Transcutaneous Temperature-Controlled Radiofrequency Treatment: Improvement in Female Genital Appearance, Sexual Dysfunction, and Stress Urinary Incontinence

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Sejal Ajmera Desai, MD, MBBS, MS; Zahaan Vakil, MD; and George Kroumpouzos, MD, PhD, FAAD

Abstract

Background: Transcutaneous temperature-controlled radiofrequency (TTCRF) treatment is an emerging modality for vulvovaginal rejuvenation. However, clinical experience with this modality is limited.

Objectives: The aim of this study was to examine the efficacy of TTCRF treatment in improving female genital appearance, sexual function, and stress urinary incontinence (SUI).

Methods: Forty-eight patients complaining of sexual dysfunction (SD; n = 41) and/or SUI (n = 37) were included. Most patients had ≤3 TTCRF sessions. To evaluate the aesthetic results, photographs of the genital area taken before treatment were compared to those taken 6 weeks posttreatment in a blinded manner. Prior to treatment and 6 weeks after the final session, the Female Sexual Function Index (FSFI) questionnaire was administered to participants complaining of SD and the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-UI-SF) to those with complaints/symptoms of SUI. Preprocedure scores were compared with postprocedure scores by paired *t* test.

Results: Aesthetic improvement was noted in all patients. Preprocedure mean total FSFI score was 21.77 vs the respective postprocedure score of 25.79 ($P < 0.00001$). Most FSFI domains improved (pre- vs post-TTCRF mean score): sexual desire (from 2.99 to 3.54), arousal (from 3.14 to 3.83), orgasm (from 3.14 to 4.39), pain (from 4.41 to 5.04) ($P < 0.00001$ for all) and satisfaction (from 3.75 to 4.42; $P = 0.001$). Mean preprocedure ICIQ-UI-SF score was 10.10 and decreased to 4.81 ($P < 0.00001$) postprocedure.

Conclusions: A substantial improvement in genital appearance was observed. Assessment based on validated instruments demonstrated significant improvements in sexual function and SUI. TTCRF is a safe and effective treatment for these conditions.

Level of Evidence: 4

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Dr Desai is a consultant obstetrician and gynecologist, Indian Academy of Vaginal Aesthetics, Mumbai, India. Dr Vakil is a resident, Department of Internal Medicine, Seth GS Medical College and King Edward Memorial Hospital, Mumbai, India. Dr Kroumpouzos is a clinical associate professor, Department of Dermatology, Alpert Medical School of Brown University, Providence, RI, USA.

Corresponding Author:
Dr George Kroumpouzos, Department of Dermatology, Rhode Island Hospital, APC 10, 593 Eddy Street, Providence, RI 02903, USA.
Email: gk@gkderm.com; Instagram: @gkdermatology

Vulvovaginal Rejuvenation

An ever-increasing number of women are expressing concerns regarding the appearance and function of their genitalia. Frequently encountered complaints include age-related conditions such as vaginal laxity, orgasmic dysfunction, and stress urinary incontinence (SUI). Aside from functional consequences, these conditions have an effect on women's sexuality and sense of well-being. Feminine or vulvovaginal rejuvenation refers to procedures that primarily reduce the width of the vagina for cosmetic reasons or to improve vaginal laxity and urinary incontinence.[1] Noninvasive energy-based devices, including lasers and radiofrequency (RF), are increasingly being used for vulvovaginal rejuvenation.[2-5] One such modality, transcutaneous temperature-controlled radiofrequency (TTCRF), has been gaining attention and is the focus of this study.

