







Use of radiofrequency for the treatment of urinary incontinence in women: a systematic review

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INTRODUCTION

Urinary incontinence (UI) is defined as involuntary loss of urine¹, affecting 25–45% of women, depending on the population². Its classification is based on the pathophysiology and clinical condition of the patient, with the most common being urgency (UUI), stress (SUI), and mixed (IUM).

The SUI is characterized by the involuntary loss of urine due to a cough or physical exertion³. The etiology is multifactorial, which may be related to inadequate support and/or weakening of the pelvic floor muscles (PFM), deficiency in the closing mechanism of the urethral meatus, and reduction of collagen synthesis in the pelvic structures^{4,5}. The dysfunction has social and psychological impacts, especially on the well-being of the individual. The main risk factors are age, obesity, menopause, pregnancy, parity, and type of delivery².

The treatment varies and depends on the classification of incontinence, the patients' perception of symptoms, and their daily life habits⁶. According to the literature^{7,8}, surgical techniques, drug therapy, and conservative treatments, such as PFM exercises and electrical stimulation, have been shown to improve UI symptoms. Currently, the search for alternatives and safe treatment methods with high cure rates are the targets of research to avoid surgical interventions. Radiofrequency (RF) therapy has been studied as a possible therapeutic modality for SUI, in addition to its increasing clinical use as a non-surgical and non-pharmacological treatment⁹.

RF is a minimally invasive procedure involving the application of alternating current that creates electrical fields and generates

heat by conversion only in the treatment area. Its frequency can vary from 30 kHz to 300 MHz, and the energy emission mode depends on the number of electrodes, which can be monopolar, bipolar, tripolar, or multipolar¹⁰. RF can be used to treat SUI and MUI as it promotes submucosal collagen denaturation in the bladder neck and throughout the lower urinary tract, causing tissue retraction in these structures. Therefore, urinary symptoms are expected to be minimized as they are related to the pathophysiology of these types of incontinence⁸.

The search for treatment options that are quick to apply, less invasive, safe, and with fewer adverse effects has been growing rapidly, and this therapeutic modality is a good treatment option. Thus, this review highlights the effectiveness and complications of RF therapy for the treatment of UI in women.

METHODS

This systematic review was conducted from June 2020 to May 2021 by searching articles on the Web of Science, Lilacs, Scielo, PubMed, Cochrane, Pedro, Embase, Science Direct, CINAHL, and Scopus platforms. The following descriptors were used by combination: ["Woman" OR "Women"] AND ["Urinary Incontinence" OR "Urge urinary incontinence" OR "Stress Urinary incontinence"] AND ["Radiofrequency" OR "Radio Waves" OR "Pulsed Radiofrequency Treatment" OR "Radiofrequency Ablation" OR "Radiofrequency Therapy"].

The study population was composed of women with UI using any type of RF as an intervention, and there may be

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Conflicts of interest: the authors declare there are no conflicts of interest. Funding: This study was conducted with the support of the Coordination for the Improvement of Higher Education Personnel – Brazil (CAPES) – Financing Code 001.

Received on July 27, 2021. Accepted on August 16, 2021.

divergences between the studies related to cost and time of application. Regarding the comparison of treatments, there were no limitations, and the various treatments included no treatment, placebo, vaginal estrogen, or pelvic floor muscle training (TMAP).

The main outcome was the volume of urinary loss measured using the Pad test. Secondary outcomes were urinary loss measured by voiding diary and impact of UI on quality of life, which were assessed using validated International Continence Society questionnaires. Non-urinary variables, such as alterations related to the vaginal epithelium, vaginal dryness, and sexual function were also considered as secondary outcomes. The systematic review was conducted by two authors to select and evaluate the studies and by another to analyze the differences. The kappa test was performed to analyze the inter-rater agreement.

The following were included: clinical trials regardless of randomization and blinding and prospective studies conducted between 2016 and 2021, without language limitations. The exclusion criteria were as follows: studies with less than 3 months of intervention/follow-up; gray literature; animal and cytological studies; articles whose main objective was to evaluate the use of other types of energy for the treatment of UI; and articles aimed at rejuvenating vaginal, fecal incontinence, vaginal atrophy, and other urinary tract diseases.

The PARSIFAL platform was used to verify duplicate studies and the Mixed Methods Appraisal Tool (MMAT) in the 2011 version to assess the methodological quality of the articles.

RESULTS

A total of 279 articles were identified, of which 70 were duplicates and 181 were excluded after consideration by title and abstract. Six studies (n=247 women) were selected for final analysis (Figure 1). The inter-rater kappa test showed an agreement of 76% ($\kappa=0.76$; $p<0.001$).

