Fisioterapia & Saúde Funcional

Literature Review

Non-ablative radiofrequency in the treatment of pelvic floor dysfunctions: A systematic review

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ABSTRACT

Background: Radiofrequency has been used in clinical practice as a promising resource for pelvic floor disfunctions despite the lack of information about the effectiveness. **Objective:** To analyse the therapeutic responses and safety of non-ablative monopolar RF in pelvic floor disorders. **Methods:** Searches were carried out in the PubMed, Capes, BVS, Scielo, PEDro, Cochrane and PLoS ONE databases. Randomized clinical trials (RCTs) were included with no language or year of publication limitations. The selection was conducted by two independent evaluators and the discordant cases were decided by a third evaluator. Of 438 studies found, 24 met the eligibility criteria and had their full text checked for inclusion. Seven RCTs were included. Data were extracted independently by the two reviewers using standardized forms, bias was assessed using the Physiotherapy Evidence Database (PEDro) scale, and methodological quality was assessed using the Grading of Recommendations Assessment, Development, and Evaluation criteria (GRADE). The sample included 654 participants aged between 26 and 66 years old, diagnosed with sexual dysfunction, vaginal laxity, mixed and stress urinary incontinence and vulvovaginal atrophy. The studies indicate a positive influence of the application of RF in the treatment of the mentioned disorders. Only two studies were reported with side effects. **Conclusions:** RF proved to be effective in the treatment of pelvic floor disorders, especially regarding sexual dysfunction and vulvovaginal atrophy. Adverse effects found are mild to moderate in severity, suggesting that RF therapy does not pose a major health risk. Studies with higher quality and methodological rigor need to be conducted.

Keywords: Radiofrequency Therapy; Pelvic Floor Disorders; Physical Therapy Specialty.

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INTRODUCTION

Pelvic Floor Dysfunction (PFD) is a common disorder in male and female individuals that encompasses several nosological conditions, which can affect various dimensions of their life such as a negative impact on social, psychological, and financial spheres (1). According to Wu et al. (2014), about 25% of women aged over 20 years have some type of PFD, the most frequent being urinary incontinence, with a prevalence of 17%. Furthermore, it is likely the prevalence of 9.4% for anorectal dysfunctions and 2.9% for pelvic organ prolapses. The study indicates to a great tendency towards a significant growth in the prevalence rates of all PFDs as the age of the participants increases (2).

Although the number of studies on PFDs in males is reduced compared to females, Cohen et al. (2016) (3) suggest that the disorders are not uncommon. Men be likely to exhibit PFDs commonly related to sexual, anorectal, urinary and pain aspects. The prevalence of erectile dysfunction is approximately 40% in men in their 40s, with an estimated increase of 10% each decade of life. Another common condition is urinary incontinence, which can involve about 70% of individuals undergoing prostatectomy (4,5).

The treatment PFDs involve surgical, pharmaceutical or conservative approaches. However, conservative treatments are first-line treatments for many PFDs. Amongst the techniques explored in conservative treatment by the physiotherapy professional, there are pelvic floor muscle training (PFMT), manual therapy, electrotermophototherapeutic treatments such as electrical stimulation and photobiomodulation, and other devices such as vaginal dilators, vibrators, and biofeedback (6). Non-ablative radiofrequency (RF) has been highlighted in the urogynecological area due to its innovative system and its various application modalities. The resource is characterized by being a high frequency current that generates heat by conversion, reaching deep into the tissue layers, promoting tissue oxygenation, nutrition and vasodilation. Furthermore, it constitutes a non-invasive modality capable of stimulating changes in collagen reorganization, leading to neocollagenesis and neoelastogenesis through the generation of thermal energy and, consequently, the activation of fibroblasts (7).

RF has been used in clinical practice as a promising resource for certain gynecological disorders, including the relief of symptoms of genitourinary menopause syndrome and the treatment of stress urinary incontinence, anal incontinence and vaginal laxity, despite the lack of information and robustness in the quality of the studies found about the effectiveness of RF on others PDFs (8,9). Therefore, the present study purposes to investigate the therapeutic responses and safety of non-ablative monopolar RF, to identify the effectiveness of the resource in the treatment of men and women diagnosed with PFDs.