TTCRF Mechanism of Rejuvenation

TTCRF combines RF, an established technology proven safe and effective for treatment of skin laxity, with feedback controls for the monitoring and maintenance of tissue temperature via thermocouples and thermistors in the treatment probe.[6] The operator can apply a precisely controlled RF at a preselected temperature setting. This enhances the control of energy that is delivered, which enhances safety. TTCRF uses real-time temperature monitoring and regulation, ensuring that the therapeutic temperature is maintained during the treatment.[7]

Energy-based devices such as TTCRF enhance vulvovaginal rejuvenation by inducing thermal-dependent matrix remodeling which involves neocollagenesis and neoelastogenesis. These devices have been shown to increase type 1 collagen production in the extracellular matrix via stimulation of fibroblasts. This process increases neovascularization, resulting in improved lubrication of the vulvovaginal area.[4] Also, treatment with energy-based devices is associated with an increase in glycogen content and small nerve fiber density in the papillary dermis, as documented by histopathologic examination of posttreatment biopsy specimens.[5] Finally, restoration of vaginal milieu and flora associated with increases in *Lactobacillus* activity and more acidic mucopolysaccharides leads to improved mucosal hydration.[8]

TTCRF Studies

Alinsod conducted a study on 25 sexually active females and reported a reduction in "time to orgasm" by almost half.[6] Significant vaginal tightening, improved vaginal moisture, and enhanced vulvar and clitoral sensitivity were noted in almost all patients. The procedure was found to be very safe. In a Polish study of 53 patients, TTCRF was used in the treatment of vaginal laxity, SUI, and sexual disorders.[9] The study used a 7-item questionnaire and documented statistically significant improvements in vaginal tightening, controlling urinary incontinence during coughing, and frequency of feeling urgent. In a small series of 10 South American patients, Leibaschoff et al demonstrated the usefulness of TTCRF treatment for genitourinary syndrome of the menopause.[7] Improvements in urinary incontinence were documented with the use of the Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF). An increase in vaginal health index and decrease in visual analog score for dyspareunia reflected improvements in the vaginal symptoms.

TTCRF treatment was reviewed by Wańczyk-Baszak et al who found it safe, tolerable, and effective.[10] Its excellent safety profile, apparently superior to that of surgical modalities being used for vulvovaginal rejuvenation, and very short recovery have been highlighted as particular advantages of TTCRF therapy. Nevertheless, clinical experience with TTCRF treatment is limited, and data in the Indian population are lacking.

OBJECTIVES

The study aimed at demonstrating the efficacy of TTCRF treatment in improving female genital appearance and treating sexual dysfunction (SD) and SUI in a western Indian population.

METHODS

Patient Selection

This interventional, single-arm study was conducted from July 2017 to April 2020. Women with complaints and/or symptoms of SD, SUI, or both were included in the study. None of the participants were anorgasmic. Exclusion criteria were other complaints such as overactive bladder, concomitant vulvar lesions or disease such as lichen sclerosus et atrophicans, abnormal Papanicolaou test results, vaginal bleeding, and vaginal width more than 3 fingers. SUI was diagnosed based on history, ie, complaints of urinary leakage on raised intraabdominal pressure such as from cough, sneeze, exercise, and examination, ie, direct observation of urine loss when a patient is asked to cough or bear down with a full bladder. Patients with grade III SUI (Ingelmann-Sundberg severity classification[11]) were not excluded from the study. No patients underwent labiaplasty during the study period. Intravaginal estrogen was not used by any patients during the study period, and Kegel exercises were not part of the treatment regimen.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.[5] Written informed consent for inclusion in the study and photography was obtained from all participants. The manuscript does not include identifiable information.

Evaluation of Aesthetic Results

Evaluation of the aesthetic results was performed via serial photography, ie, comparison of photographs taken prior to the first TTCRF session and 6 weeks after the final session. Photographs were always taken at the same location, with 1 camera and the same lighting. Evaluation of change in wrinkles, skin quality, and tumescence of labia majora was based on a 3-point Likert scale with 3 possibilities: (1) worse; (2) unchanged; (3) improved. Photographs were evaluated by the authors in a blinded manner regarding the chronologic order in relation to therapy (before vs after).