Radiofrequency procedure

The studies diverged regarding the devices, parameters, temperature, form of application, and number of sessions. It was observed that the monopolar RF^{11,12} and non-ablative^{13,14} RF were the most used. Two studies^{11,12} used the Viveve system protocol (220 pulses of 90 J/cm² in the vaginal introitus). An article¹³ used Spectra G2 Tonederm®, which applies a high frequency of 0.5 MHz. In the study using the Votiva device¹⁵, the parameters were adjusted according to the conditions of the volunteers. An article¹⁴ used the ThermiVa device without specifying the parameters. Another¹⁶ configured the device at 45 W and 4 MHz to supply power to 64 microneedles, 0.2 mm

in length, allocated in an area of 8 mm × 8 mm. Of the studies that specified the temperature, it ranged between 39–45°C¹³⁻¹⁵.

Two studies^{11,12} divided the treatment area into quadrants of the vaginal opening, with each quadrant having five consecutive pulse passages. One study applied RF to the external urethral meatus¹³, two^{14,15} applied in the vaginal canal and labia majora, and one¹⁷ in the urethral meatus and vaginal wall.

Regarding treatment sessions, two studies^{11,12} used one session for group I and two for group II, with an interval of 6 weeks; one study¹³ described a weekly application for 5 weeks; one study¹⁵ did not specify; and two others^{14,16} performed treatment every 30 days for three months. All studies performed follow-ups, ranging from 1 to 12 months¹¹⁻¹⁶. These and other detailed information from the articles are shown in Table 1.

Primary outcomes

The volume of urinary loss was analyzed using the Pad test as the primary outcome^{11-13,16}. Allan et al.¹¹ showed in their 6-month study that the leakage volumes of the absorbent weight were similar between the randomized groups at the final assessment. The authors reported that 69% of the overall sample achieved a >50% improvement in pad weight. In the second study¹², with a 12-month follow-up, there was a difference between the randomized groups in relation to the weight loss of the pad, which was >50%. The group that received the two interventions showed a 54% improvement. In the group that received only one intervention, the evolution rate was 50%.

The study by Lordelo et al.¹³ evaluated the individual evolution of each patient with a 1-h Pad test for three months. It was observed that 70% of the patients had a reduction in UI, 20% did not complain of additional loss, and 30% showed worsening of the additional loss.

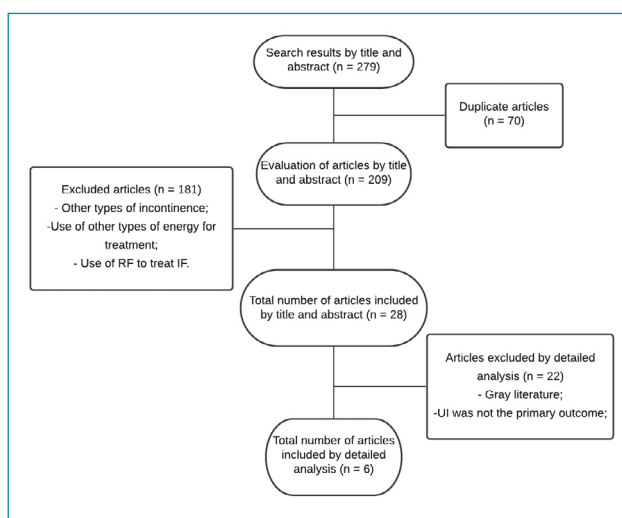


Figure 1. Flowchart of the study inclusion process.

Table 1. Detailed table of articles included (n=6).

