Received: 14 May 2021 | Revised: 2 July 2021 | Accepted: 2 July 2021

DOI: 10.1002/nau.24748

CLINICAL ARTICLE

Neurourology and Urodynamics | ICS | SUFU | WILEY

Transvaginal radiofrequency energy for the treatment of urinary stress incontinence: A comparison of monopolar and bipolar technologies in both pre- and post-menopausal patients

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Abstract

Aim: A study to compare the effect of two different radio frequency energy models (mono polar and bipolar) for the treatment of urinary stress incontinence.

Methods: Retrospective chart review, which was conducted at 2 sites, 69 patients received treatment with a bipolar radiofrequency device. Out of those 69 patients, 13 patients received bipolar in conjugation with CO_2 laser treatment, while 32 patients received monopolar frequency. The study protocol normally consists of three sessions of treatment. Each session was four weeks apart with a whole 6-month duration follow-up. Results were evaluated by urogenital distress inventory (UDI)-6 questionnaire before and after treatment.

Results: The bipolar group improved UDI-6 scores across time more so than did the monopolar group with some evidence suggesting that the bipolar radiofrequency treatment was more effective compared to the monopolar radiofrequency. Three months after treatment, the bipolar group UDI-6 values were lower than those of the monopolar group. Six months after treatment, the UDI-6 scores increased in both groups, suggesting decrease efficacy with time however, the bipolar group's UDI-6 scores were consistently lower than the monopolar group's scores.

Conclusion: This study shows benefit of both monopolar and bipolar radiofrequency device in patients with stress urinary incontinence and mixed UI, with bipolar RF more efficacious than monopolar RF. More randomized prospective studies are needed to confirm these findings.

KEYWORDS
radiofrequency, stress incontinence

1 | INTRODUCTION

It is well known that the etiology of stress urinary incontinence (SUI) is multifactorial. Weak support of the anterior vaginal wall and a weak sphincter muscle which can no longer maintain a water tight seal as well as decrease collagen in urethral walls have all be cited as contributing factors.[1–3]

The impact of SUI on women's life quality regarding everyday activities is significant. Incontinence also has a great psychological impact on women causing social isolation, obesity, and depression.[4] Women reporting UI also complain of sexual dysfunctions in a significantly higher number than women with no incontinence[5]

Over the past decades there has been an evolution in the treatment of SUI with emphasis on more conservative office-based treatment. Conservative treatment have historically included education, behavior modification and pessary[6] and physical therapy.[7] Most of these treatment are temporary and may not improve symptoms in some patients.[8] Bulking agent have been used with some success compared to more conservative therapy,[9] but commonly lack long term durability thus requiring repeated injections.[10] Synthetic mid urethral slings remain the most efficacious treatment of SUI,[11] however perceived complications rate and adverse events makes this options less appealing for many women.[12]

The recent ban of mesh in UK, New Zealand, and Australia[13–15] and the negative image that patient have on mesh promotes continued efforts to identify alternative options for treating SUI.

Less invasive and office-based treatments are becoming more popular due to safety and minimal invasiveness. These include office-based procedures with energy sources, such as laser[16,17] and radiofrequency (RF) devices.[18] Radiofrequency energy is known to improve healing of tissue by neo callogenesis through activation of fibroblasts and retraction of existing collagen.[19]

Radiofrequency energy can be delivered by either a monopolar or a bipolar platform. In monopolar the energy passes from the active electrode through a handpiece managed by the operator to the body and exits through a grounding pad (passive electrode). The advantage of monopolar RF is the ability to concentrate energy in a small area, cutting tissue with small coagulation zone and simplicity of a hand piece. In a bipolar design both electrodes are applied to the treated tissue. It limits its ability to concentrate the RF energy but allows utilization of all the RF energy for tissue heating. This method is more effective when volume heating is required. Bipolar technology has more versatility to control RF penetration and depth which is a function of the distance between the two electrodes. It also allows for more uniform energy deposition into the tissue and more accurate control of tissue heating and better control of penetration depth.[18]

Since the early 2000s, RF energy has been delivered by a variety of methods to the vagina, urethra, and periurethral tissue to address genitourinary complaints. More recently multiple RF delivery systems have been advocated to treat stress incontinence with very minimal outcome data to date.[20–23] To date there are no studies that compares the clinical outcomes of patients treated with monopolar versus bipolar radiofrequency devices. Also fractional CO_2 laser therapy of the vaginal canal has been shown to be effective for genitourinary syndrome of medicine, but is also advocated by some clinicians as a treatment for urinary incontinence. No previous study has looked at the input of combined CO_2 laser treatment in conjugation with RF treatment.

