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SOCIETY POSITION STATEMENTS

Radiofrequency-Based Devices for Female Genito-Urinary Indications: Position Statements From the European Society of Sexual Medicine

Javier Romero-Otero, PhD,[1,2] Roy Lauterbach, PhD,[3] Antonio Aversa, PhD,[4] Ege Can Serefoglu, MD,[5] Borja García-Gómez, MD,[1] Arie Parnhan, MD,[6] Marta Skrodzka, MD,[7] Michael Krychman, PhD,[8] Yacov Reisman, PhD,[9] Giovanni Corona, PhD,[10] and Lior Lowenstein, PhD[3]

ABSTRACT

Introduction: Radiofrequency (RF)-based treatment has been introduced as an esthetic alternative treatment for various medical indications without the scientific backup of a satisfactory body of evidence. Furthermore, the United States Food and Drug Administration issued a warning regarding the safety of energy-based technologies for indications such as vaginal "rejuvenation," cosmetic vaginal treatment, vaginal conditions related to menopause, and symptoms of urinary incontinence and sexual function on July 30, 2018.

Aim: To perform a thorough review of the existing literature regarding RF-based vaginal devices for the treatment of female genitourinary indications and summarize the evidence available in a few short statements.

Methods: A thorough review of the literature regarding RF treatments for gynecological indications was performed based on several databases. Studies that included at least 15 patients were eligible for analysis.

Main Outcome Measure: Efficacy of RF devices for different genitourinary indications.

Results: Although a high level of heterogeneity of studies poses a serious challenge, the committee reached a decision on several statements related to the use of RF-based devices for genitourinary indications.

Clinical Implications: RF-based vaginal treatments have not been studied thoroughly enough in order to establish decisive recommendations regarding their safety and efficacy.

Strength & Limitations: These position statements have been established by a group of experts. The lack of strong evidence makes it difficult to give decisive recommendations.

Conclusions: Further randomized controlled trials with proper methodology and design are required to establish both benefits and possible harm these treatments may have in both short and long term for all the different indications studied. **Otero JR, Lauterbach R, Aversa A, et al. Radiofrequency-Based Devices for Female Genito-Urinary Indications: Position Statements From the European Society of Sexual Medicine. J Sex Med 2020;17:393–399.**

Key Words: Efficacy; Genitourinary Indications; Radiofrequency; Safety

INTRODUCTION

Radiofrequency (RF) treatments have become increasingly popular during the last several years as alternative nonsurgical tissue remodeling treatment modalities in the field of sexual and gynecological medicine. These techniques have been commercially promoted as effective for various gynecological indications including alleviation of genitourinary syndrome of menopause (GSM) symptoms and treatment of stress urinary incontinence (SUI) and vaginal laxity.[1–3]

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[1]Urology Department, Hospital Universitario 12 de Octubre, Madrid, Spain;

[2]Hospital Universitario HM Montepríncipe, Boadilla del Monte, Madrid, Spain;

[3]Department of Obstetrics and Gynecology, Rambam Health Care Campus, Haifa, Israel;

[4]Department of Experimental and Clinical Medicine, Magna Graecia University of Catanzaro Magna Graecia, Catanzaro, Italy;

[5]Department of Urology, Bahceci Health Group, Istanbul, Turkey;

[6]The Christie NHS Foundation Trust, Manchester, UK;

[7]Andrology Department, University College, London, UK;

[8]Southern California Center for Sexual Health and Survivorship Medicine, CA, USA;

[9]Flare-Health, Amstelveen, the Netherlands;

[10]Endocrinology Unit, Medical Department, Azienda USL, Maggiore-Bellaria Hospital, Bologna, Italy

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When it comes to vaginal laxity treatment, physicians have frequently recommended pelvic floor physical therapy and/or Kegel exercises, with low compliance and conflicting results.[4,5] Topical, nonprescription vaginal tightening products have been suggested as alternative treatments, but these may cause severe disruption of the vaginal ecosystem, resulting in vaginal mucosal erosion, increased vaginal discharge, and an increased rate of infections.[6] Furthermore, both safety and efficacy of these products for the treatment of vaginal laxity have not been established scientifically. Surgery may also be performed to tighten the introitus if alternative treatments fail. Although some studies have demonstrated improvement in sexual function,[7–10] surgery is considered an invasive approach, with potentially serious adverse effects such as suburethral trauma and scar tissue formation that in turn may lead to dispareunia in addition to the need for a postoperative recovery period.[11]

There are currently several minimally invasive, RF-based devices that are being used to treat vaginal laxity, none of which have Food and Drug Administration (FDA) or European Medicines Agency (EMA) clearance or approval for vaginal laxity treatment.