Evaluation of Sexual Function and Urinary Incontinence

SD and severity of the SUI were evaluated with the Female Sexual Function Index (FSFI) questionnaire (scoring scale, 2-36)[12] and the ICIQ-UI-SF (scoring scale, 0-21),[13] respectively. The FSFI is a 19-item questionnaire divided into 6 content domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. The FSFI has been found to be sensitive for detecting outcomes after treatment.[14] SUI symptom severity categorization according to ICIQ-UI-SF score includes mild (score, 1-5), moderate (score 6-12), severe (score, 13-18), and very severe (score, 19-21) groups.[13] Patients were asked to complete the FSFI and ICIQ-UI-SF questionnaires before the first session. The instruments used in the study have been extensively validated and are accepted worldwide.[12,13] A specific validation in the study population was not required because all participants spoke English and no translations into any local languages were required. Moreover, the instruments are devoid of any culturally specific connotations, and there was no need to adapt the instruments culturally. Participants provided a good feedback on the questionnaires before the first session.

Procedure

Patients were treated in a private gynecology practice. A ThermiVa device (ThermiAesthetics, Southlake, TX) was used to perform TTCRF treatment of the vulvovaginal region. This device has a monopolar RF console, a slim, S-shaped, linear, 1.5 cm × 20 cm treatment probe, and a foot switch. The probe tip has an RF emitter which is applied to the tissue. Feedback mechanisms on the probe allow the tissue temperature to be monitored and the RF energy emission to be modulated.[14] The patient is placed in the standard lithotomy position with a neutral return pad placed under her buttocks. A lubricant gel is required but no anesthesia. The vagina is divided into 4 treatment zones: anterior, posterior, left, and right. The vagina is treated by moving the probe back and forth with the active end always being in contact with the vaginal mucosa. The anterior wall is treated for 8 minutes and the subsequent 3 quadrants for 5 minutes each at a set temperature of 47°C. For vulvar application, the probe is used with a circular motion at a temperature of 40°C for 2 minutes on each labium and 1 minute on the clitoris and introitus. These parameters follow the manufacturer's guidelines and publications by leading TTCRF users.[14] The overall treatment took 28 minutes as compared to <30 minutes in the study by Alinsod.[14] Vulvar treatment took 5 minutes, as long as in the study by Kuzlik and Kuzlik.[9] Time counting starts after therapeutic temperature is reached (there is a "warm-up" time of 30 seconds to 3 minutes in each treatment zone).

The advantages of the device are that it is noninvasive and painless, and produces no smoke or odor. There is no downtime, and the patient may return immediately to her usual activities including sexual intimacy. For optimal results we recommend 3 sessions at monthly intervals and a fourth session a year later. Also, in patients with severe symptoms we often recommended more than 3 sessions.

Follow-Up

Patients were followed-up for a period of 5 months after the final session. Six weeks after the final session, patients were asked to complete the FSFI and ICIQ-UI questionnaires again.

Statistical Analysis

Categoric data, ie, participant age and session distributions, and frequencies of symptoms/complaints, are presented as percentages. Numeric data are presented as mean, standard deviation, and standard error of mean. The pre- and postprocedure mean total FSFI and ICIQ-UI-SF scores were compared by paired-sample *t* test. A similar comparison was performed for each of 6 FSFI domains and SUI symptom severity groups. $P < 0.05$ was taken as statistically significant. Statistical analysis was

Table 1. Participant Age and Session Distributions

Age, years	Number of patients (n = 48)	Percentage
21-30	3	6.25
31-40	9	18.75
41-50	21	43.75
51-60	8	16.67
61-70	1	2.08
71-80	3	6.25
≥81	3	6.25
Number of sessions	Number of patients (n = 48)	Percentage
1	10	20.83
2	12	25
3	21	43.75
>3	5	10.42

Percentage values are rounded to the second decimal.

Table 2. Main Complaints and Symptoms in Participants (n = 48)

Symptoms	Number of patients	Percentage
Vaginal laxity	32	66.67
Vaginal dryness	22	45.83
Pain during intercourse	18	37.5
Reduced arousal and desire	35	72.92
Reduced orgasm	16	33.33
SUI	37	77.08

Percentage values are rounded to the second decimal. SUI, stress urinary incompetence.

performed with SPSS version 23.0 software (IBM Corp., Armonk, NY).