The objective of this study was to retrospectively compare outcomes of a monopolar RF platform to bipolar RF platform in women with stress and mixed urinary incontinence with or without genitourinary syndrome of medicine and to determine whether RF therapy can improve urinary function in women who have been treated with a fractional CO_2 laser for genitourinary syndrome of medicine.

2 | MATERIALS AND METHODS

This was a IRB approved retrospective chart review which was conducted at two sites. Between January 2017 to December 2019 all women who opted for conservative treatment of their stress or mixed urinary incontinence with a radiofrequency device were reviewed. All procedures were performed by the respective investigator at each site.

The inclusion criteria required females to be 18 years or older with a main complaint of SUI, which was demonstrated using a cough test. Patients with stress predominant mixed urinary incontinence were also included in the study. Exclusion criteria included pregnant women, breastfeeding women, patients with pelvic prolapse greater than stage II, patients with a history of previous surgery for SUI, patients with neurological disease affecting the bladder, and patients with previous history of having radiofrequency treatment for SUI.

Patients were categorized according to the type of radiofrequency energy received. Patients received either mono polar or bipolar radiofrequency treatment according to what device was available during that period in which patients presented with the symptoms. One hundred and one patients were eligible for enrollment in this study. Sixty-nine patients received treatment with a

TABLE 1 Showing device description of different radiofrequency devices used

Device	Votiva FormaV by Inmode	TermiVA by TermiGen	Tempsure Vitalia by Cynosure
Technology	Bi-polar RF	Monopolar RF	Monopolar RF
RF frequency	1 MHz	460 kHz	4 MHz
Maximal RF power	65 W	50 W	300 W
Temperature control	RF power is adjusted to maintain required temperature	RF power is adjusted to maintain required temperature	RF power is adjusted to maintain required temperature
Impedance monitoring	Yes	Yes	Yes

Abbreviation: RF, radiofrequency.

bipolar radiofrequency device. Out of those 69 patients, thirteen patients received bipolar in conjugation with CO_2 laser treatment at the same session to address genitourinary syndrome of menopause, while 32 patients received monopolar. Each center had different monopolar radiofrequency device, so two devices were tested in this study.

Three different radiofrequency platforms were used in the two sites, this included Votiva FormaV (InMode), ThermiVA (ThermiAesthetics), and Tempsure Vitalia (Cynosure). Table 1 shows the different devices used during the procedures.

2.1 | Procedure description

The therapy consisted of three treatment sessions approximately 4 weeks apart. A standardized technique was utilized in which the intravaginal tip was applied to the mucosal surface of the vaginal introitus and the entire anterior vaginal wall. The tip of the introducer was moved back and forth remaining in direct contact with the tissue for a period of 7–10 min at a temperature of 43°C.

The main goal of this study was to determine if there was a meaningful difference in urogenital distress inventory (UDI)-6 scores with the bipolar versus monopolar treatment from baseline to three months after treatment and baseline to 6 months after treatment. Two sets of between- and within-subjects analysis of variance (ANOVA) tests were computed, the first being for the baseline to 3-month mark, and the second being for the baseline to 6-month mark. Also referred to as a mixed model ANOVA, this procedure allows researchers the ability to determine if there is a difference between group (in this case, the bipolar and monopolar treatments) and a difference by time (also in this case, the baseline to the 3- and 6-month mark, respectively). Finally, a third ANOVA was conducted that included the three time points in one model. Given the paucity of patients who made it to the 6-month appointment compared to those who made it to the 3-month appointment, it was deemed important to run the two tests to maximize use of the sample size at the various time points as well as the third test inclusive of the patients who made it through the three time points.

2.2 | Assessment of response

One of the most widely used symptom questionaries in the study of pelvic floor disordered is the UDI. The UDI contain 19 questions about lower urinary tract symptoms separated into three scales: irritative symptoms, obstructive/discomfort symptoms and stress symptoms. Respondents are asked if they have a particular symptom and if they do, to assess the degrees it bothers them on a four-point scale from "not at all" to "greatly." A shortened version of the UDI is the UDI-6, a six-question instrument that correlates well with the longer version. UDI-6 was used as a standardized objective method for assessment of progress regarding both the stress and urge components of leakage. The UDI-6 was administered at the screening visit and after each visit for up to 6 months. Adverse events and concomitant medications were collected at each of the follow-up visits.