RF is typically deeper than laser in its penetrative capacity within the tissues using a lower frequency and longer wavelengths. RF penetration depth is also dependent on modality, with monopolar systems penetrating most deeply. Unlike unipolar RF systems, other RF systems with bipolar, monopolar, and multipolar configurations (with or without a cooling feature) can deliver energy externally to the vulva as well as to the vaginal mucosal epithelium and lamina propria.[12–14]

Despite the histological rationale for the use of RF for vaginal rejuvenation, the efficacy and safety of this treatment modality have been scarcely assessed. Furthermore, while a few RF-based devices have been previously commercially marketed as possible treatments of vaginal laxity and SUI, the FDA recently issued a warning regarding false marketing claims made by several companies. In addition, the FDA emphasized the need for caution when considering energy-based procedures for the treatment of vaginal rejuvenation and cosmetic procedures.[15] The promotion of these procedures has reached beyond the setting of medical treatment and is currently part of the service catalog introduced by many esthetic treatment centers, with no regard to the level of clinical evidence. Health-care professionals including plastic surgeons, dermatologists, urologists, and others, although underequipped and undertrained, are offering various vaginal and vulvar health procedures.

In light of this situation, the aim of the present study is to provide the European Society for Sexual Medicine (ESSM) position statement on this topic, laying down the current evidence, the possible conflicting issues, and the need for further clarifications.

METHODS

A comprehensive PubMed, Web of Science, Embase, Medline, and Cochrane Library search was conducted based on the following keywords: radiofrequency vaginal application, genitourinary symptoms, genitourinary syndrome of menopause, vaginal laxity, urinary incontinence or sexual dysfunction, and rejuvination. Studies from January 1, 1969, up to July 30, 2018, were included.

Owing to the limited presence of ramdomized clinical trials, studies including a minimum of 15 patients were included in the review. The search was also restricted to full-text articles written in English.

Owing to the limited level of evidence and a lack of good study quality and design, recommendations as per the Oxford 2011 Levels of Evidence criteria were not possible. However, specific statements on each topic are provided, summarizing the ESSM position based on long deliberations among a board of experts comprising clinicians from the ESSM board and scientific council, aiming at taking the first step in developing a coherent evidence base and treatment protocol.

PRECLINICAL RESEARCH

Limited evidence suggests that RF-based applications may affect cellular changes in the connective tissue layer of the vagina (statement 1).

Evidence

Cooling monopolar RF (CMRF) has been demonstrated to induce fibroblast activation and new collagen production in several tissues.[16] However, no data regarding vaginal mucosal epithelium has been published thus far. Based on this study, CMRF-proposed mechanism of action is cellular changes in the connective tissue layer elicited by energy-related heating of the tissue. This results in fibroblastic activation, collagen formation and restoration, and likely innervation and neovascularization. The restorative process occurs over time, possibly up to 90 days, and improves the overall integrity and function of the tissue.

Expert Opinion

Although preliminary results suggest that CMRF can result in positive outcomes in different tissues, the results should be replicated in vaginal tissues.

VULVOVAGINAL SYMPTOMS OF GSM

Currently, there is insufficient evidence to support the use of RF-based vaginal applications for the treatment of GSM (statement 2).

