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Radiofrequency Therapy As A Treatment For Women With Stress Urinary Incontinence: A Systematic Review

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ABSTRACT

The most frequent type of urine incontinence is stress urinary incontinence (SUI), which affects from 4%-14% of younger women and 12%-35% percent of older women. Management of SUI ranges and can be tailored to patient's need. The use of radiofrequency is one of the current studies being investigated as a minimally invasive treatment for SUI. Radiofrequency is an electromagnetic energy that capable to remodel and produce immediate structural alteration with tissue in contact. The tissue action is confined and does not extend to the underlying viscera. The goal is to activate subsequent fibroblast and retract collagen. Later it induces ingrowth granulation tissue and this in turn is replaced by predominant fibroblastic response. In the end, continued healing response will result in mature fibrosis and complete resolution of inflammation process. The hypothesis is that radiofrequency treatment can reduce urinary loss in a safe manner and improve quality of life. Systematic search of literatures was conducted in May 2021 using several article databases such as Medline/PubMed, Scopus and ProQuest. The keywords used in for searching these databases were "stress urinary incontinence", "radiofrequency". A total of 38 studies were reviewed after duplication removal, but only 12 studies contained available and relevant for analysis. Six studies evaluated transvaginal approach, five studies evaluated transurethral approach and one study evaluated laparoscopic approach. The best reported improvement from transurethral approach in radiofrequency demonstrated in 76% of treated patients showed decrease in daily incontinence episodes with 35% became fully continent. Transvaginal approaches reported mixed results with 3 studies reported improvement of symptoms and quality of life, however other studies suggested its low effectiveness. There is still lack evaluation in comparing radiofrequency treatment with other available treatment of SUI. Transurethral is promising modality in radiofrequency treatment in SUI. All the studies that used transurethral approach in this review was proven to increase participants quality of life and able to reduce episode of incontinence. This review highlights the need of more evidence and future randomized controlled trial in comparing it with other available treatments.

1. INTRODUCTION

Urinary incontinence is involuntary loss of urine. This condition can affect patient health and their quality of life. There are several types of urinary incontinence. The prevalence of urinary incontinence in population-based studies ranges from 9,9% to 36,1% [1]. Although urinary incontinence often reported in women, after 80 years of age, both sexes are affected equally [2].

The most common one in stress urinary incontinence (SUI). SUI is involuntary leak of urine secondary to increase of abdominal pressure. This greatly affect patient's quality of life because leak of urine can be triggered by simple activity such as sneezing, coughing, or laughing. SUI is estimated to affect about 4%-14% of younger women and 12-35% of older women [3]. There are various risk factors that can affect occurrence of SUI. Bump and Norton have designed a model to group several risk factors into several categories based on their effect in pelvic disorder [4]. Several stand out risk factors include aging, obesity, smoking, pregnancy and route of delivery [3]. The cause of SUI can be multifactorial. Inadequate support of pelvic organ or anterior vaginal wall in women can affect intrinsic urethral mechanism. Reduction of collagen in urethra walls was observed histologically in urethral support or sphincter dysfunction [5].

Management of SUI ranges from lifestyle intervention to operative approaches. Approach of SUI treatment should involve changes of behavior including weight reduction, smoke cessation and dietary modification. Medication or surgery can be tailored to patient's need [6]. One of the current studies developed as a management of SUI was the used of radiofrequency. It is a minimally invasive procedure that uses diathermic process. Radiofrequency has been used in various medical field. Dermatologic used it for its tissue ablation capacity, whereas orthopedists apply its modality in joint capsule remodeling [7].

Radiofrequency is an electromagnetic energy that capable to remodel and produce immediate structural alteration with tissue in contact. These effect on tissue is localized without extension to underlying viscera. The goal of radiofrequency therapy is to activate subsequent fibroblast and retract collagen. Later it induces ingrowth granulation tissue and this in turn is replaced by predominant fibroblastic response. In the end, continued healing response will result in mature fibrosis and complete resolution of inflammation process.

There are several types of approaches in radiofrequency treatment. The initial method in radiofrequency treatment was laparoscopic approach. However, this approach have been left out since its high incidence of vesicoavaginal and urethravaginal fistulas [8]. Other approach is transurethral radiofrequency. The radiofrequency device that has been adjusted to urethral meatus is used in the process. Patient lays in lithotomy position and active electrode is placed on external urethral meatus. When starting, high frequency wave is then omitted using electromagnetic wave generator. The procedure is then repeated in several sessions [5].

The hypothesis is that radiofrequency treatment is able to reduce urinary loss in a safe manner and improve quality of life. However, this practice is still rarely used, especially in Indonesia. This review is aimed to systematically evaluate radiofrequency treatment as a management option of women with SUI.