METHODS

The present study is a systematic literature review, registered in the Prospective International Registration of Systematic Reviews (PROSPERO), with registration number CRD42021278826. The digital bibliographic search of articles and scientific publications was carried out in an advanced way in the PubMed, Capes, BVS, Scielo, PEDro, Cochrane and PLoS ONE databases between July and August 2021. Guided by the recommendations of the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA, 2009) (10). We aimed to verify the safety and therapeutic response of non-ablative monopolar RF in the treatment of men and women diagnosed with PFDs. This question could generate descriptors referring to the population (individuals diagnosed with pelvic floor disorders), intervention (radiofrequency therapy), comparison (individuals undergoing sham/placebo therapy or any other treatment) and outcomes (improvement of symptoms related to pelvic floor disorders) (PICO).

The keywords used in this search strategy, according to the Medical Subjects Headings (MeSH), were “radiofrequency therapy”, “radiofrequency treatment”, “pelvic floor disorders”, “pelvic floor dysfunctions”, “urinary incontinence”, “fecal incontinence”, “sexual dysfunctions, psychological”, “penile induration”, “intestinal constipation”, “menopausal genitourinary syndrome”, “vaginal laxity”, “menopausal vulvo-vaginal atrophy”, “vulvo-vaginal atrophy”, “pelvic pain”, “pelvic organ prolapse”, “vaginismus”, “dyspareunia”, “vulvodynia”, “interstitial, cystitis”, “anorgasmia”, “orgasmic disorder” and “dysorgasmia”. Boolean operators “AND”/“OR” were used. The filters "clinical trial", "article" and "case report" were applied to certify a specific search. When the databases did not offer filters, these were utilized manually during the subsequent selection steps. Searches were carried out in all languages, with no restrictions regarding publication dates.

Study selection and data extraction

Each of the articles found were checked for duplication, and those that were duplicates were excluded, following the initial database search. Only randomized clinical trials (RCTs) were selected. Which included adult individuals diagnosed with PFDs, who received at least one application of monopolar non-ablative RF alone or associated with techniques such as PFMT and Kegel exercises, compared to techniques such as placebo/sham treatment, Kegel exercises and/or PFMT. Studies using ablative RF, bipolar RF and/or surgical or invasive procedures, performed in animals, children, pregnant women, patients with neurological disorders and/or studies with other designs were excluded.

The searches were carried out by two independent evaluators who, based on the results obtained in the databases, selected the studies that approached the theme of interest based on the titles and abstracts. When these sections did not provide satisfactory information for selection, the full text was checked. In the subsequent step, the same reviewers independently assessed the studies in full and carried out the selection according to the eligibility criteria. Discordant cases were evaluated and decided by a third evaluator. Authors, year of publication, characteristics of participants, characteristics of groups and type of intervention, outcomes, and results of variables of interest were obtained independently by the two reviewers, using a standardized form adapted for the study. Data analysis was carried out descriptively, followed by categorization of the extracted data into thematic groups based on the variables of interest.

Assessment of risk of bias in studies

The risk of bias of the included RCTs was analysed using the Physiotherapy Evidence Database (PEDro) (11) scale provided by the PEDro digital platform. Publications with scores greater than six were considered at lower risk of bias, while studies with scores equal to or less than six were considered at high risk of bias. The analysis was performed independently by two evaluators and disagreements were resolved by discussion and consensus with a third evaluator.