Detailed information of included articles					
Authors/ Year/ Country	Study type and methodological quality (MMAT)	N° and characteristic of the population	Main exclusion criterion(a)	Follow-up	Intervention
Allan et al. ¹¹ ; 2019. Canada	Unblinded randomized clinical trial; 75%	35 women participated, aged over 35 years, and diagnosed with mild to moderate SUI	Pregnant women who gave birth or breastfed in the last 6 months; Women with abnormal pelvic examination, with pelvic organ prolapse greater than grade II	6-month follow-up, completed by 29 women	Monopolar radiofrequency; 220 pulses of 90 J/cm; Group 1: 1 session; Group 2: 2 sessions
Allan et al. ¹² ; 2020. Canada	Unblinded randomized clinical trial; 25%	35 women, over 35 years of age, and diagnosed with mild to moderate SUI participated in the study	Pregnant women who gave birth or breastfed in the last 6 months; Women with abnormal pelvic examination, with pelvic organ prolapse greater than II	12-month follow-up, completed by 25 women	Monopolar radiofrequency; 220 pulses of 90 J/cm; Group 1: 1 session; Group 2: 2 sessions
Lordelo et al. ¹³ ; 2017. Brazil	Non-randomized clinical trial; 50%	10 women, between 43 and 66 years old, participated, with SUI being the main complaint reported	Women with organ prolapse; Chronic degenerative neurological diseases; Intrauterine copper device; Pacemaker; Pregnant women; Submitted to previous treatment for SUI	Follow-up, 1, 2, and 3 months after the end of the treatment	Non-ablative radiofrequency, Spectra G2 – Tonederm® in the external urethral meatus; 5 sessions, with weekly frequency; Temperatures ranging from 39–41°C
Caruth et al. ¹⁵ ; 2018. USA.	Prospective clinical trial; 50%	30 women participated, between 40 and 60 who reported weakness in the PFM and vaginal flaccidity	Presence of implanted metallic or electronic device; Current or history of cancer; Pregnancy or lactation; Use of hormone replacement therapy	2-month follow-up after treatment	Bipolar device based on continuous or fractional radiofrequency; Cutting temperature of 43°C; 1 session;
Leibaschoff et al. ¹⁴ ; 2016. Argentina.	Randomized, double-blind, controlled, and descriptive clinical trial; 25%	20 postmenopausal women with symptoms of SUI and vaginal laxity participated in the study	Women who had undergone surgery before; Recurrent presence of urinary tract infection; BMI >35	12 weeks of follow-up	Used ThermiVa®; 3–5 min per area, with T=40–45°C; total ≥30 min; 1 treatment every 30 days for 3 months
Slongo et al. ¹⁶ ; 2021. Brazil.	Randomized clinical trial; 100%	117 women, 45–65 years of age, complaining of SUI or MUJ, with a predominance of stress, participated in the study	Stages III and IV pelvic organ prolapse; History of previous surgery for prolapse or UI; TMAP in the last 12 months; Hormone replacement in the last 6 months	3 months of intervention, no follow-up, only evaluation after one month of intervention	Microablative fractional radiofrequency was configured at 45 W and 4 MHz to power 64 microneedles, 0.2 mm in length, allocated in an area of 8 mm x 8 mm; RF applied monthly for three months; TMAP – 12 weekly sessions, lasting for 60 min

BMI: body mass index; UI: urinary incontinence; SUI: stress urinary incontinence; IUM: mixed urinary incontinence; MAP: pelvic floor muscles; MAF: pelvic floor muscles; RF: radiofrequency; TMAP: pelvic floor muscle training.

In contrast, another study¹⁶ found that the 1-h Pad test had a mean significant decrease of 7.22 g after treatment in all groups ($p < 0.001$) but no differences between them ($p = 0.987$). However, the authors did not justify why the results were similar.

Secondary outcomes

Secondary outcomes were divided into urinary and non-urinary variables. Among the urinary variables, the urinary loss was recorded by the voiding diary^{11,12}, and the impact of UI on quality of life was evaluated using the following questionnaires: Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF)^{14,16}, Incontinence Impact Questionnaire Short Form (IIQ-7)^{11,12,15}, and Urogenital Distress Inventory (UDI-6)^{11,12,14}.

In their first study, Allan et al.¹¹ reported an 80% decrease in leakage episodes in both groups according to the 7-day voiding diary. A sustained improvement was observed for 6 months in relation to the subjective measures, based on the UDI-6, IIQ-7, and ICIQ-UI-SF questionnaires, compared to the initial assessment. In a second study¹², 64% of randomized subjects reported fewer episodes of leakage compared to that at the baseline. They also showed a decrease in UI symptoms and an improvement in quality of life through the UDI-6 and ICIQ-UI-SF questionnaires.

Regarding the use of questionnaires, Slong et al.¹⁶ observed that there was a significant improvement between the groups in the evaluation of the ICIQ-UI-SF, highlighting a better result in the RF group with TMAP, which evolved from 13.6 ± 3.8 – 8.2 ± 5.2 .

In Caruth's study¹⁵, there was an improvement in the impact of UI (62.7%) and quality of life (64.6%) in the 2-month evaluation using the IIQ-7 and ICIQ-UI-SF. Leibaschoff et al.¹⁴ observed a significant difference between the control (17.3 ± 0.78) and active (11.4 ± 0.66) groups in relation to the ICIQ-UI-SF. The UDI-6 also showed an improvement between groups (33.7 ± 12.5 versus 16.2 ± 6.0).