2. Materials and Methods

Systematic search of literatures was conducted in May 2021 using several article databases such as Medline/PubMed, Scopus and ProQuest. The keywords used in for searching these databases were "stress

urinary incontinence", "radiofrequency". Both peer reviewed and non-peer reviewed were included in this review.

Several variables collected from literatures were study design, number of participants, gender proportion, age, treatment duration, other therapies, and treatment comparison. The citation results were then processed using EndNote X9 software (Thomson Reuters, Carlsbad, CA, USA).

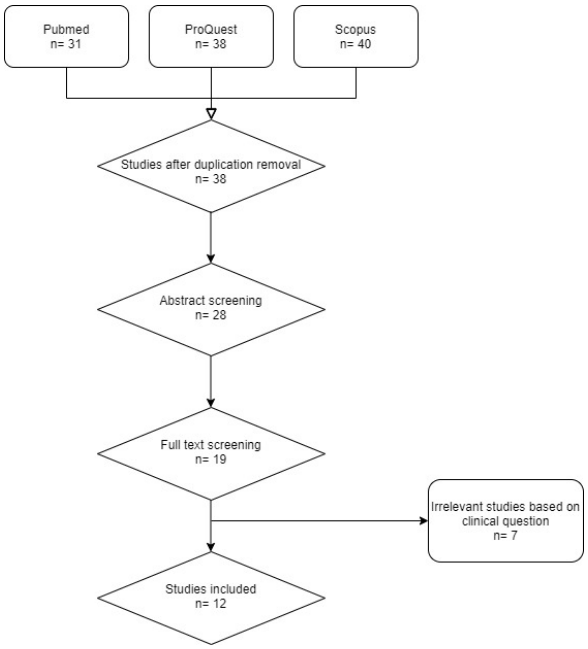

Figure 1. Systematic Search

3. Result

Initial use of radiofrequency treatment initiated with laparoscopic approach from [9] who conducted a multicenter prospective study. Ninety-four women who had genuine SUI that met the inclusion criteria were included in the study. Prior to enrollment in the study, participants were required to performed kegel exercises or pelvic floor electrical stimulation for 3 months. Cure rate was determined by negative Valsalva leak point pressure (VLPP) postoperatively. It was achieved in 78% of women in 6 months. Statistical improvement of Wagner quality-of-life test at 1 year in 81% of participants. From 7-day voiding diary it was observed reduction of leaking episodes in 72.8%, no change in 23.5%, and an increase in 3.7%. participants.

Transvaginal approach of radiofrequency in treating SUI was pioneered by [10]. The transvaginal method took an average of 30 minutes to complete, and the average treatment temperature was 82°C. After 12 month follow up 73% of participants being continent or improved and 72% of patients required 1 or no pads daily. Later [11] reviewed 18 women treated with radiofrequency device used by [21]. The remaining seven participants exhibited mixed urine incontinence with a prevalence of stress, while 11 had proven SUI. All patients had urethral hypermobility as defined by a Q-tip test. 1 year after the treatment, number of leaks was decrease. However, 10 (62.5%) of the patients had a positive cough stress test. Ten (62.5%) were not satisfied. Seven (43.8%) patients sought additional treatment after 1 year of procedure [11]. Study by [12] also found low effectiveness of transvaginal radiofrequency approach with a cure rate of 45.8%, and 37.5% of patients going on to seek other treatment.

On contrary to [11], [12] study by [13] confirmed the monopolar radiofrequency is effective and safe

treatment of SUI and vulvo-vaginal laxity. The therapy provision was consisted of intravaginal and subsequent extra-vaginal treatment to 27 women. Sixteen subjects (59.3%) reported decrease of leakage with 15 women (55.6%) are completely leak-free. Improvement of SUI also observed in study by [14] that compares single session and double session of non-ablative, cryogen-cooled, monopolar radiofrequency (CMRF). More than half reduction of pad weight was observed

