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The Therapeutic Effect of Monopolar Radiofrequency Therapy on Urinary Symptoms and Sexual Function

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Abstract: Objectives: Stress urinary incontinence (SUI) negatively affects the quality of life and sexual function in women. This study aimed to evaluate the efficacy of radiofrequency (RF) therapy in reducing SUI symptoms and its impact on sexual function. **Methods:** Thirty-four women with SUI were enrolled and underwent a single RF treatment session using the Viveve® System (Viveve Medical Inc., USA) with parameters of 90 J/cm² and 220 pulses per hour. Assessments at baseline and 6 months post-treatment included perineal ultrasound and personal interviews to evaluate lower urinary tract symptoms and sexual function. Urodynamic studies, voiding diaries, and questionnaires such as the Female Sexual Function Index (FSFI), Overactive Bladder Symptom Score (OABSS), Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire-7 (IIQ-7), and International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) measured outcomes. **Results:** RF therapy significantly improved sexual function, with higher FSFI scores in all domains except pain at 6 months. SUI symptoms were significantly reduced, as indicated by improved scores on OABSS, UDI-6, IIQ-7, and ICIQ-SF, alongside better voiding diary results. Anatomical changes included reduced bladder neck mobility, decreased vaginal width, and a reduced rotation angle of the proximal urethra. Conclusions: RF therapy is effective and safe for treating mild to moderate SUI and enhances sexual function, potentially due to changes in vaginal topography. These results suggest RF therapy as a viable non-surgical option for managing SUI and improving sexual health.

Keywords: Stress Urinary Incontinence (SUI); Radiofrequency (RF) therapy; female sexual function; Viveve® system; urodynamic studies; non-surgical treatment

1. Introduction

Stress Urinary Incontinence (SUI) is a prevalent lower urinary tract disorder characterized by urine leakage during activities that increase intra-abdominal pressure, such as exercise, laughing, or coughing [1]. From 2005 to 2016, the prevalence of urinary incontinence was approximately 53%, with 26% attributed to SUI and 10% to urgency urinary incontinence alone [2]. In the U.S., sixteen billion dollars are spent annually on treating urinary incontinence, with thirteen billion specifically allocated to SUI [3]. Similarly, annual medical costs in Taiwan doubled or even tripled from 1997 to 2011, highlighting the rising prevalence of SUI despite advancements in medical care [4].

Effective non-surgical treatments for moderate SUI include pelvic floor muscle training, biofeedback, and electrical stimulation, while surgical interventions are recommended for severe cases. Medical treatments for moderate SUI, such as Duloxetine hydrochloride, Tolterodine, and mirabegron, often lead to significant side effects, including voiding dysfunction and urinary tract infections [5–7]. Post-operative complications from surgical treatments also remain a concern [8–10]. Consequently, there is an urgent need for alternative therapeutic strategies for SUI.

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Non-ablative fractional lasers, non-ablative radiofrequency (RF), and intense pulsed light, initially utilized for skin rejuvenation, have been adapted for vulvovaginal rejuvenation over the past few decades [11,12]. The primary cause of SUI is often linked to the relaxation of the urethral sphincter or pelvic floor muscles [13]. RF therapy emits focused electromagnetic waves to heat the tissue, inducing collagen folding and stimulating elastin regeneration, enhancing tissue elasticity [14,15]. Histological evidence supports the effectiveness of RF treatment on vulvovaginal tissue, restoring vaginal elasticity and improving conditions like SUI [16,17].

Sexual dysfunction in women with SUI significantly impacts their quality of life, causing embarrassing symptoms like urine leakage during sexual activity, leading to anxiety, reduced sexual desire, and avoidance of intimacy. The severity of pelvic organ prolapses, often associated with SUI, correlates with sexual dysfunction [18,19]. Urinary incontinence significantly impacts midlife sexual functioning, with psychosocial burdens leading to feelings of inadequacy and strained relationships [20–22].

