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ORIGINAL ARTICLE

New concept for treating urinary incontinence after radical prostatectomy with radiofrequency: phase 1 clinical trial

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Abstract

To describe the clinical response and side effects of radiofrequency treatment in patients with urinary incontinence after radical prostatectomy. This is a phase 1 clinical trial with 10 men up to 65 years of age who had urinary incontinence after radical prostatectomy, post void residual volume < 50 ml verified by ultrasonography, pad test ≥ 1 g, and PSA < 0.2 ng/ml. pad test and self-administered questionnaires were used to assess clinical response. Scales were used to measure treatment satisfaction and improvement in symptoms. Participants underwent five sessions of 2 min of non-ablative endoanal radiofrequency (41 °C). The evaluated co-primary endpoints were urinary incontinence volume and urinary symptoms, analyzed by the Wilcoxon nonparametric test; residual volume, and self-reports to assess safety. The participants' mean age was 57.5 ± 4.9. The initial pad test score was 6.5 g (1.7–50.0) with a final score of 2.0 g (0.0–9.0) ($p < 0.01$). Ultrasonography showed no alteration of residual volume. A decrease of urinary loss was found in nine patients, three of them showed a complete resolution of urinary loss. A decrease in irritative micturition symptoms was found as well, but no improvement in the quality of life was shown. Regarding treatment satisfaction, two patients were neutral, six satisfied, and two very satisfied. Limitations included pain while the endoanal electrode was inserted. Four patients indicated pain during treatment, but overall results were positive. The reduction of urinary loss and irritative micturition symptoms increased patients' satisfaction scores, without improving their perception of quality of life.

Keywords Prostatectomy · Radiofrequency · Urinary incontinence

Introduction

Radical prostatectomy (RP) is the most effective surgical treatment method for prostate cancer and is associated with some comorbidities, among them, urinary incontinence (UI). Studies show that the main cause of UI after radical prostatectomy (UIRP) is sphincter failure [1].

According to the International Continence Society, UI is the complaint of any involuntary urine leakage [2]. Incontinence usually has a negative impact on the individual's quality of life (QoL) [3] and its prevalence ranges from 2.5 to 90% [4].

The first-line treatment for UIRP is pelvic floor muscle (PFM) training [5]. Studies show that PFM training increases the continence rate to 90%, 7 months after surgery [1]. However, treatment with conservative techniques such as PFM training usually takes a long time, and incontinence may be persistent despite treatment [2–5].

There is a constant search for techniques that could help improve UIRP therapy, such as non-ablative radiofrequency (RF), a method that already has been tested in women with stress urinary incontinence (SUI) [6] and with vaginal laxity [7, 8]. However, no RF studies have been found to treat UIRP. The RF is a diathermic technique leading to ion mobilization, and, due to the controlled increase in temperature, there is a physiological response: the production of collagen [9, 10]. Therefore, RF could be applied in the male external urethral meatus (EUM), the same way as the technique is applied to women. However, the distance between EUM and bladder

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neck is greater in men. Intraurethral application, in turn, is limited in men because of urethral injury risk. This phase I clinical study presents clinical results and adverse effects of an innovative non-ablative endoanal RF for the treatment of UIRP, and whether there is a short-term change in QoL after the application of the technique.

Materials and methods

This is a pilot study that precedes a randomized clinical trial with men with clinical complaints of UI after radical prostatectomy. The accessible population was made up of men who were referred to the Pelvic Floor reference center (CAAP), in the city of Salvador, Bahia. The survey took place at CAAP from January to June 2017.

The participants of the study were duly informed about the objectives of the study, the possible risks and benefits. All of them signed the free, prior, and informed consent form as soon as they accepted to participate in the study, thus in compliance with the Declaration of Helsinki and as approved by the Research Ethics Committee of the Bahian School of Medicine and Public Health. It was registered at ClinicalTrials.gov (NTR: 03048799) as a randomized clinical trial preceded by a pilot study.