RESULTS

Forty-eight female patients enrolled in the study. All patients completed the study. Mean participant age was 48.9 years (range, 26-84 years). The age group 41 to 50 years was the biggest, comprising 43.75% of patients (Table 1). Forty-one of 48 patients were sexually active at the time of the study. The chief complaints were SUI (77.08%), reduced arousal and desire (72.91%), and vaginal laxity (66.67%) (Table 2). Most patients had more than 1 complaint. Two patients had pelvic organ prolapse on examination. Approximately 90% of patients had up to 3 TCCRF treatment sessions (Table 1). A substantial percentage (45.83%) of participants chose to have fewer than 3 sessions mainly because they were happy with the improvement they experienced after 1 or 2 sessions. Increased frequency of urination on the first day postprocedure was noted in 1 patient, and settled within 24 hours with oral fluids. No other patient complaints or complications were noted.

Genital Appearance

Aesthetic improvement of wrinkles, skin quality, and tumescence of labia majora was noted in 100% of patients (Figures 1-3).

Total FSFI and ICIQ-UI-SF scores

Preprocedure total FSFI scores ranged from 2.6 to 32.4 (mean [standard deviation], 21.77 [6.87]), and the postprocedure ones from 2.6 to 33.4 (mean, 25.79 [6.93]). The mean total FSFI score showed an 18.47% increase after treatment ($P < 0.00001$; Table 3). Twenty-nine participants had a pretreatment total FSFI score ≤26.55, which is indicative of SD.[12] The scores of 10 of these patients (34.48%) improved to normal range FSFI scores (ie, >26.55) posttreatment. The mean pretreatment ICIQ-UI-SF score was 10.10 [4.89] and the respective posttreatment score 4.81 [4.45] ($P < 0.00001$; Table 3).

FSFI Domain Scores

As shown in Table 4 and Figure 4, all FSFI domains, ie, sexual desire, arousal, orgasm, satisfaction, and pain, showed statistically significant improvement. However, the improvement in lubrication during sexual activity did not reach statistical significance. Some patients reported reduced time to orgasm and better orgasms. Four patients reported a renewed ability to orgasm, as reflected by increases in FSFI index for orgasm: 2 with 0 preprocedure score achieved a 2.8 postprocedure score, and 2 with a very low preprocedure score (1.6) achieved a 4.4 postprocedure score.

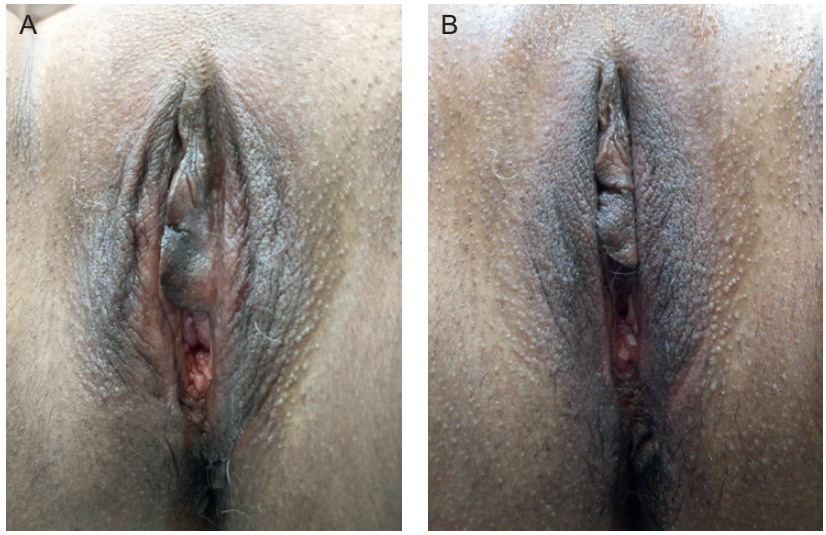

Figure 1. This 46-year-old female had received TTCRF treatment. Vulva and vaginal introitus: (A) before and (B) 6 weeks after after 1 TTCRF session. TTCRF, transcutaneous temperature-controlled radiofrequency.