However, no studies have yet investigated the effects of RF on SUI patients using pelvic floor ultrasound to objectively validate urethral angles. Therefore, we aim to evaluate monopolar RF therapy's impact on SUI symptoms using SUI-related questionnaires, urodynamic tests, and urogenital topography via perineal ultrasound. This comprehensive assessment will objectively validate the therapeutic effects of RF on both urinary symptoms and sexual function, providing crucial insights into this promising treatment modality.

2. Materials and Methods

This study was conducted at the Department of Obstetrics and Gynecology, Kaohsiung Medical University Hospital, from March 2019 to February 2021, involving 39 patients with mild to moderate Stress Urinary Incontinence (SUI). Inclusion criteria included: (1) pre-surgical condition for SUI; (2) age >20 years; (3) sexual activity within the past three months; and (4) postpartum period > six weeks. Exclusion criteria included: (1) vaginal bleeding; (2) malignancies; (3) urinary infections; (4) pelvic organ prolapse; (5) pregnancy; (6) vaginitis or other infections; (7) implanted medical devices; (8) genital fistulas; and (9) vulvodynia.

The intervention involved a single session of vaginal monopolar radiofrequency therapy using the Viveve® System (Viveve Medical Inc., USA) with an energy output of 90 J/cm² over one hour (220 pulses). Follow-up assessments were conducted at baseline and six months post-treatment.

Assessment tools included the Vaginal Laxity Questionnaire (VLQ) [23], Overactive Bladder Symptom Score (OABSS) [24], Urogenital Distress Inventory 6 (UDI-6) [25], Incontinence Impact Questionnaire 7 (IIQ-7) [26], Incontinence Questionnaire short form (ICIQ-SF) [27], and Female Sexual Function Index (FSFI) [28]. Additionally, pad tests measured urine leakage, with >1g increase over one hour indicating a positive result [29]. Urodynamic studies, including uroflowmetry, cystometry, and urethral pressure profilometry, were performed using a 6-channel urodynamic monitor (MMS; UD2000, Enschede, Netherlands). Positive detrusor overactivity was noted with uninhibited contractions during cystometry.

Additionally, patients maintained a voiding diary to record frequency, volume, and episodes of incontinence over a 24-hour period. This diary was used to gather subjective data on urinary patterns and was reviewed during follow-up assessments to provide further insight into the treatment's impact on SUI symptoms.

Trans-perineal ultrasound measured bladder neck mobility, vaginal area, and proximal urethral rotation angle using a Volusion General Electric Sonography 730 Expert device (GE Healthcare, USA) with a 3.5-MHz curved linear array transducer [30]. Measurements were taken at baseline and six months post-treatment under both rest and strain conditions. The study protocol, sanctioned by the Ethics Committee of Kaohsiung Medical University Chung-Ho Memorial Hospital, conforms to the principles delineated in the Declaration of Helsinki regarding human participant involvement. Before the initiation of treatment sessions, informed consent is obtained from all participants.

3. Results

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The study included 34 participants with a mean age of 43.8 ± 8.8 years and a mean BMI of 22.7 ± 3.5 kg/m². The severity of stress urinary incontinence (SUI) was assessed using the International Consultation on Incontinence Questionnaire (ICIQ). Prior to treatment, the distribution of SUI severity was as follows: 17.7% mild, 64.7% moderate, and 17.7% severe, with no cases of very severe SUI. Six months post-treatment, 76.5% of participants (26 out of 34) showed significant improvement in their SUI symptoms. (Table 1)

Table 1. clinical background of the participants. Data are given as mean± standard deviation or n(%).

	Pre-treatment (n=34)	Post-treatment (n=34)
Mean age (years)	43.8±8.8	
Mean BMI (kg/m²)	22.7±3.5	
SUI grade by ICIQ		
Mild	6 (17.7)	
Moderate	22 (64.7)	
Severe	6 (17.7)	
Very severe	0	
Efficacy for SUI		26/34 (76.5%)
Follow-up (months)		6 months

BMI, body mass index; SUI, stress urinary incontinence; ICIQ, International Consultation on Incontinence Questionnaire. * p< 0.05, Student's t-test.