Inclusion criteria were men up to 65 years of age, with the complaint of UIRP and who presented an acceptable post void residual volume (PVRV) < 50 ml verified by USG [11], 1-h pad test ≥ 1 g [12], and PSA < 0.2 ng/ml [13]. Excluded were patients with less than 45 postoperative days, patients with chronic degenerative neurological diseases, implantable cardioverter defibrillators, and iatrogenic metals in the pelvic region.

The data was collected by means of a basic questionnaire with sociodemographic information (age, marital status, education, occupation, among others) and clinical data (information on RP, urinary symptoms, self-reported diagnosis of hemorrhoid, and previous pathologies such as diabetes and hypertension, among others), and a 3-day voiding diary was requested. The questionnaire survey was conducted individually in a separate room, and other questionnaires were self-administered.

The International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) was used to assess the impact of UI on the QoL and to qualify the patients' urinary loss. The overall score varied from 0 to 21 points, and it was considered that the higher the score, the greater the negative impact was on the QoL [14].

The International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ-OAB) aims to assess the symptoms of bladder filling. The score ranges from 0 to 16 points, with greater values indicating increased symptom severity [15].

At the first meeting, the muscular strength (MS) of the pelvic floor was evaluated by anal unidigital introduction. The instruction was given to perform a maximum contraction of the perianal musculature and to repeat the contraction three times, of which the best result was registered. The strength of the contractions was assessed using the modified Oxford Grading Scale: Degree 0 = no noticeable contraction, 1 = flicker/trace contraction, 2 = contraction with low intensity, with gravity eliminated, 3 = moderate contraction against gravity, characterized by compression and small elevation of the posterior wall in the cranial direction, 4 = satisfactory contraction, with compression and elevation of the posterior wall towards the pubic symphysis, and 5 = strong contraction, firm compression of the examiner's finger with positive movement towards the pubic symphysis [16].

The transabdominal USG study was carried out to assess the presence of post void residual volume (PVRV) before and after treatment. The ultrasonography evaluation was carried out by a specialist in diagnostic imaging with 12 years of experience, using a TOSHIBA Xario® ultrasound device (manufacturing year 2013). A PVRV of less than 50 ml was considered acceptable [11]. During the USG assessment, the distance of the radiofrequency electrode, used for the endoanal treatment, to the surgical anastomosis scar, was also checked to ensure that the electromagnetic wave was applied at or close to the desired location during the radiofrequency therapy treatment.

The USG examination was performed with images obtained by a 5.0-MHz convex transducer, covered by a plastic film and room-temperature echographic water-soluble gel. The patient was in a left lateral decubitus position with semi-flexed lower limbs allowing transperineal echographic assessment. The patient was instructed to empty the bladder before the procedure. The active radiofrequency probe was properly covered by a condom (Blowtex®), lubricated with room temperature echographic water-soluble gel, and then positioned in the anal canal (Fig. 1).

Soon after, the 1-h pad test was done to quantify the urinary loss [2]. The volunteer was considered incontinent with a pad weight ≥ 1 g [12].

After the evaluation, the ten volunteers continued with the non-ablative endoanal RF treatment. Five RF sessions took place, with a 7-day interval. The number of sessions and interval duration were based on a pilot study, in which non-ablative RF was applied to the EUM [6]. The treated participants were placed in a lateral decubitus position. The session had an average duration of 10 min.

The RF treatment protocol was used in the form of capacitive electric transfer, monopolar configuration, with a CAPENERGY MEDICAL® device, model C500, manufacturing year 2016.