Assessment of the quality and strength of recommendation of studies

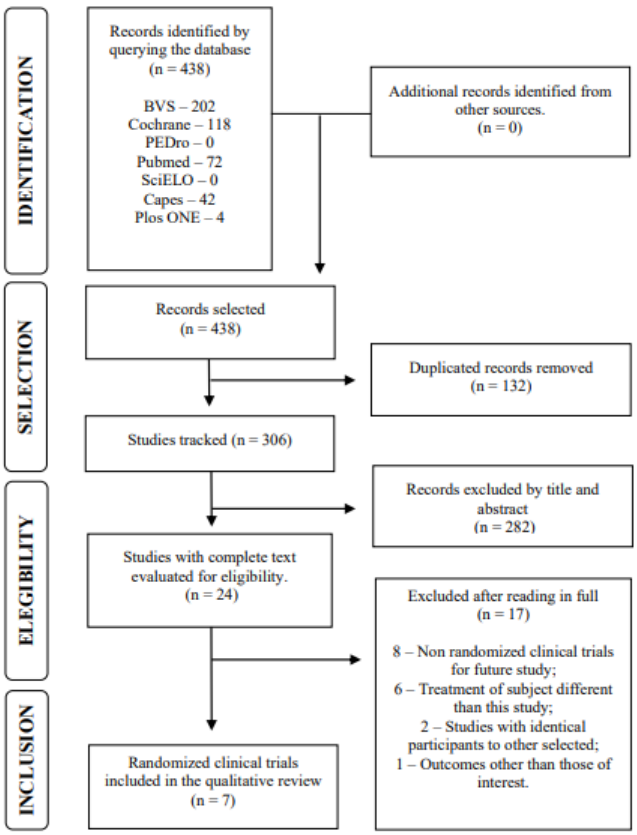
To assess the quality and strength of evidence recommendation, the GRADE system was used, proposed by the Grades of Recommendation, Assessment, Development and Evaluation group. Which assesses the level of scientific evidence, inconsistencies, imprecision, among others (12). All articles were maintained in the present research, regardless of the level of evidence.

RESULTS

Inclusion of studies: flowchart

Figure 1 depicts the PRISMA flow chart shows the study selection process. Four hundred and thirty-eight studies were found. From those, after excluding duplicates and title and abstract, 24 full-text publications were evaluated for eligibility. After reading them in full, 17 publications were excluded, on the other hand, including, seven references that presented the object of analysis.

Figure 1. Study selection flowchart. PRISMA, 2009 (10).



Characteristics of the included studies and participants

The selected studies were published between 2016 and 2020 in Brazil, the United States, Russia, Colombia and Iran, all of which were RCTs. The sample included only women, aged between 26 and 66 years, with a clinical diagnosis of sexual dysfunction, vaginal laxity, mixed urinary incontinence, stress urinary incontinence and vulvovaginal atrophy. The sample size ranged from 13 and 240, totalizing 654 participants.

Assessment of risk of bias in studies

With regard to the assessment of the risk of bias in the selected studies based on the PEDro Scale analysis, the evaluated RCTs obtained a total score between five and eight, considering a maximum score of 10 points. The criteria that most presented methodological flaws were: the blinding parameters of the professionals who administered the therapy and of the evaluators of the final outcomes. In contrast, the criteria comprising homogeneity between groups, statistical comparison between intervention and control groups, and the presence of precision and variability measures, were met by all included studies. Of the seven studies analysed, three had a score equal to or less than six, while the other four had a score between seven and eight, as shown in Frame 1.

Frame 1. Assessment of the risk of bias of the included studies - PEDro Scale. (11) Legend: Green symbols: "yes"; Symbols in red: "no".

	Evaluation Criteria											
	1	2	3	4	5	6	7	8	9	10	11	**Total Score**
DOBROKHOTOVA[13] et al. 2020	●	●	●	●	●	●	●	●	●	●	●	6/10
EFTEKHAR[14] et al. 2019	●	●	●	●	●	●	●	●	●	●	●	5/10
KRYCHMAN[15] et al. 2018	●	●	●	●	●	●	●	●	●	●	●	5/10
BRASIL[16] 2017	●	●	●	●	●	●	●	●	●	●	●	8/10
KRYCHMAN[17] et al. 2017	●	●	●	●	●	●	●	●	●	●	●	7/10
LEIBASCHOFF[18] et al. 2016	●	●	●	●	●	●	●	●	●	●	●	7/10
LORDÊLO[19] et al. 2016	●	●	●	●	●	●	●	●	●	●	●	8/10

Assessment of the quality and recommendation strength of the evidence

As for the assessment of the quality and recommendation strength of the evidence by the GRADE System (12), four articles were classified as moderate, representing 57% of the studies, one was classified as low (14%) and two studies were classified as very low in the level of quality and strength of recommendation of evidence (29%).