Review of the chart reveals 13 patients who were previously treated with CO_2 laser for genitourinary syndrome of menopause and later got treated with bipolar radiofrequency for stress and mixed incontinence. UDI-6 questionnaire was also used with these patients as an assessment of progress to standardize the outcome across all patients. There were no patients receiving CO_2 laser treatment simultaneous with radiofrequency energy.

3 | RESULTS

There was no difference between patients in both groups in terms of age, body mass index, and type of incontinence (Table 2).

TABLE 2 Demographics of the patient

	Bipolar		Monopolar		BP/CO_2	
	Number of patients (mean)	*SD*	Number of patients (mean)	*SD*	Number of patients (mean)	*SD*
Age groups, years						
35–39	_	_	1	_	_	_
40–44	_	_	2 (43.5)	0.7	_	_
45–49	3 (47)	2.8	_	_	_	_
50–54	5 (51.6)	1.8	3 (51.6)	2	3 (51)	1.7
55–59	6 (57.3)	1.8	4 (56.5)	2	1	_
60–64	9 (62.4)	1.5	6 (62)	1.6	_	_
65–69	12 (66.9)	1.4	2 (67)	2.8	3 (67.3)	2
70–74	6 (70.5)	0.5	9 (71.8)	1.3	2 (72)	1.4
>75	15 (78.6)	3.9	5 (79)	4.5	4 (77.5)	2
	Mean	*SD*	Mean	*SD*	Mean	*SD*
BMI	28.9	5.62	29.26	6.34	28.39	4.05
BMI categories	*n*	%	*n*	%	*n*	%
BMI < 20	–	–	1	3.1	–	–
BMI < 20–24	8	14.3	5	15.6	3	23.1
BMI < 25–29	29	51.8	10	31.3	3	23.1
BMI ≥ 30	19	33.9	16	50	7	53.8
Incontinence	*n*	%	*n*	%	*n*	%
MUI	36	64.3	21	65.6	9	69.2
SUI	3	5.4	2	6.3	0	0
SUI/MUI	5	8.9	1	3.1	1	7.7
UUI	5	8.9	1	3.1	0	0
UUI/MUI	7	12.5	7	21.9	3	23.1

Abbreviations: BP, bipolar; BMI, body mass index; MUI, mixed urinary incontinence; SUI, stress urinary incontinence; UUI, urge urinary incontinence.

The first test (baseline to 3 months) included 66 bipolar patients and 32 monopolar patients. The effect of time was significant ($F [1, 96] = 175.53$, $p < 0.001$], while the treatment was not ($F [1, 96] = 0.03$, $p = 0.88$). There was no interaction effect. The second test (baseline to 6 months) included 26 bipolar patients and 30 monopolar patients. Again, the effect of time was significant ($F [1, 54] = 105.55$, $p < 0.001$), while the treatment was not ($F [1, 54] = 0.061$ $p = 0.44$). There was no interaction effect. Interestingly, the model that was inclusive of the three time points tells a more nuanced story. As in the 6-month model, there were 26 bipolar patients and 30 monopolar patients. Once again, the effect of time was significant ($F [2, 108] = 116.26$, $p < 0.001$), and the effect of treatment was approaching statistical significance ($F [1, 54] = 2.12$ $p = 0.15$); the interaction effect was also approaching marginal significant ($F [2, 108] = 2.18$, $p = 2.13$). This indicates that there is a subtle effect of the two treatment types at various time points. Consulting the pairwise comparisons of means display what is actually occurring. Both groups UDI scores drop significantly from baseline to three months; however, the bipolar group drops more dramatically compared to the monopolar group ($F [1, 54] = 3.12$, $p = 0.08$). Then, both groups slightly raise from three months to 6 months; while the interaction difference from baseline to 6 months for the two groups isn't marginally statistically significant anymore, the trend still remains

TABLE 3 UDI-6 score in MP and BP before treatment, 3- and 6-month after treatment

Method		Mean	Std. Deviation	*N*
UDI-6 before treatment	BP	42.13	11.01	26
	MP	42.35	14.10	30
	Total	42.25	12.65	56
UDI-6 after treatment 3 months	BP	15.85	7.48	26
	MP	22.75	13.09	30
	Total	19.54	11.31	56
UDI-6 after treatment 6 months	BP	20.66	9.24	26
	MP	24.57	13.17	30
	Total	22.75	11.58	56

Abbreviations: BP, bipolar; MP, monopolar; UDI, urogenital distress inventory.