The RF equipment had two electrodes. An active one was inserted in the endoanal region after the patient was requested

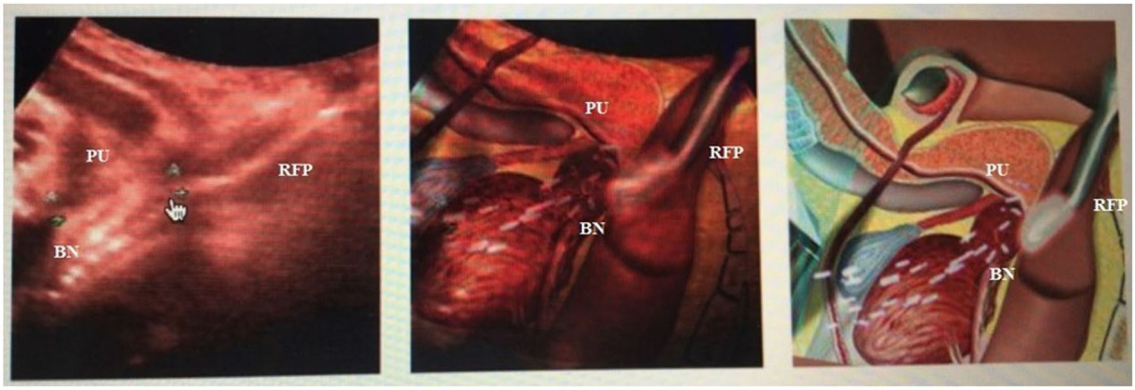

Fig. 1 Ultrasound image of an active radiofrequency probe into the anal canal. Echographic image superimposed on the drawing of a male pelvis. The figure shows bladder neck (BN), proximal urethra (PU), and distal rectum which contains a linear hyperechogenic image with a wider and curved edge that represents the active radiofrequency probe (REP). The calipers show the measurements of the linear distance between the surface of the probe's edge and the bladder neck (2.1 mm)

to perform a Valsalva maneuver. Non-lubricated condoms of the brand Blowtex®, and a water-soluble gel of the brand Carbogel® for the emission of electromagnetic waves, were used. The active electrode was equipped with a temperature sensor at its tip, and based on the information it provided, the generator emitted the waves to reach the temperature set. The other, dispersive electrode, was attached to the patient's hip and functioned as a return electrode (Fig. 2). The frequency used was 1.0 MHz, with power ranging from 3 to 4 kilojoules (kJ) and temperature set at 41 °C. Upon reaching the desired temperature, the generator maintained the temperature stable for 2 min, with the therapist slowly performing half-circle motions (Fig. 3).

To evaluate the clinical response at the end of the treatment, a re-evaluation took place, a week after the last session. The patients were re-evaluated through the pad test and ICIQ-SF and ICIQ-OAB questionnaires. In addition, a new 3-day voiding diary was requested. In order to receive a subjective evaluation from the participants regarding the used treatment technique, a 5-point Likert Scale was used: 1—very dissatisfied, 2—dissatisfied, 3—neutral, 4—satisfied, 5—very satisfied. Improvement of symptoms were evaluated after the five sessions, using the modified VAS for UI, where a score of 0 means maximum improvement and a score of 10 represents no improvement.

In order to verify safety by the presence of adverse effects or interruption of treatment, the participants were asked to indicate any of signs and symptoms (pain, hematochezia or hematuria, burning, dysuria, and altered urinary flow) during and after the treatment technique. They were also asked whether the treatment or session was interrupted. Another method of verifying adverse effects was the reassessment

Fig. 2 Dispersive (plate) and active electrode of the radiofrequency device. (Source: Image provided by the responsible researcher)

Fig. 3 RF treatment through half-circle motion. (Source: Image provided by the responsible researcher)

of the presence of PVRV through transabdominal USG, performed 7 days after conclusion of the treatment.

To prepare the database and descriptive analysis, the Statistical Package for Social Sciences (SPSS), version 14.0 for Windows, was used. The normality of variables was verified using the Kolmogorov-Smirnov test. The results were presented in tables. The categorical variables were expressed in absolute and percentage values—*n* (%). Continuous variables with normal distribution were expressed as mean and standard deviation (± SD), and those with asymmetric distribution, as median and interquartile range (IQR). The comparison analysis of the initial and final pad test, USG, and questionnaires was performed using the Wilcoxon nonparametric test. The comparison analysis of the 3-day voiding diary (initial–final) was done by using the paired *t*-test, considering a level of significance of 5% ($p < 0.05$).