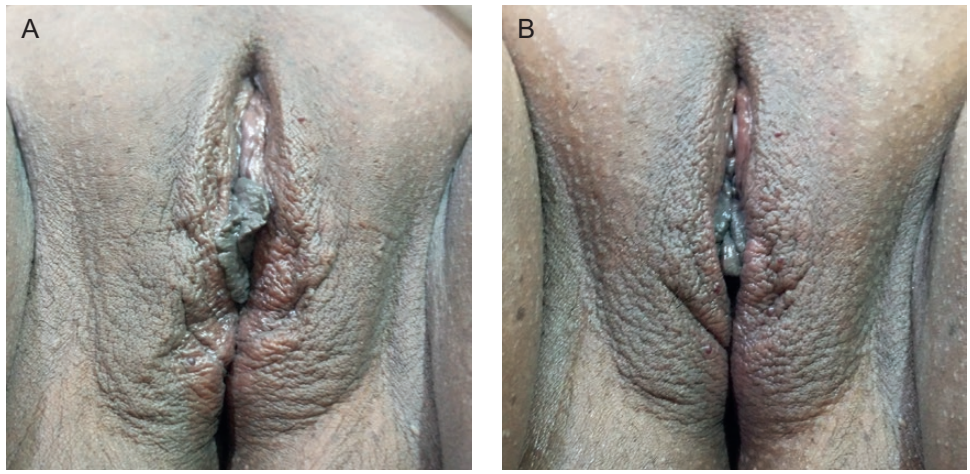

Figure 2. This 45-year-old female had received TTCRF treatment. Vulva and vaginal introitus: (A) before and (B) 6 weeks after 3 TTCRF sessions. TTCRF, transcutaneous temperature-controlled radiofrequency.

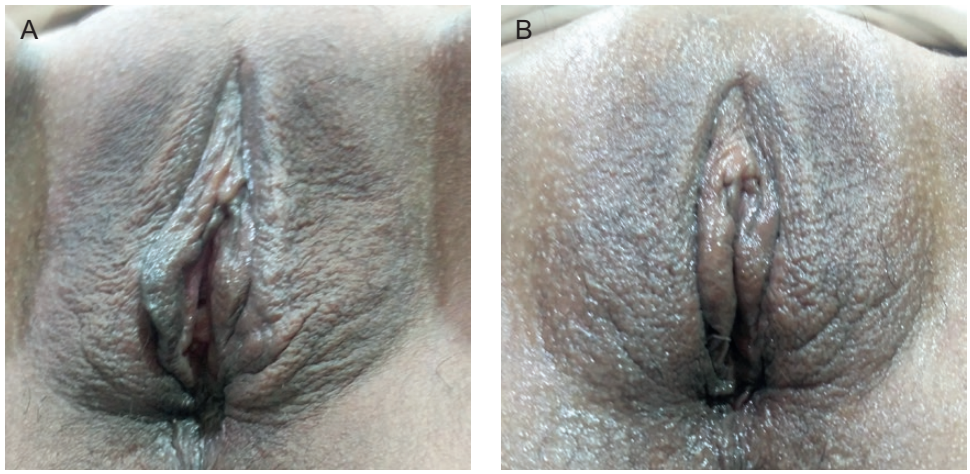

Figure 3. This 42-year-old female had received TTCRF treatment. Vulva: (A) before and (B) 6 weeks after 3 TTCRF sessions. TTCRF, transcutaneous temperature-controlled radiofrequency.