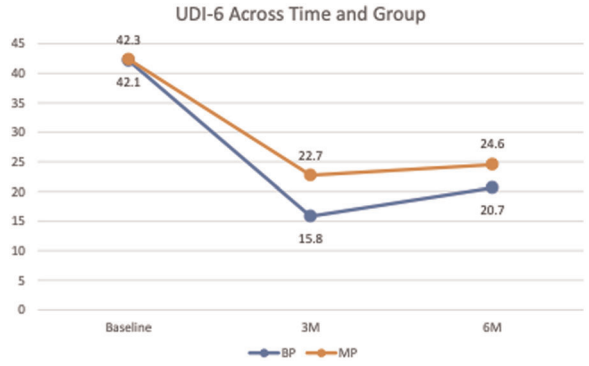

FIGURE 1 UDI-6 score in monopolar and bipolar before treatment, 3- and 6-month after treatment. UDI, urogenital distress inventory

(F [1, 54] = 0.93, $p = 0.34$]. Regardless, both groups still improved from baseline to 6-month follow-up. This lack of statistical significance from baseline to 6-month follow-up is likely a result of the insufficient sample size by which is needed to achieve sufficient power for determining interaction differences. Thus, the bipolar group improved UDI-6 scores across time more so than did the monopolar group, especially at the three-month mark, at least when considering patients who had complete baseline, 3- and 6-month records. The following table and graph display where these differences lie (Table 3) (Figure 1).

There were two secondary aims of this study. The first was to determine if incontinence type. Extrapolating from initial UDI-6 questionnaires, women were categorized into predominant SUI, urge urinary incontinence (UUI), or mixed urinary incontinence (MUI). An analysis was then performed to determine if any of the treatment regimes had an effect on UDI-6 over time. The same set of three tests were conducted. Given this was a secondary outcome of this study, the ANOVA test results will only be reported for the full model (inclusive of all three time points). In this test, there was a main effect of time (F [2, 106] = 65.33, $p < 0.001$) and a main effect for incontinence group (F [2, 53] = 5.28, $p < 0.01$). This indicates that while there are differences by incontinence group and by time, those two factors do not interact (F [4, 106] = 0.59, $p = 0.67$). In other words, all three incontinence groups decrease in UDI-6 values at the same relative magnitude across time, though the incontinence groups differ from one another. Considering the pairwise comparisons, only the MUI group differed statistically from the SUI group. That is, at the three time points, the MUI group was statistically higher than the SUI group in UDI-6 values. The following table displays the means, standard deviations, and sample sizes of the three incontinence groups across time (Table 4).

The final secondary goal of this study was to determine whether having previous exposure to fractional CO_2 of the vaginal canal had an effect on UDI-6 scores across time. The same set of three tests were conducted. Given this was also a secondary outcome of this study and that the story told by all three tests was the same, the ANOVA test results will only be reported for the full model (inclusive of the three time points). In this test, there was a main effect of time (F [2, 108] = 83.32, $p < 0.001$) but not a main effect for CO_2 group (F [1, 54] = 1.07, $p = 0.31$). There was also no interaction effect (F [2, 108] = 0.46, $p = 0.63$). In other words, CO_2 exposure did not interact the effect of passage of time. The

TABLE 4 UDI-6 score of the three incontinence groups before treatment, 3- and 6-month after treatment

Incontinence group		Mean	Std. Deviation	*N*
UDI-6 before treatment	MUI	45.93	11.45	35
	SUI	32.13	13.55	7
	UUI	38.08	11.76	14
	Total	42.25	12.65	56
UDI-6 after treatment 3 months	MUI	21.47	11.88	35
	SUI	11.89	3.54	7
	UUI	18.56	11.13	14
	Total	19.54	11.31	56
UDI-6 after treatment 6 months	MUI	24.87	11.27	35
	SUI	14.27	7.46	7
	UUI	21.71	12.57	14
	Total	22.75	11.58	56

Abbreviations: MUI, mixed urinary incontinence; UDI, urogenital distress inventory; SUI, stress urinary incontinence.

