32
	Frequency(≤3 hr between voidings)	1.93	2.03	1.54
	Cut down fluid	0.93	0.90	0.90
	Affect Daily task	1.55	1.38	0.93
	Avoid situations where no toilet	1.66	1.24	1.07
	Interfere with physical activity	2.14	1.66	0.97
	Interfere with social life	1.38	1.28	1.28
	Overall interference with life	1.93	1.45	0.93
	How long symptoms bothered(>1year)	2.62	2.62	2.00
	Rest of life with no change(mixed feelings or worse)	4.66	4.00	2.48

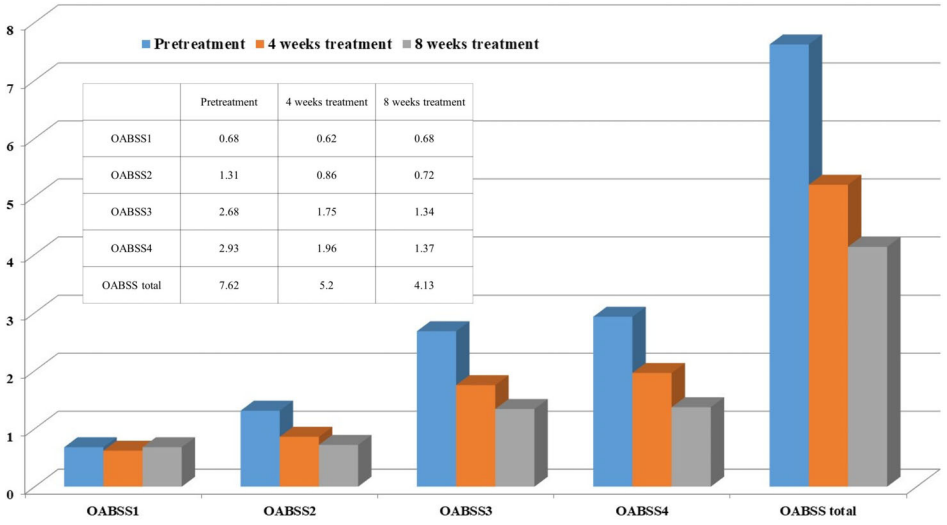
FIGURE 3 Scores on the Bristol female lower urinary tract symptom questionnaire for A, Lower urinary tract symptoms, B, Sexual function, and C, quality of life before treatment and after 4 and 8 weeks treatment

participants said that the advantages of the device are that it can be used in everyday life and that it is relatively easy to learn how to use it.

4 | DISCUSSION

This study of a low-frequency home-care incontinence treatment device with hyperthermia and microvibration confirmed symptomatic improvements in overall urinary incontinence in women. This is an effective treatment for SUI, mixed urinary incontinence, and urge incontinence.

The first-line treatment for urinary incontinence includes pelvic floor muscle training (ie, Kegel exercises), lifestyle modifications (ie, weight loss, timed voiding, bladder training, and fluid optimization), incontinence pessaries and intravaginal devices, as well as medications such as estrogen, anticholinergics, β_3-adrenoceptor agonists, and serotonin–noradrenaline reuptake inhibitors.[1] Pelvic floor exercises such as Kegel exercises or biofeedback are non-surgical options. Overall, the mid-urethral sling operation has been shown to have a high success rate in symptom improvement. Because of patients' fear of surgery, conservative treatment is often preferred over surgical treatment. Various complications, such as bladder perforation, tape



	Pretreatment	4 weeks treatment	8 weeks treatment
OABSS1	0.68	0.62	0.68
OABSS2	1.31	0.86	0.72
OABSS3	2.68	1.75	1.34
OABSS4	2.93	1.96	1.37
OABSS total	7.62	5.2	4.13

FIGURE 4 Overactive Bladder Symptom Scores (OABSS) before treatment and after 4 and 8 weeks treatment. OABSS1, OABSS2, OABSS3, OABSS4

erosion, urinary retention, and postoperative pain, may occur.[21] Non-surgical treatment can be tried in place of surgical treatment. Among the various options, low-frequency electrical current and radio-frequency therapies have been used.[22-24]

The idea that low-frequency current affects pelvic floor muscles is longstanding.[25] Studies have shown that electrical stimulation affects urinary incontinence, dysuria, and lower urinary tract symptoms.[26] However, when applied at low frequencies, the effects can be similar to lower electrical stimulations reported in previous studies.[26] These treatments often involve intraurethral stimulation, which can lead to pain and urethral mucosal injury with long-term treatment. In contrast, intravaginal stimulation may lower the efficiency of energy transfer to the urethral sphincter, but it has the advantage of transmission of general stimulation to the pelvis. In the present study, we used three stimuli to the pelvic organs and urethral sphincter, pelvic diaphragm, and detrusor muscle simultaneously using a transvaginal probe. In other studies, the effects of electrical stimulation and vibration on skeletal muscle were shown to increase simultaneously.[27] Such electrical stimulation and microvibration could increase the contractile forces acting on the muscle fibers. In addition, contemporaneous hyperthermia treatments can increase the blood flow to the pelvis and relieve the pain caused by intramuscular pelvic congestion. The simultaneous transmission of the three stimuli, or energies, could maximize the therapeutic effect by inducing synergy.