Table 1. Study Characteristics and Treatment

Reference	Study Design	n	Age	Approach	Duration	Comparison	Patients' charac
[10]	Prospective, multicenter study	120	Mean 49.9 years	Transvaginal	1 session, 30 minutes duration	-	Women with genui
[19]	Prospective study, Phase 1 clinical trial	10	Mean 53.10 years±7.08 (43-66)	Transurethral, high frequency wave, 0.5MHz	5 sessions of treatment, with a weekly frequency. Each session lasted for 2 minutes.	-	SUI main symptoms urgency, urinary loss 1g in a one-hour P
[18]	Prospective study, Clinical trial	139	Median 42 years (26-87)	Transurethral	1 session, 30 minutes duration	-	SUI secondary to bladde hypern
[13]	Prospective study, non-randomized, multicentric study	27	Mean 44.78±10.04 years (28-66)	Transvaginal	3 sessions, once a week frequency.	-	Mild- moderate S vagina
[17]	Retrospective	21	Mean 52.2 ± 13.2	Transurethral	1 session therapy	Sham treatment	Patients with SUI for at
[14]	Prospective, randomized controlled trial	29	Mean group control 46.5 years. Mean group treatment 42.9 years	Transvaginal	2 sessions therapy six weeks apart	1 session therapy	Mild-to-moderate defined by the 1-hour P 50 g le
[16]	Prospective, randomized controlled trial	173	Mean 50 years (range 22-76)	Transurethral	1 Session therapy, 9-minute	sham treatment	Women with SUI, bladde hypermobility, and lea pressure (LPP) 60

					radiofrequency delivery		
[11]	Retrospective	18	mean age was 57.8 years (40–78)	Transvaginal	1 session performed under local anesthesia	-	Women with sympt pure stress urinary incon or mixed urinary incon with a predominance of related urine l
[15]	Prospective, clinical trial	41	mean age was 48.8±10.7 years (35–81)	Transurethral	Participants were divided into 4 groups and underwent radiofrequency treatment for 7.5 – 15 minutes	-	Women with SUI and ev of bladder outlet hypern
[20]	Prospective, randomized double blind controlled trial	20	mean age treatment group 55±5.8. mean age control group 56,9 ± 3.1	Transvaginal	3 sessions 4 weeks apart, total 30 minutes per session	Sham treatment	Postmen women with sympt SUI and/or
[12]	Retrospective, chart review	24	mean age 47.0±9.4	Transvaginal	1 session, 38 minutes per session	-	Women with stress incon due to urethral hypern
[9]	Prospective, multisite study	94	mean age 48.7 ± 7.6 years	Laparoscopic	1 Operation session with average operating time was 54.3 ± 10.4 minutes	-	Women with genuin incon

Table 2. Study Outcomes

Reference	Outcome measure	Definition of Success	O
[10]	Leak episodes, urodynamic evaluation, pad use and complication	Decrease of leak episodes and pad use	At 12-month fol 79 of 109 patients (73%) reported being continent or improved. and 12 months 69%, 70% and 72% of patients, respectively, req or no pads daily. On urodynamic evaluation at 12-month fol 76.0% of the patients did not leak with a Valsalva ma
[19]	Urine loss measured using Pad test	Decrease of urine loss	There was a reduction of urine loss in all participants 1 mon procedure. Nine participants reported satisfaction of the tre
[18]	incontinence quality of life (I-QOL), urogenital distress	improvement of I-QOL and decrease	At 36 months, intent-to-treat analysis (n = 139) revealed sig improvements in quality of life. Mean I-QOL score improved 17

	inventory (UDI-6) instruments	UDI-6 score	from baseline (P = .0004), while mean UDI-6 score im (decreased) 19 points (P =
[13]	Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ UI SF)	improvement of ICIQ-UI SF and VVLQ result	Urinary leak decrease from 2-3 times (2.15±1.03 points treatment) to once a week (1.00±0.78 points post-treatment) an never (0.44±0.51 points a month follow-u Sixteen subjects (59.3%) reported decrease of leakage and 15 (55.6%) completely leak-free after 1
[17]	I-QOL survey and incontinence episode frequency (IEF)	Improvement of I-QOL and decrease of IEF	After 3 years, mean overall I-QOL score was 12.7 ±26 and patients achieved 50% or more reduction in fre
[14]	1-hour pad-weight test (PWT), Incontinence Impact Questionnaire-Short Form (IIQ-7), and International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence-Short Form (ICIQ-UI-SF)	reduction of PWT, improvement of symptoms based on Urogenital Distress Inventory (UDI-6) and ICIQ-UI-SF	More than 50% reduction of PWT at 6 months in group 1 (single therapy) was 68.8% and in group 2 (double session therapy was Clinically meaningful score decreases in UDI-6, CIQ-UI-SF an
[16]	I-QOL score, incontinence episode and Leak Point Pressure (LPP)	Increase of I-QOL score and LPP	In 12 months follow up 74% participants experienced ≥10-point i of I-QOL. Patients in treatment group demonstrated an increase i LPP at 12 months (13.2 ± 39.2cmH20), while sham treatmen decrease to (-2.0 ±33.8 c
[11]	number of daily stress urinary incontinence episodes	Decrease number of episodes	The mean number of leaks per day was 5.7 preoperatively and r to 2.7 after treatment. The postoperative analysis included 16p with ten (62.5%) of them reporting SUI symptoms. A positive stress test was also found in 10 (62.5 %) of the patients. One (6.3%) was satisfied, while ten patients (62.5%) were not. Within seven individuals (43.8 percent) requested further incon tre
[15]	I-QOL score, incontinence episodes and daily pad use	Improvement of I-QOL score and decrease of incontinence frequency	75%–80% of patients in all four groups have improved I-QO baseline score for all participants was 50.4±16.2 with improvement ≥10 points over baseline. The reduction i incontinence frequency at 6 months was statistically signific groups and pad use decrease significantly in on
[20]	ICQ-SF, UDI-6, Vaginal Health Index (VHI) Scores.	Improvement of incontinence symptoms	After 12 months follow up there is improvement of the ICIQ before and after in the treatment group (17.3 ± 0.78 to 11.4 ± UDI-6 also revealed statistical improvement from baseline to the