Application protocols

The evaluated RCTs established the application of RF in the extra and intravaginal region, at temperatures ranging from 38°C to 45°C, for approximately two to five minutes in each application zone. The number of sessions varied between one and eight with intervals of one to six weeks between them, as described in Table 1. The collection of information about the time of application and the interval between RF sessions was hampered, in view of the lack of description of these aspects in certain selected studies.

Table 1. Characteristics of RF application protocols of the included studies.

Author/Year/Country	Area of application	Temperature	Time of application	Number of sessions	Interval
DOBROKHOTOVA[13] et al. 2020/Russia	Extravaginal (vaginal introitus, labia majora and groin) and intravaginal	Control based on the patient's subjective sensations	3 - 4 minutes in each zone	3	1 week
EFTEKHAR[14] et al. 2019/Iran	Extravaginal and intravaginal	38 - 44°C	Not informed	3	4 to 6 weeks
KRYCHMAN[15] et al. 2018/USA	Extravaginal (vaginal introitus, avoiding the urethra)	Cryogenic cooling	Not informed	1	Not informed
BRASIL[16] 2017/Brazil	Extravaginal (external urethral meatus)	39 - 41°C	2 minutes in each zone	5	1 week
KRYCHMAN[17] et al. 2017/USA	Extravaginal (vaginal introitus, avoiding the urethra)	Cryogenic cooling	Not informed	1	Not informed
LEIBASCHOFF[18] et al. 2016/Colombia	Extravaginal (labia major and minor) and intravaginal	40 - 45°C	3 – 5 minutes in each zone	3	1 month
LORDÊLO[19] et al. 2016/Brazil	Extravaginal (labia major)	39 - 41°C	2 minutes in each zone	8	1 week

Evaluation of outcomes

Information about the instruments used to assess the outcomes of the RCTs included in the present study are described in Table 2. The Oxford Scale, the Perineometer and the PERFECT examination scheme and the Vaginal Health Index scheme were used for the purpose of physical assessment and the functionality of the pelvic muscle floor. The Visual Analog Scale was used to measure pain intensity. The Female Sexual Function Index (FSFI) and Pelvic Organ Prolapse/Incontinence Sexual Questionnaire (PISQ-12) and The Female Sexual Distress Scale – Revised (FSDS-R) were used to evaluate sexual function. In order to qualifies the symptoms and evaluating the frequency, severity and impact on quality of life of urinary incontinence, the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF), Inventory of Urogenital Distress (UDI-6), King's Health Questionnaire (KHQ), Pad test, and voiding diary were applied. The Vaginal Laxity Questionnaire (VLQ) was applied to assess vaginal laxity and the Pelvic Organ Prolapse – Quantification (POP-Q) scale to quantify pelvic organ prolapse.

Table 2. Instruments for evaluating the outcomes of the included studies.

	FSFI	POP-Q	PISQ-12	VHI	VLQ	PERFECT	UDI-6	KHQ	Pad Test	ICIQ-UI SF	VAS	FSDS-R	OE	PM	VD	BVM
DOBROKHOTOVA[13] et al. 2020/Russia	●	●												●		●
EFTEKHAR[14] et al. 2019/Iran			●	●						●	●					
KRYCHMAN[15] et al. 2018/USA	●				●											
BRASIL[16] 2017/Brazil	●					●		●	●				●		●	
KRYCHMAN[17] et al. 2017/USA	●				●							●				
LEIBASCHOFF[18] et al. 2016/Colombia				●			●			●	●					●
LORDÊLO[19] et al. 2016/Brazil	●															

Legend: FSFI: Female Sexual Function Index; POP-Q: Pelvic Organ Prolapse - Quantification; PISQ-12: Pelvic Organ Prolapse/Incontinence Sexual Questionnaire; VHI: Vaginal Health Index; VLQ: Vaginal Laxity questionnaire; PERFECT: The PERFECT Scheme for pelvic floor assessment; UDI-6: Urogenital Distress Inventory; KHQ: King's Health Questionnaire; ICIQ-UI SF: International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form; VAS: Visual Analog Scale; FSDS-R: The Female Sexual Distress Scale - Revised; OE: Oxford Scale; PM: Perineometer; VD: Voiding Diary; BVM: Biopsy of The Vaginal Muscosa.

