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Non-Ablative Transvaginal Radiofrequency in the Treatment of Stress Urinary Incontinence: Review of the Literature

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Abstract

Background: Urinary incontinence is defined as the involuntary loss of urine, which can affect up to 45% of women after menopause. Radiofrequency is a non-invasive procedure that involves the application of an electromagnetic wave that through heat generation promotes neocollagenesis and neoelastinogenesis in the vaginal epithelium. This energy-based technology has been studied as a potential alternative for the treatment of genitourinary syndrome of menopause and urinary incontinence. **Objective:** To review the recent literature (from 2020 to June 2022) on the use of transvaginal radiofrequency in the treatment of stress urinary incontinence, by searching articles at databases of Capes, PubMed Cochrane and Scielo. **Methods:** The descriptor terms "Urinary Incontinence/therapy" [Majr] AND "Urinary Incontinence, Stress/therapy" [Majr] AND RADIOFREQUENCY-Search Results-PubMed, ["woman" OR "women"] AND ["urinary incontinence" OR "stress urinary incontinence"] AND Radiofrequency were used, with a filter for the period 2020 to 2022. **Conclusion:** The studies evaluated in this review demonstrated significant results of radiofrequency in the resolution or reduction of complaints of women with urinary incontinence, especially stress urinary incontinence, but most of these studies presented a low methodological quality. There is, therefore, a lack of studies with longer follow-ups, evaluation of cost-effectiveness, randomized clinical trials with objective outcomes and the use of validated questionnaires with international acceptance.

Keywords

Radiofrequency, Urinary Incontinence, Genitourinary Syndrome of Menopause, Vaginal Atrophy

1. Introduction

Urinary incontinence (UI) is defined as the involuntary loss of urine. It affects 25% to 45% of women, depending on the population studied, and may lead to physical, emotional and social discomfort [1]. Classification is based on clinical conditions such as stress (SUI), urgency (UUI) and mixed (MUI). SUI is characterized by the involuntary loss of urine due to physical exertion (e.g. sports activities), coughing or sneezing [2]. It occurs when intra-abdominal pressure exceeds urethral pressure. There are two main mechanisms that explain stress urinary loss: 1) urethral hypermobility, which occurs due to loss of support of the pelvic floor by musculature weakening and deficient connective tissue due to reduced synthesis of collagen. Thus, there is insufficient closure of the urethra and bladder neck in response to increased intra-abdominal pressure; 2) intrinsic sphincter deficiency occurs due to loss of muscle tone and urethral mucosa, leading to insufficient closure of the urethra. Intrinsic sphincter deficiency is associated with more significant urinary losses and lower efforts [3].

The main risk factors associated with SUI are age, menopause, obesity, pregnancy and high parity. Treatment varies and depends on the classification of incontinence, the patient's perception of symptoms and clinical condition. Proposed treatments are surgical correction, drug therapy and conservative treatments such as pelvic floor muscle exercises (PFME) and electrostimulation. Currently, there is a search for safe and effective alternative treatments that avoid invasive surgical treatments. Radiofrequency (RF) has been studied as a therapeutic modality for SUI.

RF is a non-invasive procedure that involves the application of an electromagnetic wave that can range from 30 kHz to 50,000 kHz. This wave produces three phenomena on the tissue: vibration, rotation of dipole molecules, and molecular distortion. The conduction of the electric current generates heat that varies from 40˚C to 45˚C and that stimulates the fibroblasts of the treated tissue, leading to the synthesis of collagen and elastin fibers (neocollagenesis and neoelsatinogenesis) [1] [4].

The search for less invasive and safer treatments with fewer side effects and quick application has been increasing rapidly and substantially. Thus, the aim of this review is to compile the literature findings on the effectiveness and safety of RF in the treatment of SUI in menopausal or climacteric women.

2. Methodology

This review searched for articles in Portuguese and English using the PubMed, Cochrane and Scielo databases. The descriptors "Urinary Incontinence/therapy" [Majr] AND "Urinary Incontinence, Stress/therapy" [Majr] AND RADIOFREQUENCY-Search Results-PubMed, ["woman" OR "women"] AND ["urinary incontinence" OR "stress urinary incontinence"] AND Radiofrequency were used, with a filter for the period from 2020 to 2022.