Table 3. Pre- and Posttreatment Mean Total FSFI and ICIQ-UI-SF Scores

	Mean [SD], preprocedure	SEM	Mean [SD], postprocedure	SEM	Percentage change	*P* value
FSFI score (n = 41)	21.77 [6.87]	1.07	25.79 [6.93]	1.08	18.47%	<0.00001[a]
ICIQ-UI-SF score (n = 37)	10.10 [4.89]	0.80	4.81 [4.45]	0.73	52.38%	<0.00001[a]

The mean, SD, SEM, and percentage change values are rounded to the second decimal. FSFI, Female Sexual Function Index; ICIQ-UI, International Consultation on Incontinence Questionnaire-Urinary Incontinence; SD, standard deviation; SEM, standard error of the mean. [a]Statistically significant.

Table 4. Pre- and Posttreatment Mean FSFI Domain Scores (n = 41)

FSFI domain	Preprocedure mean [SD]	SEM	Postprocedure mean [SD]	SEM	Percentage change	*P* value
Desire	2.99 [1.00]	0.15	3.54 (0.95)	0.14	18.39	<0.00001[a]
Arousal	3.14 [1.23]	0.19	3.83 (1.23)	0.19	21.97	<0.00001[a]
Lubrication	4.02 [1.69]	0.26	4.52 (1.27)	0.19	12.44	0.06
Orgasm	3.14 [1.60]	0.25	4.39 (1.52)	0.23	39.81	<0.00001[a]
Satisfaction	3.75 [1.64]	0.25	4.42 [1.46]	0.22	17.87	0.001[a]
Pain	4.41 [1.90]	0.29	5.04 [1.66]	0.26	14.29	<0.00001[a]

The mean, SD, SEM, and percentage change values are rounded to the second decimal. FSFI, Female Sexual Function Index; SD, standard deviation; SEM, standard error of the mean. [a]Statistically significant.

ICIQ-UI-SF Scores in SUI Symptom Severity Groups

Regarding pretreatment total ICIQ-UI-SF scores, 8 patients had mild (score, ≤5), 15 moderate (score, 6-12), and 14 severe/very severe (score, 13-21) SUI (Table 5). Differences between pre- and posttreatment scores were statistically significant across all SUI symptom severity groups (Table 5). Notably, 11 patients (29.7% of SUI patients), of whom 5 had mild, 4 had moderate, and 2 had severe SUI symptoms, achieved a postprocedure score of 0.

Efficacy of a Single Session

In patients who received a single treatment (n = 10), the mean total FSFI score improved from 23.47 to 27.64, and the mean ICIQ-UI-SF score decreased from 11 to 4.5 postprocedure. However, these differences were not statistically significant.

Patient Satisfaction

Six weeks after the final session patients answered a 3-choice question about the degree of their satisfaction (ie, "not satisfied," "satisfied," and "very satisfied" options). Forty-one (85.4%) patients were very satisfied, 5 (10.4%) moderately satisfied, and 2 (4.2%) unsatisfied with the results of the procedure. Satisfied patients reported a postprocedure improvement in vaginal laxity and lubrication. Patient satisfaction was maintained during the follow-up period.

DISCUSSION

This study shows that TTCRF is an effective modality for SD and SUI. Additionally, a substantial aesthetic improvement of the vulvar area, ie, decreased wrinkling, improved skin quality, and less sagging of the labia majora, was noted in all patients after completion of treatment. Almost all (95.8%) participants were satisfied with the results.

TTCRF Efficacy for Vaginal Laxity

Vaginal laxity was one of the most common patient complaints in our study, reported by 66.67% of participants. A survey conducted by the International Urogynecological Association showed that 84% of the physicians believed that vaginal laxity was underreported and 95% that it impacted on sexual function.[15] Before the advent of TTCRF treatment, Millheiser et al conducted the first transvaginal human study to explore the short-term tolerability, safety, and efficacy of monopolar RF with a cooling module for treating vaginal laxity.[16] The study showed improvements in vaginal laxity and sexual function. Vulvovaginal tightening and improvements in vaginal atrophy symptoms were reported in a TTCRF series by Alinsod and Leibaschoff.[6,7]

Two studies utilized monopolar RF with integrated cryogen. The cryogen-cooled monopolar radiofrequency trial showed an improvement in vaginal laxity and arousal and orgasm domains of the FSFI scale.[17] A similar study on vaginal introital laxity and sexual satisfaction showed a sustainable 12-month effectiveness with respect to improved