Analyse of outcomes

Table 3 depicts the objectives, group characteristics, main results and conclusions and adverse effects of treatment of the RCTs included.

Table 3. Purpose, groups, main results, and adverse effects of the included studies.

Author	Purpose	Groups	Results	Adverse Effects	PEDro Scale
DOBROKHOTOVA et al. 2020/Russia[13]	To evaluate the efficacy and safety of postpartum RF therapy in patients with vaginal laxity and other early manifestations of PFDs.	**IG:** RF + Kegel exercises n = 30 **CG:** Kegel exercises n = 14	In the long-term postpartum, there was a significant improvement in the anatomical and functional status of the vulvovaginal region and perineum for IG ($p < 0.05$). There was relief of the initial manifestations of PFDs (incomplete bladder emptying, urinary dribbling, foreign body sensation in the vagina, vaginal dryness, vaginal flatus and dyspareunia) in IG patients compared to CG ($p < 0.05$).	No complaints	6
EFTEKHAR et al. 2019/Iran[14]	To compare the effect of RF and Laser on mixed urinary incontinence and vulvovaginal atrophy in menopausal Iranian women.	**IG1:** RF n = 80 **IG2:** Laser n = 80 **CG:** placebo n = 80	RF group showed a significant decrease in mixed urinary incontinence symptoms, compared to the placebo group ($p = 0.003$). An improvement in symptoms of vulvovaginal atrophy was observed in the RF group compared to the placebo (-15,813, $p < 0.001$). A significant difference in Vaginal Health Index scores was found in the RF group compared to the placebo (10,425, $p < 0.001$), indicating improved vaginal health in women who received a treatment with RF.	Not informed.	5
KRYCHMAN et al. 2018/USA[15]	Evaluate the impact of RF treatment on the vaginal introitus in each of the FSFI domains.	**IG:** RF n = 73 **CG:** Sham (≤1J/cm2) n = 35	RG group scored higher than subjects from the sham treatment group in all FSFI domains six months after the intervention. An analysis of the change in covariance from baseline analyzes showed significant medians in favor of active treatment for the criteria “sexual arousal” ($p = 0.004$), “lubrication” ($p = 0.04$) and “orgasm” ($p = 0.007$). In addition, RF treatment was associated with clinically important and statistically significant improvements for the criteria of “sexual desire” [Odds ratio (OR) = 3.01 (1.11-8.17)], “arousal” [OR = 2 .73 (1.06 -7.04)] and “orgasm” [OR = 2.58 (1.08-6.18)].	Vaginal discharge, mild uterine cramps, and feeling hot during or after the procedure. Details found in Krychman et al. [17]	5