The objective of this study was to perform not a systematic review of the lite-

rature, but to stimulate the review of knowledge generated in this area and to encourage new research on this topic.

All original research (clinical trials, prospective studies, retrospective studies, case series, review articles, systematic reviews, and abstracts) were included in this review process. Eighteen articles were identified, and 10 were selected after evaluation of the title and the abstract. Articles that included evaluations of premenopausal women, author reviews, articles whose primary objective was not UI and articles that evaluated other types of energy in the treatment of UI were excluded.

3. Discussion

3.1. Types of RF and Protocols

The studies diverged regarding the devices, parameters, temperature applied to vaginal tissue, form of application, and number of sessions. RF can be divided into ablative, microablative, and non-ablative, monopolar and bipolar, according to energy dissipation and the action of the electromagnetic wave on the tissue. Non-ablative monopolar RF has been found to be the most widely used [1]. The monopolar form passes from an active electrode conductor handled by the operator to the body, exiting by passive electro (grounding). The advantage is that the energy concentrates in a small and precise area, besides requires handling of only one part. In the bipolar form, both electrodes are located on the operator's handle, so the energy flows directly from one electrode to the other, and this increases the ability to concentrate the energy, generating a thermal effect on the tissue. Bipolar technology allows, through the distance between the two electrodes, greater control and uniformity of RF, but with less penetration and depth of energy [5].

Microablative RF promotes the discharge of fractional electromagnetic energy causing evaporation of the cell and the consequent protein denaturation of the tissue. It uses 0.2 mm long micro-needles that generate microscopic columns of ablative thermal lesions in the epidermis and upper dermis [6] [7].

The monopolar protocols varied according to the papers reviewed [1]. Those that described temperature cited a range of 39˚C to 45˚C in the transvaginal transducer. Others applied energy by dividing the vagina into quadrants and others only to the urethral meatus and anterior wall of the vagina. One study used a temperature of 43˚C with the patient in the lithotomy position for a period of 7 to 10 minutes, applying energy to the entire anterior vaginal wall and vaginal introitus for three sessions at 4-week intervals [8]. Another study used monopolar non-ablative RF with the temperature set at 41˚C while maintaining circular movements for two minutes in the anterior and posterior vaginal walls for five sessions at 7-day intervals [9]. The studies that used bipolar RF applied energy only to the anterior wall of the vagina and vaginal introitus, adjusting the temperature to 43˚C for a period of seven to ten minutes, for two or three sessions with an interval of four weeks [8] [10]. In the non-ablative modality, the

use of topical anesthetic is not necessary. The microablative protocol consists of applying lidocaine to the vaginal walls and introitus and antisepsis. Application of RF under direct vision on the anterior and posterior walls and vaginal introitus, for three sessions at 30-day intervals, recomendation to use barrier cream for two to five days after treatment, and avoid sexual intercourse for 10 days [6] [7].

3.2. Primary Outcomes

The primary outcomes analyzed were based on the response to quality of life questionnaires (ICIQ-SF). Pinheiro *et al.*, in a pilot study with 11 postmenopausal women, showed that among six participants with pre-treatment urinary complaints, at the end of three months of intervention, 5 (83.3%) had shown improvement in the score, with two participants referring complete improvement. However, two participants had a higher score at the end of the treatment; among these, one started with symptoms of urinary loss after the first session [9].

Mezzana *et al.* in a non-controlled retrospective study with 54 women ranging in age from 40 to 71 years (mean, 70.1 years) using bipolar RF grouped the participants into a scale of SUI severity: 7 (13%) mild, 33 (61%) moderate and 14 (26%) severe. At the follow-up visit, 4 months after treatment, participants' symptomatology improved: 35 (65%) had mild SUI, 18 (33%) moderate and 1 (2%) severe [10].

Abdelaziz *et al*, in a retrospective study comparing bipolar vs. monopolar RF treatment in women with different types of UI, evaluated 69 women, with ages ranging from 35 to 79 years, applying the UDI-6 questionnaire. Both RF modalities were effective in improving UI-related quality of life scores, included at 6 months post-treatment. In subgroup analysis by UI types (stress incontinence, urge incontinence, mixed incontinence), there was consistent improvement in all three groups of incontinence with no statistical difference favoring one group over other. A limitation of the study, as a retrospective study, a true power analysis was not performed, statistical analysis was hampered [8].