Results

The sample consisted of 10 individuals with UI after radical prostatectomy, all of them over 50 years of age. The sociodemographic characteristics are presented in Table 1. About the clinical aspects, six patients reported loss of urine in squirts. Seven reported urinary loss to occur mainly during coughing and sneezing, two reported to have hemorrhoid, and three claimed to be sexually active. The median level of muscle strength was 3.0 (3.0–3.2) (Table 2).

Table 1 Sociodemographic characteristics of 10 patients with UIRP (Salvador, BA)

Variables	
Age, mean ± SD	57.5 ± 4.5
Education, *n* (%)	
High school completed	05 (50.0)
Elementary school completed	01 (10.0)
Elementary school not completed	03 (30.0)
Analfabetic	01 (10.0)
Civil status, *n* (%)	
Married	05 (50.0)
Single	04 (40.0)
Divorced	01 (10.0)
Religion, *n* (%)	
Catholic	08 (80.0)
Non-religious	02 (20.0)
Race (ancestry), *n* (%)	
Multiracial ancestry	06 (60.0)
African ancestry	04 (40.0)

SD standard deviation, *n* number of participants

Table 2 Clinical characteristics of 10 patients with UIRP (Salvador, BA)

Variables	
Muscle strength, median (IQR)	3.0 (3.0–3.2)
Type of loss[¥], *n* (%)	
Squirts	06 (66.7)
Drops	02 (22.2)
Squirts and drops	01 (11.1)
Moment of loss[¥], *n* (%)	
While coughing	07 (77.8)
While sneezing	07 (77.8)
Changing body posture	06 (66.7)
While walking	04 (44.4)
While laughing	04 (44.4)
Obese, *n* (%)	01 (10.0)
Diabetes mellitus, *n* (%)	01 (10.0)
Systemic arterial hypertension, *n* (%)	03 (30.0)
Hemorrhoid, *n* (%)	02 (20.0)
Constipation, *n* (%)	01 (10.0)
Sexually active, *n* (%)	03 (30.0)

IQR interquartile range, *n* number of participants

[¥] Total of nine participants

Of the 10 participants, seven had surgery more than 6 months before the study took place. The assessment of urinary loss through the pad test showed an initial median of 6.5 g (1.7–50.0) and final of 2.0 g (0.0–9.0), which is statistically significant ($p < 0.01$). The delta of the pad test showed a reduction of 5 g (1.0–33.0). Thus, at the end of the five radiofrequency sessions, nine patients showed a decrease in pad test scores and three showed a complete resolution of urinary loss (Table 3).

The evaluation of the impact of UI on the QoL, based on the ICIQ-SF questionnaire, showed a pre-treatment median of 15.5 (12.7–17.2) and a posttreatment value of 13.5 (8.2–15.2). The decrease in the score after treatment was not significant ($p = 0.10$). The score of the ICIQ-SF is based on the results of the median frequency of urine loss which was 4 (3–4.25), before the treatment, corresponding to "many times per day", and improved to 2.5 (2–4) corresponding to "twice or three times per week" after the treatment. The median amount of urine patients indicated to lose before the treatment was 3 (2–4), corresponding to "a moderate volume," after treatment patients indicated it had improved to 2 (2–4.5), corresponding to "a small volume". The median impact of the urine loss the patients indicated to experience in their daily life was 9.5 (5–10) before the treatment, a score that improved to 8 (4.25–9.25), after treatment.