BRASIL 2017/Brazil[16]	To verify the clinical response, quality of life, sexual function and satisfaction with non-ablative RF treatment for stress urinary incontinece in women.	**IG:** RF + PFMT n = 13 **CG:** Sham (equipment switched off and glycerin heated) + PFMT n = 9	RF+PFMT group showed a greater reduction in urinary loss compared to the sham group, with a mean difference between groups of -9.54 (95% CI -18.8 to -0.3). The RF+PFMT showed an increase in strength, endurance, resistance and fast of the PERFECT scheme ($p<0.05$ for all), while the sham group only showed an increase in endurance ($p=0.027$). The RF+PFMT suffered a positive impact from the KHQ in the domain of physical limitation and severity of symptoms ($p<0.05$). 11 (88%) women in the IG reported being very satisfied compared to only four (44%) in the CG. There was no change in sexual function.	No complaints.	8
KRYCHMAN et al. 2017/USA[17]	To determine the efficacy and safety of RF treatmentr for women diagnosed with vaginal laxaty.	**IG:** RF n = 108 **CG:** Sham (≤1J/cm2) n = 56	The % of women in the RF group reporting no laxity at six months after treatment was 43.5 (47 of 108) compared with 19.6 (11 of 56) in the sham group (P = .002 by X^2 test). At one and three months after treatment, the % of individuals without vaginal laxity were higher for RF group, but without significance up to six months after treatment. Differences in FSFI and FSDS-R total scores (RF vs sham) were 1.8 (P = .031) and -2.42 (P .056), respectively, in favor of RF group.	15 adverse effects in RF group: vaginal discharge, feeling of warmth, vulvovaginal discomfort, vaginal infection, paresthesia, coital bleeding, inadequate lubrication, uterine spasm, vulvovaginal edema, skin itching. 07 adverse effects in the sham group: feeling of heating, inflammation, genital itching, metrorrhagia, uterine spasm, vaginal discharge.	7
LEIBASCHOFF et al. 2016/Colombia[18]	To evaluate the effects of RF treatment in the treatment of women suffering from menopause-related stress urinary incontinence and to assess treatment-associated vaginal histological changes.	**IG:** RF n = 10 **CG:** Sham (equipment switched off) n = 10	RF was associated with a significant ($p < 0.01$) improvement in ICIQ-SF and UDI-6 scores. Seven of 10 patients (70%) had a negative cough stress test after the treatment protocol. Improvements were maintained through the 12th week of follow-up. The results were supported by the positive histological changes observed in the vagina of study participants. RF treatment was well tolerated with no complications reported in the study patients.	Not informed.	7
LORDÊLO et al. 2016/Brazil[19]	To evaluate clinical responses to non-ablative RF in terms of its cosmetic outcome on female external genitalia and its effect on sexual function.	**IG:** RF n = 21 **CG:** Sham (equipment switched off and glycerin heated) n = 22	Women randomized to IG had an overall FSFI score 3.51 higher after RF treatment, while the CG had an overall score just 0.1 point higher ($p = 0.003$). For the RF group domains of satisfaction and excitement showed the best results after treatment ($p = 0.002$ and $p = 0.005$, respectively). Satisfaction response rates were 76% and 27% for RF and Sham groups, respectively ($p = 0.001$).	No complaints.	8

Legend: CG: Control Group; FSDS-R: The Female Sexual Distress Scale – Revised;FSFI: Female Sexual Function Index; ICIQ-UI SF: International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form; IG: Intervention Group; KHQ: King's Health Questionnaire; PERFECT: The PERFECT Scheme for pelvic floor assessment; PFDs: Pelvic Floor Disfunction; PFMT: Pelvic Floor Muscle Training; RF: Radiofrequency; UDI-6: Inventory of Urogenital Distress; VHI: Vaginal Health Index.

DISCUSSION

The present systematic review was designed to evaluate the effectiveness of non-ablative monopolar RF treatment and its safety in the treatment of PFDs. Regarding the results obtained by the included RCTs, there was consensus on the effectiveness of RF in the treatment of women diagnosed with vaginal laxity, sexual disfunction, mixed urinary incontinence, stress urinary incontinence, vulvovaginal atrophy, and certain symptoms of other PFDs. Regarding the safety of the resource,

two studies reported the presence of vaginal discharge after the application of RF, in addition to the fact that, in one of them, there was a report of mild cramps and a feeling of heat in the region during or after the procedure. In three of the selected studies, there were no complaints about adverse effects and in two of them no information about this aspect was mentioned. Based on this information, it can be stated that, in general, RF treatment is a safe and completely tolerable resource.

The most recurrent adverse effect found was vaginal discharge. Both studies (15,17) that pointed to this finding used the RF technique with cryogen cooling. The relationship of these adverse effects with the treatment was determined based on the evaluation of the investigator. In the publication of data from the United States Food and Drug Administration (FDA), regarding the Manufacturer and User Facility Device Experience, the VIVEVE equipment, used in both studies, appears as the third (representing 14%) in the list of side effect complaints reported by patients to the FDA, when compared to other energy-based vaginal devices on the North American market (20). It is remarkable that patients in the sham group also reported side effects like those in the intervention group, as well as others not presented by the intervention group, and vice versa. Since there is no discussion about the correlation between the application of RF and vaginal discharge in the literature. We hypothesize that it may be related to changes in local blood flow, since the technique initially cools the mucosa, leading to reduced vascularity and sensitivity. Then warms up from the application of RF, increasing local vascularization, and ends with a new cooling. There are studies that demonstrate that even 120 minutes after cryostimulation withdrawal, blood flow remains reduced when compared to the initial one (22). In addition, there were reports of a feeling of heat in the region during or after the procedure. This can be justified because, although the technique promises cooling of the treated region to the participants, the action is limited to the superficial tissue, and may generate some sensation of heat by warming the deep layers (21).