Slongo *et al.* in a randomized clinical trial with 117 climateric women with SUI, compared microablative RF to pelvic floor muscle exercises (PFME) in three intervention groups: group 1 microablative RF and 3 monthly sessions; group 2 PFME with 12 weekly sessions; and group 3, simultaneous RF and PFME. The participants were evaluated before treatment and 30 days after the final treatment session. Urinary loss was evaluated with the ICIQ-SF questionnaire and a 1-hour pad test to quantify urinary loss. The three groups showed statistically significant improvement in the score of the questionnaire after treatment, and the RF + PFME group presented the most marked and significant reduction in the urinary loss, with reduction from 13.6 ± 3.8 to 8.2 ± 5.2. All groups also presented a change in the classification of urinary loss in the pad test analysis, from important to insignificant. It is worth mentioning the fact that the follow-up loss rate in the PFME group was 33.3%, while in the other groups it

was 7.6% [6].

A systematic review demonstrated that RF treatment, either non-ablative or micro-ablative, had an objective improvement in volume reduction in the pad test. However, it draws attention to the design of the studies, since few are randomized and with control groups or sham procedures. In addition, those studies present small samples—only one study presented a sample with more than 100 participants, and they also present a short follow-up period, since only one presented a 12-month follow-up [1].

3.3. Secondary Outcomes

Non-urinary outcomes include the effects of RF on vaginal epithelium, vaginal dryness and sexual function. In a study of non-ablative RF with 11 patients, improvement of GSM symptoms was reported with regard to sexual function. Following the analysis of the FSFI questionnaire, which was interpreted in terms of total score, assessing the overall quality of women's sexual performance/satisfaction, all participants showed sexual dysfunction in the pre-treatment phase. Nine of them (81.8%) showed improvement in the score, with 3 of these women no longer showing a result consistent with sexual dysfunction. After 3 months of exposure, the benefit was sustained in 72% of the participants. Most participants showed no improvement in pH (63.6%) and three showed a decrease in pH, meaning improvement in vaginal health [9].

Slongo *et al.* when analyzing the symptoms of GSM, observed that the three therapies were successful according to ICIQ-VS. The RF group achieved the most significant improvement in reducing symptom score (−9.3) compared to the RF + PFME group (−4.4) and the PFME group (−3.4). Vaginal dryness, hydration, pH, and vaginal elasticity showed improvement in the groups that used RF, regardless of the association with PFME. The FSFI scores improved significantly in both groups. The RF group improved from 19 to 21.9 and the PFME group improved from 17.9 to 19.6, although no statistical significance was reached between the groups. Dyspareunia, assessed by the Marinoff scale, improved only after RF therapy [9]. This paper described a participant in the microablative RF group who had mild vaginal burning with spontaneous improvement and mild dyspareunia after three months.

The studies that compared non-ablative RF, monopolar or bipolar, there were no records of side effects or secondary infections [8] [9] [10].

In a systematic review, other authors observed a 50.6% reduction in vaginal symptoms, a 72.1% reduction in sexual complaints sustained for two months after treatment [1].

4. Conclusions

UI remains a public health issue, given its high prevalence and impact on the quality of life of affected women, despite having a variety of treatments. Surgical management is an option that may be associated with complications and recurrences,

Table 1. Detailed table of articles included.