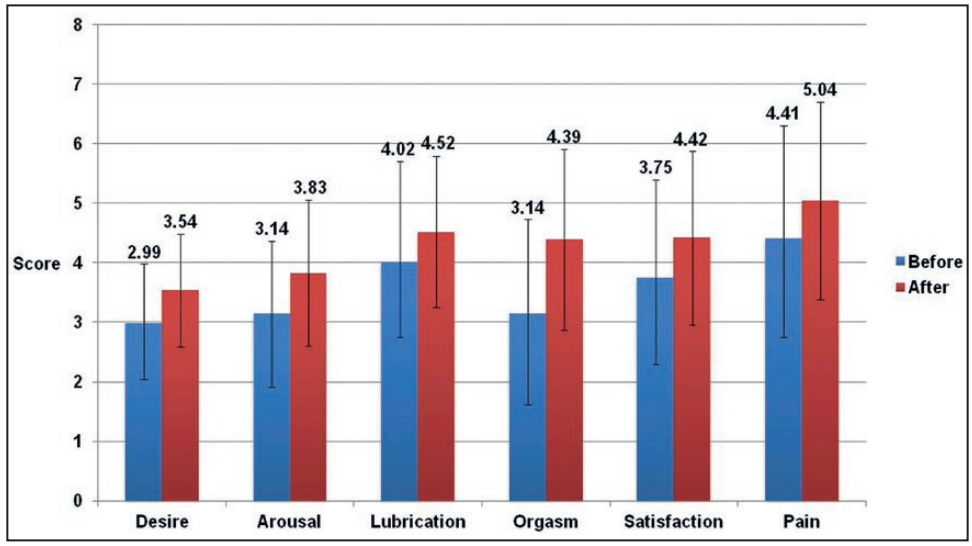

Figure 4. Graphical representation of pre- and posttreatment mean Female Sexual Function Index domain scores. Mean values are shown above the error bars. Error bars represent 1 standard deviation (standard deviation values are shown in Table 4).

Table 5. Pre- and Posttreatment Mean ICIQ-UI-SF Scores in SUI Symptom Severity Groups

SUI symptom severity	Preprocedure mean [SD]	SEM	Postprocedure mean [SD]	SEM	Percentage change	*P* value
Mild (score, ≤5) (n = 8)	3.00 [1.51]	0.53	1.00 [1.85]	0.65	66.67	0.0499[a]
Moderate (score, 6-12) (n = 15)	9.20 [1.26]	0.33	4.87 [3.36]	0.87	47.06	0.0001[a]
Severe/very severe (score, 13-21) (n = 14)	15.14 [1.99]	0.53	6.93 [5.21]	1.39	54.23	<0.0001[a]

The mean, SD, SEM, and percentage change values are rounded to the second decimal. ICIQ-UI-SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form; SD, standard deviation; SEM, standard error of the mean; SUI, stress urinary incontinence. [a]Statistically significant.

integrity at the vaginal introitus and an increase in mean FSFI scores to normal sexual function range.[18]

TTCRF Efficacy for SD

SD refers to a heterogeneous group of disorders that are characterized by a clinically significant disturbance in a person's ability to respond sexually or to experience sexual pleasure.[19] SD affects approximately 40% of women, and is encountered in women of all age groups.[20] The total FSFI score in the present study showed a statistically significant improvement, with a preprocedure mean of 21.77 [6.87] increasing to 25.79 [6.94] postprocedure. Additionally, 29 participants in our study had total FSFI scores indicative of SD, and 10 of these patients achieved normal-range FSFI scores posttreatment. To our knowledge, a similar finding has not been reported previously. A preliminary TTCRF series that did not utilize the FSFI instrument showed an improvement in orgasmic dysfunction.[7]