Similar to the present study, another study investigated a home-care device.[28] In this study[28], we confirmed that the home-care device was as effective as outpatient clinic-based devices. Approximately 83.3% of patients experienced symptom improvements. There were differences in treatment method, amount of current used, interval duration, and number of treatments per week, but our findings showed improvement in all patients. The treatment was particularly effective for the symptoms of premenstrual syndrome and pelvic pain. This may be due to electrical stimulation affecting the bladder, urethra, urethral sphincter muscle fibers, and dominant nerves, which seemed to alleviate pelvic pain. In addition, thermal energy was transmitted through the contact surface of the intravaginal probe, which is believed to promote circulation in the nearby pelvis, alleviate pain caused by pelvic congestion, and alleviate symptoms of premenstrual syndrome. It is necessary to examine the effects of the interstitial cystitis/bladder pain syndrome in diseases that cause pelvic pain.

Another notable point is that symptom improvement was mainly observed in storage symptoms, confirmed by results of the KHQ, BFLUTS, and OABSS questionnaires. Typically, electrical stimulation is primarily related to muscle contraction; however, according to Stewart et al.,[26] non-implanted electrical devices may help relieve symptoms of overactive bladder. Electrical stimulation and pelvic floor muscle training may also help improve these symptoms.[26] The results of the present study indicate significant improvements in urinary incontinence and storage symptoms. In addition to the benefit of using the device at home, there was no notable difference in symptom improvement compared with device use in the outpatient clinic. It is considered that hyperthermia treatment can be concurrently performed to improve pelvic pain and bladder pain.

Unlike devices using general electrical frequency or pulses, this device is able to use vibration and hyperthermia simultaneously. The devices used in this study generally started with microvibrations prior to electrical stimulation. It is also important for the patient to recognize the potential dangers of electrical therapy. If the skin and the probe are not in close contact, a spark can occur between the contact skin surface and the probe, which may lead to burning or pain. To prevent this, we reduced the distance by using vibration to bring the skin surface as close as possible before the electrical stimulation was initiated. This increased the adhesion of the skin and electrodes through vibration, allowing the correct frequency to safely enter the pelvic floor muscles. Some studies of vibratory stimulation in the perineal area showed reduce urine leakage, improved muscle strength, and improved QoL.[29]

In the present study, the KHQ showed that stress incontinence symptoms improved in 87.1% of patients, urgency was improved in 70.97% of patients, urge incontinence was improved in 64.52% of patients, and bladder pain and voiding difficulty were improved in 61.29% of patients. Enuresis improved in only 29.03% of patients and worsened in 45.16%. Although a more detailed analysis is needed, overall symptom improvement was observed in over half the voiding symptoms, except for frequency and enuresis. Except for enuresis, symptom aggravation occurred in fewer than four patients, and 83.87% of patients reported symptom improvement. This is similar to the 80% success reported in the study of urinary incontinence using a similar vaginal insert.[30] The improvement in SUI symptoms was remarkable, and improvement of urge incontinence symptoms was also seen in two-thirds of patients.

This study has some limitations, one of which is the lack of control settings. Comparisons to Kegel exercises, a drug treatment group, or a surgical group did not provide an accurate comparison of the symptom improvement rates or success probabilities. We plan to directly compare these with other therapies through a future randomized case–control study. Another limitation of the study was the relatively short treatment period. The results showed that symptom improvements increased with the length of the treatment period. Symptom improvements were confirmed within the relatively short period of 8 weeks, but progressive improvement with long-term treatment could not be confirmed. In addition, the study subjects were recruited according to the symptoms of urinary incontinence without distinguishing between SUI, urge incontinence, and mixed urinary incontinence. Although the number of subjects was somewhat small, it is expected that more accurate results could be obtained with a larger group of subjects. Since the study subjects were not recruited separately according to the type of urinary incontinence, relatively small numbers of patients were allocated to the detailed classification of urinary incontinence because they were recruited only with or without symptoms of urinary incontinence, as well as long- versus short-term treatment and comparison with other conservative incontinence therapies.

In conclusion, intravaginal low-frequency home-care electrical stimulation devices were effective in improving urinary incontinence symptoms. This treatment effect became more evident as the duration of treatment increased. We also confirmed that all the lower

urinary symptoms, such as urgency and frequency, were improved. If conservative treatment is preferable, improvement of urinary incontinence symptoms can be obtained using this device.

ACKNOWLEDGMENTS

This research was supported by the Bio & Medical Technology Development Program of the National Research Foundation (NRF) funded by the Ministry of Science & Information and Communications Technologies (ICT) (2018M3A9E8020861).

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How to cite this article: Bae S, Lee KW, Jeong HC, et al. Effects of low-frequency intravaginal electrical stimulation on female urinary incontinence, quality of life, and urinary symptoms: A pilot study. *Lower Urinary Tract Symptoms*. 2019;1–8. https://doi.org/10.1111/luts.12278