Sexual function was evaluated at baseline and six months post-treatment using the Female Sexual Function Index (FSFI) (Table 2). Significant improvements were observed across various domains. The mean score for sexual desire increased from 3.0 ± 0.8 at baseline to 3.5 ± 0.9 post-treatment (p = 0.002). Sexual arousal also improved, with the mean score rising from 3.1 ± 0.8 to 3.7 ± 0.9 (p = 0.001). Participants reported an increase in orgasm scores from 3.5 ± 1.3 to 4.0 ± 1.2 (p = 0.010), while sexual satisfaction scores rose from 3.9 ± 1.3 to 4.4 ± 1.1 (p = 0.015). Overall, the total FSFI score increased from 22.2 ± 5.9 to 25.6 ± 5.0 (p = 0.003), with 70.6% of participants (24 out of 34) showing improved total scores.

Table 2. Changes in sexual function before and six months post-treatment. Data are given as mean± standard deviation or n(%).

n=34	Baseline	6 months post-treatment	p value*
Desire (1,2)	3.0 ± 0.8	3.5 ± 0.9	0.002*
Arousal (3-6)	3.1 ± 0.8	3.7 ± 0.9	0.001*
Lubrication (7-10)	4.2 ± 1.4	4.7 ± 1.0	0.058
Orgasm (11-13)	3.5 ± 1.3	4.0 ± 1.2	0.010*
Satisfaction (14-16)	3.9 ± 1.3	4.4 ± 1.1	0.015*
Pain (17-19)	4.6 ± 1.5	5.1 ± 1.2	0.089
FSFI total scores	22.2 ± 5.9	25.6 ± 5.0	0.003*
Rate of improved total scores		24/34 (70.6%)	

*Statistical significance; Paired t-test.

Questionnaire assessments showed significant improvements in urinary distress and quality of life at Table 3. The Overactive Bladder Symptom Score (OABSS) decreased from 5.3 ± 3.3 at baseline to 3.3 ± 2.2 post-treatment (p = 0.02). The Urinary Distress Inventory (UDI-6) scores improved from 29.6 ± 13.9 to 17.7 ± 11.2 (p < 0.01), and the Incontinence Impact Questionnaire (IIQ-7) scores decreased from 22.1 ± 16.9 to 9.9 ± 13.0 (p < 0.01). The International Consultation on Incontinence Questionnaire-

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Short Form (ICIQ-SF) scores improved from 8.7 ± 3.4 to 5.9 ± 3.7 ($p < 0.01$). Additionally, the Vaginal Laxity Questionnaire (VLQ) scores increased from 3.15 ± 1.0 to 4.1 ± 1.2 ($p < 0.01$), with 67.7% of participants (23 out of 34) reporting higher VLQ scores.

Table 3. Questionnaire results before and six months post-treatment. Data are given as mean± standard deviation or n (%).

n=34	Baseline	6 months post-treatment	p value*
OABSS	5.3 ± 3.3	3.3 ± 2.2	0.02*
UDI-6	29.6 ± 13.9	17.7 ± 11.2	<0.01*
IIQ-7	22.1 ± 16.9	9.9 ± 13.0	<0.01*
ICIQ-SF	8.7 ± 3.4	5.9 ± 3.7	<0.01*
VLQ	3.15 ± 1.0	4.1 ± 1.2	<0.01
Rate of higher VLQ		23/34 (67.7%)	

VLQ, Vaginal Laxity Questionnaire; OABSS, Overactive Bladder Symptom Score; UDI-6, Urinary Distress Index; IIQ-7, Incontinence Impact Questionnaire; ICIQ-SF, International Consultation on Incontinence Questionnaire – Short Form. Values are expressed mean ± standard deviation or numbers *Statistical significance; Paired t-test.