The adverse effects identified in the use of RF with cryogen cooling range from mild to moderate in severity. While it seems safe for clinical applications, a cautious approach is advisable, and further research is required to ascertain all potential effects. Interestingly, a participant in the control group reported the same adverse effect. Additionally, the description of mild cramps or uterine spasms during the procedure is difficult to interpret, since the reach of the RF head and, therefore, of the emitted current, is restricted to the vaginal introitus, an anatomical point relatively distant from the uterus. It is noteworthy that just one patient discontinued the treatment due to the adverse effect presented (15). The other studies did not show adverse effects. After all, it is necessary that more studies investigate, in the short and long term, the repercussions of the technique, to draw a risk profile and understand its real severity for the health of the individual.

Regarding temperature, the RF application protocol in the included RCTs remained between 38° and 45°C. Apart from three publications that did not perform the measurement. According to the literature, the temperature range between 39°C and 45°C is clinically effective when the objective is to stimulate neocollagenesis and neoelastogenesis in the treated tissue (18,23). The parameters provided by the RCTs included recommend a time range of application of RF in each treatment zone for two to five minutes, with an interval of one to six weeks between sessions. In the same sense, studies demonstrate that the application of RF for two minutes can cause histological changes, leading to neocollagenesis (24,25). Based on an experimental study with animals, Carvalho et al. (2017) detected the presence of neocollagenesis for up to 15 days after application of RF and neoelastogenesis for at least 21 days. Based on this principle, the authors suggest an interval between applications of at least seven days (25).

All the RCTs included in this review demonstrated a risk of bias for at least two of the criteria evaluated by the PEDRo scale, and the blinding criteria of the therapists who applied the technique and the evaluators were those who showed greater criticality. It is noteworthy that the criterion that contemplates the blinding of therapists represents a previous bias and inherent to studies that use the application of RF. On the other hand, the criterion regarding blinding the evaluators, fulfilled by only one of the studies, indicates an important fragility of the included studies, since it is a blinding of great relevance and fully feasible to be carried out. These weaknesses call into vogue the relevance of blinding to a scientific study with greater reliability and lower risk of bias. Only three studies achieved scores equal to or less than six, while four had scores equal to or higher than seven points. These scores suggest that the RCTs included have, mostly, a lower risk of bias.

Regarding the evaluation of the level of strength and evidence of the studies by the GRADE System, no studies with a high level of evidence were found, especially due to the blinding criteria of the evaluators and therapists who administered the therapy. The studies that demonstrated moderate confidence in the estimated effect refer to RCTs with mild limitations. Which future studies may modify the confidence in the estimated effect and may even modify the present estimate. The main findings of studies with moderate confidence found positive effects from the application of RF, especially in domains related to sexual satisfaction and vaginal trophism.

Sexual function was the most recurrent outcome investigated by the RCTs included in the present study and was unanimously assessed using the FSFI questionnaire. The results of the studies found an increase in the overall FSFI score immediately after the conclusion of the treatment (16,19), and up to six months after the intervention (15,17), being higher for sexual arousal, lubrication, and orgasm. A single-arm prospective study that evaluated 30 premenopausal women similarly found significant improvement over six months in FSFI scores in five of the six domains, except for desire (26). These findings revalidate the physiological effects predicted from the application of the RF, since the resource raises the local temperature, generating increased tissue vascularization and, consequently, lubrication.19 Moreover, the aesthetic benefits from neocollagenesis and neoelastogenesis can reflect on the perception of body image and self-esteem, directly influencing in sexual arousal and, finally, in orgasm (19,23,26).

Three of the included studies analysed the efficacy of RFT in the vaginal laxity outcome from the Vaginal Laxity Questionnaire and physical examinations. The whole studies obtained satisfactory results, and in two of them the results were maintained for at least six months after completion of treatment. In the study produced by Krychman et al. (2018), it was possible to establish a correlation between the decrease in vaginal laity and the directly proportional increase in sexual satisfaction after RF treatment (15). Similarly, a pilot study conducted by Milheiser et al. (2010) supported these findings, obtaining a significant decrease in vaginal laxity in 87% of the participants treated, accompanied by the report of increased sexual satisfaction (27).