The improvement in mean FSFI score in our study is lower than the reported improvement after surgical vaginal rejuvenation in which full-length posterior wall vaginal tightening with perineoplasty was performed. In a study by Desai and Dixit, mean total FSFI score after surgical vaginal rejuvenation increased from 19.5 to 27 (36.48% improvement).[21] However, more robust data are needed to make comparisons among vaginal rejuvenation modalities. Nevertheless, the safety of TTCRF is far superior to that of surgical interventions (risks of such modalities include wound dehiscence, new dyspareunia, and poor vaginal lubrication after surgery[22]) and, as shown in our study, efficacy and patient satisfaction with TTCRF are high. Most importantly, a significant percentage of patients may choose a noninvasive modality because they are unwilling to undergo a surgical procedure with substantial risks.

Our study showed notably statistically significant improvements in all FSFI domains apart from lubrication during sexual activity. Although a small series by Leibaschoff et al found an improvement in vaginal dryness and dyspareunia post-TTCRF treatment,[7] our study

showed a trend towards statistical significance ($P = 0.06$) regarding lubrication during sexual activity.

TTCRF Efficacy for SUI

The present study highlights the efficacy of TTCRF for SUI, as indicated by a significantly decreased posttreatment mean ICIQ-UI-SF score. TCCRF treatment was notably effective across all SUI symptom severity groups. Therefore, the present study may help establish TTCRF as a valid noninvasive treatment option for SUI. One study evaluated the improvement of SUI after TTCRF treatment.[9] However, the study did not use a validated instrument, and components of ICIQ-UI-SF, such as the amount of urine that leaks and the impact of urinary leakage on everyday life, were not included. In a similar way to our study, Leibaschoff et al reported marked improvements in ICIQ-UI-SF scores after TTCRF treatment in a series of 10 patients.[7]

Strengths and Limitations

To our knowledge, this is the largest study to date that uses validated instruments to evaluate the effects of TTCRF treatment on 3 different aspects: genital appearance, sexual function, and SUI. Also, it is the first such study in the Indian population. One strength is that our study performed an evaluation with the widely accepted FSFI questionnaire and statistical analysis on all FSFI domains. A relevant TTCRF study did not utilize validated instruments such as the FSFI and ICIQ.[9] The use of well-established, validated instruments with exact measures of outcomes in this study helps quantify changes in sexual function and SUI which enhances confidence to the results. Also, TTCRF treatment in this study was consistent because the procedure was performed with a new device by the same well-trained healthcare provider.

Despite its strengths, this study has limitations. A bigger sample size would allow meaningful generalization and wider applicability of the results. The inability to recruit more participants is due to the low level of recognition and the fact that a substantial percentage of patients do not seek treatment of vaginal laxity and SD. A study showed that 83% of parous women concerned about vaginal laxity failed to discuss their problem with their gynecologist.[15] Moreover, 40% of women experience psychological distress from SD, but only 14% consult a physician during their lifetime.[23] Despite increasing public awareness, barriers of communication on issues regarding SD and SUI have not been broken.

Another limitation is that our study did not include a control group. A study with a blinded sham control or control group of patients who refused TTCRF may demonstrate more conclusively the usefulness of this modality. Also, the lack of reliable, objective methods to objectively quantify vaginal introital laxity and factors contributing to SD complicates the evaluation. Subjective determinations of outcomes may be biased. Furthermore, the impact of the number of TTCRF sessions on efficacy should be determined. This will help evaluate the cost-effectiveness of the procedure. Lastly, a longer postprocedure follow-up would enable assessment of the longevity of results and temporal changes in sexual function and SUI.

CONCLUSIONS

TTCRF is a noninvasive intervention for the treatment of SD and SUI. It is a safe and effective modality with no short-term adverse effects, and may be considered as a viable alternative to surgical vaginal rejuvenation. It results in significant improvements in female sexual function and yields significant symptom reduction in SUI. Additionally, the treatment can result in an aesthetic improvement of the vulvar area. Further studies with larger sample sizes and randomized control trials are required to obtain a better picture of the efficacy of TTCRF and any long-term adverse effects.

Disclosures

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