Urodynamic assessments indicated a few significant changes following treatment (Table 4). The mean pad test result decreased from 12.8 ± 19.6 grams to 5.0 ± 13.6 grams ($p = 0.013$). Detrusor pressure at peak flow increased from 10.0 ± 28.5 cm H2O to 22.7 ± 14.8 cm H2O ($p = 0.016$). Other urodynamic parameters, such as maximum flow rate (Qmax), residual urine (RU), bladder volume at first desire to void (Vfst), maximum cystometric capacity (MCC), maximum urethral closure pressure (MUCP), functional urethral length (FUL), and urethral closure pressure area (UCA), did not show statistically significant changes.

Table 4. Urodynamic changes at baseline and six months after treatment. Data are given as mean± standard deviation.

n=34	Baseline	6 months post-treatment	p value*
Pad test	12.8 ± 19.6	5.0 ± 13.6	0.013*
Vaginal Pressure (cm H_2O)	53.9 ± 16.4	53.3 ± 25.9	0.880
Qmax (ml/ sec)	26.3 ± 9.7	24.1 ± 11.4	0.214
RU (ml)	40.3 ± 42.5	49.8 ± 50.8	0.384
Vfst (ml)	182.0 ± 83.4	187.5 ± 119.5	0.779
MCC (ml)	435.0 ± 140.4	467.5 ± 181.4	0.129
Pdet (cm H_2O)	10.0 ± 28.5	22.7 ± 14.8	0.016*
MUCP (cm H_2O)	56.4 ± 20.9	58.5 ± 21.3	0.517
FUL (cm)	27.6 ± 5.4	27.6 ± 6.6	0.981
UCA (cm^2 H_2O))	900.5 ± 386.4	974.3 ± 392.0	0.174

Qmax, maximum flow rate; RU, Residual urine; Vfst, bladder volume at first desire to void; MCC, maximum cystometric capacity; Pdet, detrusor pressure at peak flow; MUCP, maximum urethral closure pressure; FUL functional urethral length; UCA, urethral closure pressure area. Values are expressed mean ± standard deviation or numbers *Statistical significance; Paired t-test.

The voiding diary results revealed notable improvements in urinary symptoms (Table 5). The frequency of urination per 24 hours decreased from 8.1 ± 2.8 times to 7.2 ± 2.1 times ($p = 0.034$), and episodes of urge incontinence per 24 hours significantly decreased from 2.0 ± 1.9 to 0.9 ± 1.4 ($p = 0.001$). Other parameters, such as voided urine volume per time, maximum urine volume, and average nocturia per 24 hours, did not show significant changes.

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Table 5. Changes in voiding diaries at baseline and six months after treatment. Data are given as mean± standard deviation.

n=34	Baseline	6 months post-treatment	p value*
Frequent urination per 24 hr	8.1 ± 2.8	7.2 ± 2.1	0.034*
Voided urine volume per time (ml)	218.8 ± 93.7	219.8 ± 98.3	0.913
Maximum urine volume (ml)	394.5 ± 146.8	388.7 ± 159.2	0.788
Urge incontinence per 24 hr	2.0 ± 1.9	0.9 ± 1.4	0.001*
Average nocturia per 24 hr	0.8 ± 0.8	0.8 ± 0.8	1.0

Values are expressed mean ± standard deviation or numbers *Statistical significance; Paired t-test.