TABLE 5 UDI-6 score in previous CO_2 laser exposure vs no exposure before treatment, 3- and 6-month after treatment

Previous CO_2		Mean	Std. Deviation	N
UDI-6 before treatment	No	42.81	13.22	43
	Yes	40.37	10.81	13
	Total	42.25	12.65	56
UDI-6 after treatment 3 months	No	20.76	12.03	43
	Yes	15.53	7.54	13
	Total	19.54	11.31	56
UDI-6 after treatment 6 months	No	23.14	12.20	43
	Yes	21.46	9.59	13
	Total	22.75	11.58	56

Abbreviation: UDI, urogenital distress inventory.

following table displays the means, standard deviations, and sample sizes of the two CO_2 groups across time (Table 5).

4 | DISCUSSION

As interest in finding minimally invasive office-based approaches for addressing urinary incontinence increase, radio frequency energy has been gaining popularity in this field. The purpose of this study was to compare the effect of two modalities, monopolar and bipolar radiofrequency technologies, on treating urinary incontinence. In our study, all patients saw improvements in UDI-6 values 3 and 6 months after treatment. There is some evidence to suggest that the bipolar radiofrequency treatment was more effective compared to the monopolar radiofrequency treatment over time. Three months after treatment, the bipolar group UDI-6 values were lower than those of the monopolar group. Six months after treatment, the UDI-6 scores increased in both groups, suggesting decrease efficacy with time with more studies needed to address whether a maintenance therapy would offer a sustained benefit to patients over extended period. However, the bipolar group's UDI-6 scores were consistently lower than the monopolar group's scores, with the bipolar group's 6-month UDI-6 scores being lower than the monopolar group's three-month scores. This may suggest longer sustained effect of bipolar energy compared to monopolar.

The study also looked at the effect of radiofrequency energy on MUI and UUI as a secondary outcome. The MUI group UDI-6 mean scores were higher than the SUI and the UUI group mean at baseline. Those values were consistent across the 3-month and the 6-month period. There was consistent improvement in all three groups of incontinence with no statistical difference favoring one group over other, suggesting positive outcome of radiofrequency treatment among different urine incontinence types. Finally, it appears that previous CO_2 exposure had no effect on UDI-6 values on patients who were previously treated with CO_2 for genitourinary syndrome of menopause.

This is the first study that addresses the outcome of different types of radiofrequency energy in the treatment of stress and mixed urinary incontinence for a relatively long follow up period up (up to six months) with a relatively large number of patients (101). It is the also the first study which addresses treatment with radiofrequency in patients who were previously treated with CO_2 laser.

Limitations of the study are that it is a retrospective study with the risk of collection bias. Our outcome is the UDI-6 scores which is a subjective outcome and gives the measure of "overall" bother and lacks the granularity to see the impact of the treatment on different components of urinary incontinence, however it is widely used as quality-of-life measure in the urogynecology population. We also didn't include any objective outcome like pad test or cough stress test due to the unavailable data from all patients regarding these outcomes which needs more compliance from patients. Second, our sample size was based on number of patients who received the treatment at the two sites. A true power analysis was not performed to determine the number of patients who would be needed to truly show a difference. Our findings of previous CO_2 laser exposure with current RF energy users is only observational with a limited number of patients that were treated with CO_2 laser at different time intervals so the findings should be interpreted with care.

5 | CONCLUSION

The study shows clear benefit of both monopolar and bipolar radiofrequency device in patients with SUI and mixed UI, with bipolar RF more efficacious than monopolar RF. These data should be interpreted with caution due to the retrospective nature of the study. To truly compare the effects of these two RF platforms a prospective randomized trial would be required.

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Ahmed Abdelaziz, Jeffrey Dell, and Mickey Karram contributed to the design and implementation of the

research, to the analysis of the results, and to the writing of the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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How to cite this article: Abdelaziz A, Dell J, Karram M. Transvaginal radiofrequency energy for the treatment of urinary stress incontinence: a comparison of monopolar and bipolar technologies in both pre- and post-menopausal patients. *Neurourol Urodyn*. 2021;1-7. https://doi.org/10.1002/nau.24748