In this review, three of the included studies evaluated the efficacy of RF in the treatment of women with urinary incontinence. In the studies of Brasil (2017) and Leibaschoff et al. (2016) the dysfunction evaluated was stress urinary incontinence, and in the first study the application of RF was performed in the external urethral tract, while in the second, in the vaginal canal (16,18). In the study by Eftekhar et al. (2019), the dysfunction evaluated was the mixed urinary incontinence, but data on the RF application zone were not available (14). Although there was no consensus on the treatment protocols used, the entire studies suggested statistically significant improvement in stress urinary incontinence and mixed urinary incontinence symptoms. These findings are supported by the principle that, at the urethral level, the application of RF can increase the diameter of submucous blood vessels, aiding in the recovery of periurethral muscles, besides stimulating neocollagenesis local neoelastogenesis, which are related to the urethral closure mechanism (18).

Eftekhar et al. (2019) evaluated the application of extra and intracavitary RF in a group of 78 postmenopausal women diagnosed with vulvovaginal atrophy, mixed urinary incontinence and other menopausal Vaginal/Genitourinary Symptoms, comparing with laser therapy and placebo groups (14). In the RF treatment group there was a significant improvement in vulvovaginal athrophy, and symptomatology related to menopausal Vaginal/Genitourinary Symptoms, when compared to the placebo group. From biopsies of the vaginal mucosa, Leibaschoff et al. (2016) suggest that the application of RF in the vaginal and urogenital epithelium can cause neocollagenesis, which seems to be closely related to vaginal trophism (18). Since systemic replacement is not always accompanied by a significant improvement in symptoms of vaginal dryness, especially in women with contraindications to the use of hormones or who do not wish to use them. Non-ablative RF can be an alternative treatment option, producing a positive impact on vaginal health and sexual function (28).

Although no RCT with the male population was included in the present review. The scientific literature suggests that there is a therapeutic response in the application of RF in the treatment of men diagnosed with PFDs. A study carried out by Sodré et al. (2019) with a male sample diagnosed with UI after radical prostatectomy, found, through the evaluation of the pad test, a significant decrease in urinary loss and bladder filling symptoms after treatment with RF endoanal non-ablative (29). The study reported that four participants handled pain while the endoanal electrode was inserted and that this sensation ceased during treatment. The application of endoanal RF in men is based on the fact that the region offers lower impedance when compared to the extracavitary application. Furthermore, the conduction of electromagnetic waves in the anal mucosa region may be greater, due to its high vascularity, low resistance to current flow and proximity to the bladder neck and the internal and external urethral sphincters (29,30).

It should be mentioned the variability between applied protocols, making it difficult to compare RCTs, as a limitation of the present study. In addition, the non-blinding of the evaluators and the heterogeneity between the risk of bias scores were limiting factors that compromised the reliability of this review. Although the RCTs mostly showed a lower risk of bias, it is worth noting that the study with the largest sample size had the highest risk of bias (five points), while the one with the smallest sample size had the lowest risk of bias (eight points). These were also some of the setbacks faced by the European Society of Sexual Medicine (31) which, despite the positive effects found, did not reach a full conclusion on the use of RF in vaginal treatments to determine decisive recommendations on its safety and efficacy (31).

CONCLUSION

The studies included in this review suggested positive results from the application of non-ablative monopolar RF in the treatment of women diagnosed with pelvic floor disfunctions. Especially regarding sexual disfunction and vulvovaginal atrophy, which were outcomes evaluated by studies with a moderate level of recommendation. Furthermore, the adverse effects found in the application of RF with cryogen cooling are of mild to moderate severity. Using it in clinical settings appears to be safe, but caution must be taken in clinical practice. However, determining its legitimate efficacy and safety is difficult, given the limitations of the study. Therefore, studies with higher quality and methodological rigor are needed, to satisfy the knowledge gaps about the efficacy and safety of the application of RF in certain pelvic floor disfunction and target populations.

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