Changes in vaginal and urethral topography were also observed post-treatment in Table 6. Bladder neck mobility decreased from 1.6 ± 0.3 to 1.3 ± 0.2 (p = 0.003). Vaginal width at Valsalva and area at both resting and Valsalva showed significant reductions. At rest, vaginal width decreased from 3.1 ± 0.4 cm to 2.9 ± 0.3 cm (p = 0.080) and vaginal area decreased from 3.1 ± 0.5 cm^2 to 2.8 ± 0.5 cm^2 (p = 0.018). During Valsalva maneuver, vaginal width decreased from 3.5 ± 1.1 cm to 2.9 ± 0.8 cm (p = 0.004), and vaginal area decreased from 4.0 ± 1.0 cm^2 to 3.1 ± 0.9 cm^2 (p = 0.001). The proximal urethral rotation angle reduced from 15.3 ± 5.0 degrees to 11.6 ± 3.1 degrees (p = 0.009)

Table 6. Changes in vaginal and urethral topography at baseline and six months after treatment. Data are given as mean± standard deviation.

n=34		**Baseline**	**6 months post treatment**	***p* value***
Bladder neck mobility		1.6 ± 0.3	1.3 ± 0.2	0.003*
Vaginal width (cm)	Resting	3.1 ± 0.4	2.9 ± 0.3	0.080
	Valsalva	3.5 ± 1.1	2.9 ± 0.8	0.004*
Vaginal area (cm^2)	Resting	3.1 ± 0.5	2.8 ± 0.5	0.018*
	Valsalva	4.0 ± 1.0	3.1 ± 0.9	0.001*
Proximal urethral rotation angle		15.3 ± 5.0	11.6 ± 3.1	0.009*

Values are expressed mean ± standard deviation or numbers *Statistical significance; Paired t-test.

4. Discussion

RF energy, functioning within a frequency range of 20 kHz to 300 GHz [31], has been employed in medical treatments for over 125 years, including diathermy, hyperthermia treatments, electrosurgical scalpels, and radiofrequency ablation [32,33]. Another key application is magnetic resonance imaging (MRI), which utilizes RF to generate body images. Our current research focuses on assessing RF's therapeutic effects on SUI and sexual function over 6 months. This study measures standard questionnaire outcomes related to SUI symptoms and sexual function, as well as bladder neck mobility and urethral rotation angles, to accurately gauge SUI conditions and potentially prevent unnecessary surgical interventions. The increasing demand for non-invasive methods like RF and laser treatments for various vaginal issues has been noted [34,35].

Studies have highlighted the beneficial impacts of laser treatments on sexual function. Eder et al., 2019 reported that 15 participants receiving two Fractional CO2 laser treatments—one at baseline and a maintenance treatment at either 12 or 15 months—saw significant improvements in total FSFI scores at follow-ups of 12, 15, and 18 months, with scores increasing from 16.2 ± 7.9 to 24.4 ± 6.9, 22.2 ± 6.7, and 25.8 ± 6.6, respectively. This underscores the laser's efficacy in treating sexual dysfunction caused by post-menopausal vaginal atrophy over a long-term period [36]. However, a study by Lou et al., 2022, compared vaginal fractional CO2 laser therapy to Kegel exercises for female sexual

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dysfunction and found no significant difference in FSFI total scores at a 12-month follow-up, except in the lubrication category [37].

Our research team explored the effects of Er: YAG vaginal laser treatment on women's sexual dysfunction, specifically in patients with Stress Urinary Incontinence (SUI). We observed a significant improvement in the overall Female Sexual Function Index (FSFI) scores, which increased from 22.2 ± 6.2 to 25.6 ± 4.5 after six months of treatment. Although the increase in the sexual desire domain was modest (from 2.8 ± 1.2 to 3.0 ± 1.0, $p = 0.07$), it suggests potential benefits of this treatment [38]. Additionally, in a comparative assessment, the use of RF treatment significantly boosted the FSFI total score from 22.2 ± 5.9 to 25.6 ± 5.0 within six months, enhancing many domains in the FSFI. These findings indicate that RF treatment may offer more rapid efficacy in improving sexual dysfunction than the Er: YAG laser. However, further research with a longer follow-up period is necessary to confirm the durability and full scope of these therapeutic effects.