GSM Definition

As per the International Society for the Study of Women's Sexual Health/North American Menopause Society Consensus Conference, GSM is defined as a collection of symptoms and signs in association with a decreased estrogen and additional sex steroid levels causing changes in the labia majora/minora, clitoris,

Table 1. Evidence table-RF treatment

Indication	No. of patients	Follow-up (months)	Observed effects	Energy	References
Genitourinary syndrome of menopause					
Objective evidence of VVA, vaginal dryness, and/or dyspareunia; VAS VVA/GSM	32	12	Improvement in self-perception of atrophy-related symptoms	DQRF	19
VHI	20	3	Improvement in vaginal health scores	RF	18
VAS for dyspareunia					
Sexual function assessment					
FSFI	159	6	Significant improvement in sexual function	RF	10,26,31
FSFI/FSDS-R	164	6	Significant improvement in sexual function, decreased distress	CMRF	11
FSFImv/FSDS-R	24	6	Improvement in sexual function, decreased distress	CMRF	20
FSFI	20	12	Significant improvement in sexual function	CMRF	24
FSDS-R					
SSQ					
SSQ	25	12	Improvement in overall sexual satisfaction	DQRF	19
ICIQ-VS	30	2	Significant improvement noted	RF	23
PFIQ-7					
IIQ-7					
ICIQ-UI-SF					
Photos (also included external treatment)					
External labial treatment					
FSFI; VAS	17	1	Improvement in FSFI Improvement in VAS	RF	25
FSFI	43	12	Overall FSFI sexual function scores increased	RF	28
Vaginal laxity					
FSFI	79	6	Significant improvement in sexual function		10
VLQ	164	6	Statistically significant Improvement	CMRF	11
FSFI mv/FSDS-R	49	6	Self-reported improvement	CMRF	20,31
Vaginal laxity and SSQ/self-reported vaginal tightness					
VLQ	30	12	Self-reported improvement	CMRF	24
VVLQ	27	1	Statistically significant Improvement	RF	22
Combined intravaginal and labial treatment					
VLQ	25	12	Improvement in self-perception of vaginal looseness Statistically nonsignificant tendency to slight deterioration in VLQ, PISQ, and SSQ at 6-9 months	DQRF	19
Labial laxity	17	1	Vulvar improvement in appearance	RF	29
Vulvar appearance photo					
Stress urinary incontinence					
ICIQ-UI-SF	241	12	Statistically significant improvement	RF	22,24,25

(continued)

Table 1. Continued

Indication	No. of patients	Follow-up (months)	Observed effects	Energy	References
Combined intravaginal and labial treatment					
PISQ-12	119	12	Improvement	DQRF	19,25
ICIQ-VS	280	2	Significant improvement	RF	23,25,26,27
PFIQ-7					
ICIQ-UI-SF					
Photographs					
IIQ-7 (also included external treatment)					
UDI-6	390	12	Statistically significant improvement	RF	18,24,25,26,27
ICIQ-UI-SF					
Cough Test					
Urodynamic testing					

CMRF = cooling monopolar radiofrequency; DQRF = Dynamic Quadripolar Radiofrequency; FSDS-R = Female Sexual Distress Scale- Revised; FSFI = Female Sexual Function Index; FSFImv = Female sexual Function index modified version; ICIQ-UI-SF = International Consultation on Incontinence Questionnaire- Urinary Incontinence Short Form; ICIQ-VS = International Consultation on Incontinence Questionnaire- Vaginal Symptom; PFIQ-7 = Pelvic Floor Impact Questionnaire; PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionaire-12; RF = radiofrequency; SSQ = Sexual Satisfaction Questionnaire; UDI-6 = Urogenital Distress Inventory; VAS = visual analogue scales; VHI = Vaginal Health Index; VLQ = vaginal laxity scale; VVLQ = vulvovaginal laxity questionnaire.

vestibule/introitus, vagina, urethra, and urinary bladder.[17] The syndrome may include genital dryness, burning, and irritation sensations; sexual symptoms include lack of lubrication, discomfort or pain, and impaired function; and urinary symptoms include urgency, frequency, dysuria, and recurrent UTIs.[13]

Evidence

The literature on GSM and RF is scant (Table 1). The Vaginal Health Index and a visual analogue scale for dryness and dyspareunia were used, and both measures were noted to be improved at the follow-up visit. Positive histological vaginal changes were noted.[18] The use of dynamic quadripolar RF was in a 12-month efficacy trial, in women with objective evidence of vulvovaginal atrophy, dryness or painful intercourse as the most bothersome symptom, reported rapid self-perception improvement in atrophy-related symptoms.[19]

Expert Opinion

Evidence regarding the use of RF treatment of GSM symptoms is lacking. Although reported positive outcomes in the aforementioned studies, large scale studies are required including comparative trials between RF and the other known medically approved pharmacological treatments for GSM.