The evaluation of symptoms of bladder filling, based on the ICIQ-OAB questionnaire, showed a significant decrease of the score ($p = 0.01$), with a median value prior to treatment

Table 3 Results and overview of surgical time, ICIQ-SF, ICIQ-OAB, 1-h pad test, VAS, and satisfaction level of 10 patients with UIRP, before and after 05 radiofrequency treatment sessions (Salvador, BA)

Patient	Time in months	ICIQ-SF Before	ICIQ-SF After	ICIQ-OAB Before	ICIQ-OAB After	Initial pad test (g)	Final pad test (g)	VAS after	Satisfaction
01	36	18	14	5	5	01	00	5	Neutral
02	10	15	16	8	6	50	18	2	Satisfied
03	04	12	9	4	5	01	00	1	Satisfied
04	07	13	13	6	3	07	06	4	Satisfied
05	25	17	13	11	10	06	00	2	Very satisfied
06	84	10	15	4	0	02	02	4	Satisfied
07	48	16	15	6	0	06	02	6	Very satisfied
08	12	20	19	11	9	50	22	5	Neutral
09	03	16	5	5	1	50	01	1	Satisfied
10	03	14	6	7	6	38	01	4	Satisfied

ICIQ-SF International Consultation on Incontinence Questionnaire - Short Form, *ICIQ-OAB* International Consultation on Incontinence Questionnaire Overactive Bladder, *g* grams, *VAS* visual analogue scale

of 6.0 (4.7–8.7), which was reduced to 5.0 (0.7–6.7). The clinical response criteria for treatment can be found in Table 3, where the results of each patient are detailed.

In relation to the evolution of urinary symptoms measured by the modified VAS for UI, a decrease in the score from 7.0 (5.0–8.5) to 4.0 (1.7–5.0) was observed, being statistically significant ($p = 0.01$). During the evaluation of the degree of satisfaction, two participants indicated to be neutral, six indicated to be satisfied, and two indicated to be very satisfied.

To quantify PVRV, according to the transabdominal USG, no change was observed on the PVRV when compared to the USG transabdominal before, 0.0 (0.0–1.7), and after the treatment, 0.0 (0.0–0.2) ($p = 0.34$); in other words, no patient had residue after treatment. The only side effect observed was pain. Four patients indicated to feel pain while the anal electrode was inserted; no pain was reported during the treatment. No other sign or symptom was reported or detected, as there was no interruption of treatment or session.

Discussion

This original phase I clinical study presents a reduction in urinary loss, checked by the 1-h pad test. Following the results of the pad test, nine participants showed a decrease and three of them had a complete response to treatment. It is important to note that the postoperative period of seven of these ten volunteers exceeded a period of 6 months. This suggests a positive clinical response of the treatment technique and not a spontaneous resolution that is expected in the first months after the surgical procedure [17].

It is known that the heat generated by RF promotes an increase of angiogenesis [18] and local vascularization, besides stimulating the collagen and elastin matrix tissue, resulting in immediate changes in the helical structure of collagen, with consequent denaturation and remodeling of its fibers. In addition, it also leads to a micro inflammatory stimulation of the fibroblasts, causing the formation of new collagen proteins (neocolagenogenesis) and elastin (neoelastogenesis) [19]. Besides that, there is also the possibility of increasing the smooth sphincter thickness [20]. Therefore, it is hypothesized that urethral closure can be promoted by the aforementioned, resulting in a significant reduction of the urinary loss. To reach the desired anatomical area to deliver RF, the endoanal access seems to be the preferred route, since the monopolar device reaches deeper tissues [9, 21].

The presence of scar tissue changes the tissue impedance, increasing its resistance. It is assumed that RF electromagnetic waves are likely to reach the proximal urethra when applied through the anal canal, even with the presence of fibrosis. Pinheiro et al. showed that monopolar RF application on hypertrophic scar after burns, with a temperature similar to that of the current study, may also stimulate the remodeling of collagen fibers by denaturation of proteins under thermal effects [22]. It can also be hypothesized that the conduction of electromagnetic waves in the mucosal region is greater, due to its high vascularization and low resistance to current flow.

The temperature of 41 °C and an application time of 2 min were based on a study that applied RF in women, which proved to be a safe and effective technique [6].