Recent studies have explored non-ablative laser therapy for treating Stress Urinary Incontinence (SUI). Nalewczynska et al. (2022) demonstrated the safety and effectiveness of pixel CO2 laser, noting slight symptom improvements and suggesting the need for maintenance treatments within 6 to 12 months [39].

Our team investigated the efficacy of two types of laser therapy—Er: YAG and pixel CO2—on SUI symptoms, collecting data over a 6-month period. The Er: YAG laser showed significant improvements in the UDI-6 and IIQ-7 questionnaires ($p = 0.006$; $p = 0.005$), which assess the distress and impact of urinary incontinence. Additionally, OABSS and POPDI-7 scores, which reflect discomfort from pelvic organ prolapse and overactive bladder syndrome, also improved significantly ($p = 0.001$; $p = 0.037$) [40]. Conversely, three treatments with the pixel CO2 laser yielded mixed results, with significant improvements in UDI-6 and IIQ-7 ($p = 0.012$; $p = 0.049$) but no significant change in OABSS scores ($p = 0.481$) [41].

In contrast to laser therapy, RF treatment demonstrated more rapid improvements in SUI symptoms. Within six months, significant reductions were observed in UDI-6, IIQ-7 ($p < 0.01$), and OABSS scores ($p = 0.02$). These results suggest that RF may be more effective than laser therapy in the short term for alleviating SUI symptoms.

Lin et al. (2017) confirmed that laser therapy improves Overactive Bladder (OAB) symptoms and urodynamic parameters, although some benefits did not persist beyond a year [42]. Blaganje et al. (2018) found that Er: YAG laser treatment significantly enhanced duration and maximum pressure during pelvic exercises, but not average pressure [43]. Alcalay et al. (2021) observed a notable reduction in the 1-hour pad test with pixel CO2 laser, with 41.4% of patients showing no SUI at 6 months [44], yet our results showed no significant urodynamic changes at 6 months [41]. In contrast, RF treatment significantly improved both the 1-hour pad test and detrusor pressure (Pdet), indicating its effectiveness ($p < 0.05$). The findings from the voiding bladder diary corroborate our earlier observations. Our current data show that radiofrequency (RF) treatment significantly reduced the frequency of urination per 24 hours ($p = 0.034$) and the incidents of urge incontinence within the same timeframe ($p = 0.001$*).

Assessments of bladder neck mobility via perineal ultrasound have become crucial in validating SUI status. Our findings from Er: YAG and pixel CO2 laser treatments showed significant decreases in bladder neck mobility and middle urethral area [41,45]. RF treatment further decreased bladder neck mobility ($p = 0.003$) and significantly reduced vaginal width at Valsalva and area under both rest and straining conditions ($p < 0.05$), as well as the proximal urethral rotation angle ($p = 0.009$). These changes suggest a strong correlation between RF therapy and the recovery of SUI symptoms. During the treatment, none of these cases reported obvious side effects.

The study faces limitations that could impact the scope and interpretation of the results. The small sample size restricts the generalizability of the findings and diminishes the robustness of statistical conclusions. A brief follow-up period of only 6 months may not adequately capture the long-term effects and any adverse outcomes associated with the RF and laser treatments.

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5. Conclusions

Our study indicates that a single vaginal RF treatment can markedly improve SUI symptoms, reflected in both questionnaire responses and perineal ultrasound measurements. The RF treatment also demonstrated significant improvements across various FSFI indexes and total scores. Given these promising results, additional randomized trials are recommended to further assess the safety and long-term efficacy of RF therapy in treating women with SUI and potentially other related conditions.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of Kaohsiung Medical University Chung-Ho Memorial Hospital (protocol code: KMUHIRB-F(II)-20180105 and date of approval: 2018/09/18).” for studies involving humans.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.
Data Availability Statement: The data that support the findings of this study are available from the corresponding author, C.Y. Long, upon reasonable request..

Conflicts of Interest: The authors declare no conflicts of interest.

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