			the treatment in the active group (37.5 ± 7,2 to 16.23 ± 6.0 showed improvement in treatment group from 11,5 ±0,67 to 19,3
[12]	effectiveness and complication	effectiveness of treatment post operatively	treatment to have low effectiveness, with a cure rate of 45.8 37.5% of patients going on to seek other treatment. Five minor complications: bleeding, pain, hematuria, catheterization, vaginal dis
[9]	Leaking episodes, pads use, The Wagner QOL, complication, urinalysis, Q-tip test and fi lling a cystometrogram with Valsalva leak point pressure (VLPP)	decrease of episode with improvement of quality of life and low complication	72.8% of patients reduced episodes and significant reduction of p in in 12 months follow up. The Wagner QOL test showed sign improvement in 81% of the patient at 1 year. Four intraop complications occurred: two bladder perforations, one sup abdominal hematoma, and one case of hypotension secon anesthesia. Postoperatively, four minor complications were two tract infections, one cannula site infection, and one case of nau vomiting. The overall complication rate was 7%. There were no related

in 69.2% of participants underwent double session therapy [14]. The effect of radiofrequency therapy on SUI in post-menopausal women studied by [20]. Radiofrequency energy was transmitted to vaginal canal and labia majora. Significant improvement of ICIQ-SF and UDI-6 scores was observed, with 7 of 10 patients (70%) had a negative cough stress test after the treatment.

Several studies focused on transurethral approach in radiofrequency. Study by [15] was conducted in 41 participants who diagnosed with urethral hypermobility and SUI. Patients were enrolled in 4 study groups. At 6 months following treatment, I-QOL overall score improvements over baseline were demonstrated by 75%, 78%, 80%, and 78% of patients in groups I, II, III, and IV, respectively. In [16] conducted randomized study with 110 women randomly assigned to the experimental group and 63 to the sham control group. In experimental group 48% of women experienced a ≥ 10-point improvement in the I-QOL score compared to 44% in the sham group. Overall, 76% of treated patients showed decrease in daily incontinence episodes with 35% became fully continent. This result then supported by next study by [17] that conducted retrospective 3 year evaluation of transurethral radiofrequency collagen denaturation treatment. Of 21 participants available for follow up, there was improvement in mean overall I-QOL score to 12.7 ±26 from baseline score 56 ±24.6. Three years evaluation study also performed by [18], that found 17 points improvement of baseline I-QOL score from 139 participants.

4. Discussion

Radiofrequency treatment is one of the medical therapies that is being developed in many health fields. It may offer real advantages in urology as a choice of treatment in women in SUI [5]. Soft tissue studies in animals have revealed reproducible and defined effects from radiofrequency energy delivery to soft tissue structures. It effects includes denaturation of collagen fibrils and acute inflammatory reaction [21].

The literature published to date suggests that it can produce long lasting improvement in quality of life of women with SUI. Although the treatment does not result in complete continence in all participants and two studies included this review found low effectiveness in transvaginal approach, it does improve urine retention and give patient satisfaction.

Transurethral is promising modality in radiofrequency treatment in SUI. All the studies that used transurethral approach in this review was proven to increase participants quality if life and able to reduce episode of incontinence. The procedure itself does not provide major complications to patients with only minor complication occur during the procedure. Nonsurgical approach also provides a one-day service in patients receiving radiofrequency treatment and can improve cost effective treatment.

There is still lack evaluation in comparing radiofrequency treatment with other available treatment of SUI in women patients. In particular, future randomized controlled trial is needed to provide better outcome in available therapies and possible combination therapies between radiofrequency and other optional treatments.

5. Conclusion

This review showed radiofrequency treatment can become the treatment of choice for women with SUI. Radiofrequency treatment can provide long-term effect in reducing incontinence episodes and improve quality of life. With limited complications and required only local anasthesia its beneficial for patients who seeks one day care treatment. However, future randomized controlled trial in comparing radiofrequency treatment with other available SUI treatment options is needed.

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