Author	Year	Study Design	N° and characteristic of the population	Main exclusion criterion	Follow-up	Intervention	Results
Mezzana *et al.*	2022	Retrospective	54 women between 40 and 71 years old, with normal CMI and SUI		4 mo	Bipolar RF in all patients, at anterior portion of the middle and distal thirds of the vagina, temp between 41˚C - 44˚C, 2 sessions, 4 weeks apart	SUI improvement in volume from "moderate quantitaty" to "none" Reduction in Loss frequency from 2.1 weekly to 0.8×.
Ribeiro *et al.*	2021	Systematic Review	Women with UI treated with any type of RF as intervention	Studies conducted for less than 3 months; animal or in vitro studies; articles whose main objective was to evaluate the use of other types of energy in the treatment of UI; articles targeting vaginal rejuvenation, fecal incontinence, vaginal atrophy and other urinary tract diseases	Studies conducted between 2016 and 2021	Any type of RF, compared to other treatments, including placebo, vaginal estrogen, PFME, or no treatment	studies have shown significant improvement in SUI-related symptoms.
Ahmed Abdelaziz *et al.*	2021	Retrospective	101 women with SUI or MUI	Women with previous surgery for SUI, prolapse greater than stage II, neurological disease, pregnant and nursing women.	6 mo	69 patients treated with bipolar RF, 32 patients with monopolar RF. 3 sessions of 7 - 10 minutes, 4 weeks apart, temp 43˚C	symptom improvement in both monopolar and bipolar RF groups.
Slongo *et al.*	2022	Randomized clinical trial	117 climacteric women aged 45 - 65 years with SUI	Patients with prolapse grade 3 or higher, previous surgery for prolapse, PMFE within the past 12 months, use of vaginal estrogen or HT within the past 6 months.	30 days	Group 1:3 monthly microablativa RF sessions; Group 2: weekly PMFE for 12 weeks; Group 3: both therapies	RF associated with PMFE obtained better results than PMFE of RF alone.
Pinheiro *et al.*	2021	Pilot Study	11 menopausal women with complaint of GSM	HT within previous 6 months, pacemaker carriers, pelvic metal, hemophiliacs, vasodilators or anticoagulants users, degenerative neurological disease, vaginal infection.	3 mo	RF non-ablative at 41˚C. 5 weekly sessions of 4 minutes.	clinical improvement in symptoms of UI, vaginal dryness, dyspareunia, pruritus, burning and sexual dysfunction

even in minimal invasive procedures. Other therapies may be recommended according to the type and intensity of UI, such as PFME, a well-established conservative treatment, but which depends directly on the woman's constant compliance. The increasing search for alternatives options that are effective, safe, and non-invasive, motivates studies and reviews. Recent studies with RF-based treatments and women with UI had showed subjective and objective improvement in symptoms, whether associated or not with PFME (**Table 1**).

The objective evaluation of UI symptoms is important to obtain clear, more accurate and reproducible data. However, among these studies, only one presented results with the evaluation of the pad test. On the other hand, when considering UI as a situation that directly interferes with the quality of life, the use of QoL questionnaires is an adequate tool because they are focused on the women symptoms and how they perceive the improvement.

The weaknesses of the studies presented in this review are the following. The effect of RF on pelvic muscles were also poorly evaluated, just one paper have included pelvic physiotherapy as an intervention arm [6]. Another issue is the small period of follow-up. In our review, only one paper evaluated the participants after 6 months, so the duration of the neocollagenesis and elastinogenesis remains unclear, as well as the clinical response duration [8]. Likewise, when we analyzed the sample of each study, only one cited a number of participants greater than 100 and a sample size estimation [6]. The other studies were retrospective with a convenience sample, pilot studies and others didn't had a control group.

Radiofrequency also has secondary effects, as improved vaginal symptoms, decreased vaginal dryness, dyspareunia and vaginal laxity. Slongo *et al.* showed a significant improvement in dyspareunia symptoms and vaginal dryness, which are the most common symptoms related to GSM and have the greatest impact on quality of life. Other markers of vaginal health also showed improvement. However, despite the reduction in dyspareunia, the overall assessment of sexual function did not show significant improvement [9].

Studies have shown that the use of energy devices are a non-surgical, non-hormonal alternative to the treatment of vaginal symptoms associated with GSM. However, the Food and Drug Administration has not yet changed its position on its safety and applicability [11].

We can conclude that, despite promising availability of short-term data, studies with longer follow-ups, cost-effectiveness evaluation, randomized clinical trials with objective outcomes are still needed.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Abbreviations

FSFI	Female Sexual Function Index
GSM	Genitourinary Syndrome
ICIQ-SF	International Conference on Incontinence Questionnaire Short Form
ICIQ-VS	International Consultation on Incontinence Questionnaire Vaginal Symptoms
PFME	Pelvic Floor Muscle Exercise
RF	Radiofrequency
RF + PFME	Combination of Radiofrequency with Pelvic Floor Muscle Exercise
SUI	Stress Urinary Incontinence
VAS	Visual Analog Scale
VHI	Vaginal Health Index
VMI	Vaginal Maturation Index