Knowing that PFM training is a conservative technique for the treatment of UIRP and knowing that the degree of muscular strength of the pelvic floor (PF) can influence the clinical response of the patients treated [4, 16], we sought to identify a median of grade 3 (moderate contraction) [16]. Thus, it is hypothesized that the reduction, as shown by the pad test, occurred due to the RF treatment and not due to the muscular

strength of the PF, as the participants had a moderate contraction before the treatment and the volunteers did not have any PF muscle training.

The postoperative time was heterogeneous. Seven participants had surgery more than 6 months before the study, and three of them had a complete response. This suggests that the reduction in pad test scores was due to the effect of the RF technique and not to a spontaneous response. However, it is mandatory to have a control group to ratify this hypothesis.

The present study focused on evaluating bladder filling symptoms by using the ICIQ-OAB questionnaire and found a significant decrease of the score. This reduction might be explained by improvement of bladder neck closure by RF energy, thus not allowing the urine to enter the proximal urethra, which would trigger the urination reflex and, consequently, urinary urgency [23].

In terms of the quality of life, no significant changes have been found through ICIQ-SF. A possible explanation of the result is that for men it might not be enough to have a decrease in the frequency and in the amount of urine loss. The urine loss and the need to use pads itself have a huge negative impact on their quality of life, and a small improvement might not be enough to change the situation significantly. This could probably be seen in the small decrease on the impact they said the loss had in their daily lives after the treatment, going from 9.5 (5–10) to 8 (4.25–9.25). Another aspect is that people are better capable to evaluate QoL over a longer period of time; therefore, it is advised to have follow-up evaluations.

When assessing satisfaction, six patients reported to be satisfied with the treatment and two indicated to be very satisfied. This was supported by a significant decrease in VAS, from 7.0 to 4.0 points. These findings demonstrate the importance of having a subjective evaluation after treatment, as the term "satisfaction" expresses a degree of congruence between the expectations of patients regarding the technique performed and their perception about the care received [24]. Therefore, a randomized clinical trial with a sample number calculated to better evaluate this question is also justified.

Non-ablative RF has shown to be a treatment with low adverse effect. None of the volunteers reported symptoms during or after treatment. When comparing the adverse effects with other forms of non-ablative treatment, such as treatment of intravaginal for genital laxity [7, 8] and external urethral meatus for female SUI [6], the results are similar to the endoanal treatment technique in men.

An important factor to be considered is that the participants did not show an alteration in the PVRV with the non-ablative endoanal RF treatment technique. This suggests that the RF treatment did not cause a short-term infravesical obstruction. It is worth mentioning that RF presents a maximum peak of collagen production up to 7 days after application of the technique [9]. For this reason, in this study, the USG was carried out 1 week after the last session. However, it is important to follow up with these participants to understand the long-term response, which is already being done by the research group.

Four participants felt pain while the endoanal electrode was inserted. This feeling ceased during the treatment. It might be related to participant's apprehension and difficulty to relax while the electrode was inserted through the anal canal. Other reasons for discomfort were that the electrode has a diameter of 2 cm and the anal canal also has defective physiological mechanisms [25].

Conclusion

The non-ablative endoanal RF treatment showed a decrease in urinary loss and bladder filling symptoms in men with UIRP. In addition, they have indicated to be satisfied or very satisfied with the innovative treatment, despite no significant change in their quality of life was indicated. Pain during the insertion of the electrode in the anus was the only adverse effect found. These results are encouraging, but it is necessary to conduct a randomized clinical trial study to demonstrate the effectiveness of the technique in this specific target group.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed were in accordance with the ethical standards of the institutional and/or national research committee and with the Declaration of Helsinki of 1964 and its later amendments or comparable ethical standards. The study was approved by the Research Ethics Committee of the Bahiana School of Medicine and Public Health (CAAE: 58851916.9.0000.5544) and registered at ClinicalTrials.gov (NTR: 03048799) as a randomized clinical trial preceded by a pilot study.

Informed consent Informed consent was obtained from the patients included in the study.

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