The so-called non-urinary outcomes considered the effects of RF in relation to changes related to the vaginal epithelium, vaginal dryness, and sexual function. However, not all studies evaluated these parameters, but those that covered these variables used the vaginal health index (VHI)^{14,16} and ICIQ Vaginal Symptoms Questionnaire (ICIQ-VS)^{15,16}. Some studies included the impact of pelvic organ prolapse and the impact of anorectal and urinary symptoms on patients' quality of life, using the Pelvic Floor Impact Questionnaire (PFIQ-7)¹⁵.

To assess vaginal and sexual symptoms and quality of life, Leibaschoff et al.¹⁴ showed differences between the control group and the active group. There was a significant improvement in

the active treatment group, from 11.5 ± 0.67 – 19.3 ± 2.01 , relative to VHI.

An author¹⁵ observed an improvement of 50.6% for vaginal symptoms, 72.1% for sexual issues, and 61.2% for pelvic floor impact on reassessment after 2 months of intervention in the ICIQ-VS and PFIQ-7 assessments. Other authors¹⁶ also found improvement in the ICIQ-VS after treatment in all groups, with the greatest improvement in the RF group (-9), followed by the RF+TMAP (-4.4) and TMAP groups (-3.4). The same authors also found improvement in vaginal moisture, fluid volume, vaginal pH, and elasticity only in the RF and RF+TMAP groups but with no difference between them. It was also observed that the epithelial integrity improved in all groups and vaginal dryness improved in the RF group. In terms of VHI, the RF+TMAP (+3.2) and RF (+2.9) groups were superior to the TMAP group (+0.5). Regarding flaccidity, there was no significant difference between the groups.

Adverse effects

No serious or unexpected adverse effects were observed¹¹⁻¹⁶. Lordelo et al.¹³ reported the presence of burning soon after the menstrual period in one patient; however, the physical examination did not show any change. Slongo et al.¹⁶ described that a participant in the RF group had mild vaginal burns with spontaneous improvement and mild dyspareunia after three months.

DISCUSSION

UI is a public health problem, with varied treatments. Of these, surgical treatment is an option, which may be associated with complications and recurrences¹⁷. Other therapies can be recommended according to the nature and intensity of the UI, such as TMAP, which is a conservative treatment option¹⁸. The growing search for safe, non-invasive, and effective alternatives has become increasingly popular, emphasized review studies like this.

RF therapy has been widely used to treat dermatological and gynecological conditions. The microablative fractional-type RF, which is used to improve skin, vaginal, and vulvar mucosal trophism¹⁹, results in promising responses in neocollagenesis and neolastinogenesis^{20,21}, consequently leading to clinical improvement. Thus, it is observed that this therapy provides a less invasive treatment for women with SUI and MUI¹¹⁻¹⁶.

The importance of objective data evaluations is known, and thus, more accurate and coherent results can be obtained with the research. However, only four studies used the 1-h pad test to measure urine volume. Regarding secondary outcomes, two studies^{13,16} evaluated PFM through digital palpation quantified by the modified Oxford scale. Another study¹⁴ performed the

cytological analysis through a biopsy. Other studies^{11,12,15} performed the evaluation using questionnaires.

Importantly, the main objective of this review was to evaluate the application of RF in relation to urine loss and not factors related to intimate esthetics and sexuality. All studies addressed patients diagnosed with SUI, and only one¹⁷ included MUI in the sample.

Only two^{12,16} studies showed a longer period of intervention. It is believed that a short period of intervention may not be able to assess the expected changes in neocollagenesis and neoelastinogenesis^{20,21} and thus may not provide reliable results. Regarding sampling, most studies¹¹⁻¹⁵ recruited a small number of volunteers, and only one had more than 100 patients in the sample¹⁶.

This review had some limitations. The studies that were included had low strength, lack of blinding, short post-intervention follow-up, and lack of clear description of randomization. Despite these limitations, it was observed that RF is an alternative therapy, proving to be effective and safe

for the issues evaluated, which, according to the studies, is an alternative for the conservative management of patients with SUI.

CONCLUSIONS

The studies included in this review showed significant results of RF to resolve or minimize the complaints of women with SUI; however, according to the MMAT, the methodological quality of the studies was low. Therefore, more randomized, controlled, and blinded clinical trials are needed to provide safe therapy.

AUTHORS' CONTRIBUTIONS

MLAS: Investigation, Writing – review & editing. **MAPSS:** Investigation, Writing – review & editing. **FCR:** Formal Analysis, Writing – review & editing. **GPMG:** Supervision, Writing – review & editing. **LSE:** Supervision, Writing – review & editing. **MTABCM:** Supervision, Writing – review & editing.

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