VAGINAL LAXITY

Owing to the lack of a uniformly accepted definition of vaginal laxity, we cannot draw any specific recommendations regarding the role of RF-based vaginal application devices in treating this condition (statement 3).

Laxity Definition

Vaginal laxity is commonly considered a patient-reported condition lacking standardized criteria for diagnosis and severity grading. Furthermore, no expert consensus or scientific data exist on the subjective and objective parameters that are to be used for clinical characterization of this condition.

Evidence

Several articles have reported the use of RF in women complaining of symptoms related to vaginal laxity (Table 1). Results from case series demonstrate that RF may be a suitable noninvasive procedure for the treatment of vaginal laxity. Follow-up time varied between 1 and 12 months after RF treatment. All studies reported subjective improvement in either laxity symptoms or sexual function parameters. The longer follow-up studies that examined tolerability and safety found RF treatment for vaginal laxity to be safe and well tolerated.[19,20]

Expert Opinion

While preliminary data are promising, with respect to treatment efficacy of genitopelvic laxity, energy-based devices and accompanying procedures differ substantially with respect to

treatment modality, protocols, study design, patient population, duration of procedure, and reporting efficacy and safety parameters, making the results difficult to interpret and determine consistent effects. Each RF system and its published scientific data should be examined individually. Future larger randomized controlled trial (RCT)/sham-controlled data are necessary.[21] Finally, as stated previously, the lack or general agreement on vaginal laxity definition limits the validity of the available results.

STRESS URINARY INCONTINENCE

Preliminary data suggest that the use of RF-based vaginal applications may improve mild to moderate subjective and objective symptoms of SUI, but the available data do not allow drawing any firm recommendation (statement 4).

Evidence

Several prospective observational studies have assessed the efficacy of RF vaginal treatments for SUI[18,19,22–27] (Table 1). These studies included a follow-up period of between 1 and 12 months. Only a single clinical RCT compared RF treatment with sham treatment.

Between 57 and 78% of patients reported substantial improvement in symptoms after RF treatment. The treatments were reported to be well tolerated with no serious adverse events.

In addition, to the patient-reported outcomes, one RCT reported results from punch biopsies at the urethra-vesicle junction before and after the treatments were performed, showing positive histologic changes.[18]

Expert Opinion

The number of patients included and the available studies is too small to draw final conclusions. Larger patient numbers, longer follow-up, and additional sham-controlled RCTs, in carefully delineated populations, are necessary to make further recommendations, concerning the validity, efficacy, and safety of RF use for this conditions.

SEXUAL HEALTH

Preliminary evidence, derived from secondary end points, suggests that RF-based vaginal applications may mainly improve arousal and orgasm domains. There is urgent need for well-designed studies before recommendation for the use of RF devices for treatment of sexual complains (statement 5).

Evidence

Few studies examined the effect of RF treatment on sexual health (Table 1).[10,11,20,28–31] Most studies reported pretreatment and post-treatment Female Sexual Function Index scores revealed improvement in both the orgasm domain and the arousal domain after treatment. CMRF is the only treatment modality which has been investigated with sham-controlled RCT study, which demonstrated domain changes as measured by the Female Sexual Function Index.[11]

Patients were treated both externally and internally with no difference between the 2 modalities in reported effect and treatment consequences in short (1 month) and long (12 months) follow-up periods.[10,11,20,28–31]

Expert Opinion

Studies are very heterogeneous and include both premenopausal and postmenopausal women who suffer a decrease in sexual health from different factors, thus making it difficult to draw absolute recommendations regarding the population of choice that would best benefit of RF treatment.

SAFETY

Adequate safety profile of RF-based vaginal applications needs to be further assessed through well-designed short- and long-term sham-controlled RCTs (statement 6).

Evidence

The medical device reports based on global clinical commercial experience have not revealed any serious adverse events or safety concerns of use of the device. Overall, the CMRF is safe and well tolerated. RCT safety results[11] report that in both treated and control populations, similar rates of treatment-emergent adverse events were documented. Therefore, the treatment was found to be safe and well tolerated as assessed by adverse events and patient reports.

Mild pain and bleeding (which could be due to the treatment of the entire canal) are the most frequent adverse events reported.

Expert Opinion

While most commercial data support that RF is safe and effective for vaginal treatment, only one trial followed patients prospectively and reported incidence of both sham and treatment intervention arms in a prospective fashion. Further RCT data are necessary to reinforce the long-term safety profile of RF with cooling and those without.

CONCLUSIONS

Clinical research in this setting remains poor, and the impact of the for mentioned histological changes on vaginal signs and symptoms has not been clearly established. In light of this scenario, we have identified a number of unmet needs that require addressing before evidence-based recommendations regarding the use of these treatment modalities for vaginal treatments may be reached. First, a consensus should be reached regarding uniform terminology regarding these interventions. Although the term "rejuvenation" has been adopted by some authors, it appears to be a trademarked commercial term which lacks a standardized definition of signs, symptoms, indications, and treatment criteria.[27] The need for

standardized terms includes commonly claimed conditions that are arguably indications for intervention such as vaginal laxity and relaxation. Second, RCTs are imperative for determining the efficacy of these interventions. In addition, owing to the fact that some of the studies are based on patient-reported outcomes regarding symptom improvement, a dummy blinded control group is essential to prevent biases related to patients' expectations of therapy. Finally, efficacy assessments of vaginal RF-based applications should be based on validated and homogeneous measurement tools which may allow comparisons between studies.

With regard to the safety of RF-based applications, all of the studies consistently reported no serious adverse events and a low rate of mild to moderate adverse events aside mechanical discomfort during interventions. Nevertheless, these findings must be taken cautiously considering the lack of RCTs and long-term follow-up on the effects of these therapies. Furthermore, the FDA has recently issued a warning regarding the limited evidence supporting the use of RF treatment of vulvovaginal atrophy.[15]

The limitations of this statement document may include the search strategy and information sources. As a result, although the search terms included in this review are widely used, the search might have ruled out studies assessing RF efficacy in vaginal conditions that were not reported as "rejuvenation." It is noteworthy, however, that various narrative reviews have been examined for individual studies, which have been added to the evidence pool. Unpublished studies until July 30, 2018, if exist, were not included in this statement document.

In summary, RF-based applications have demonstrated some beneficial effect in short-term efficacy for treatment of symptoms associated with genitourinary complaints. Safety-wise, only a number of studies have reported adverse events, and most studies did not aim to evaluate safety at all, but rather treatment efficacy alone. Thus, the effects of RF-based applications for various vaginal conditions require further confirmation in well-designed RCTs with long-term follow-up periods and emphasis on short- and long-term safety before proper evidence-based recommendations can be reached.

Corresponding Author: Javier Romero-Otero, PhD, Hospital Universitario HM Montepríncipe, Montepríncipe Avenue, 28660, Boadilla del Monte, Madrid, Spain. Tel: +34635476494; Fax: +34917994906; E-mail: jromerootero@hotmail.com

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STATEMENT OF AUTHORSHIP

Category 1

(a) Conception and Design
Javier Romero Otero; Roy Lauterbach; Yacov Reisman; Giovanni Corona; Lior Lowenstein

(b) Acquisition of Data
Javier Romero Otero; Borja García Gómez

(c) Analysis and Interpretation of Data
Javier Romero Otero; Borja García Gómez; Giovanni Corona; Michael Krychman

Category 2

(a) Drafting the Article
Roy Lauterbach; Antonio Aversa; Ege Can Serefoglu; Arie Pamhan

(b) Revising It for Intellectual Content
Marta Skrodzka; Michael Krychman; Lior Lowenstein; Yacov Reisman; Giovanni Corona

Category 3

(a) Final Approval of the Completed Article
Javier Romero Otero; Giovanni Corona; Lior Lowenstein

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