ISSN 1855-9913

Journal of the Laser and Health Academy
Vol. 2022, No.1; www.laserandhealth.com

Erbium Laser Thermo-Therapy for Female Stress Urinary Incontinence – 18 months Follow-up

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ABSTRACT

Introduction

Stress urinary incontinence (SUI) is a common cause of urinary incontinence affecting a large number of women and significantly influencing their quality of life. In the last decade, vaginal Er:YAG laser therapy was introduced as a minimally invasive treatment option for SUI.

Objective

The purpose of this study was to evaluate the long-term efficacy and safety of erbium laser treatment for female stress urinary incontinence (SUI).

Methods

In this single-center prospective study covering the period from April 2014 to January 2016, we performed non-ablative Er:YAG laser thermal therapy on 132 female patients suffering from stress urinary incontinence. The patients received two laser sessions with a 4-6 week interval. Follow-ups were performed at 3 and 18 months. For assessment of stress urinary incontinence, ICIQ-UI SF and ISI by Klovning questionnaires were used. Patient satisfaction was measured using an 11-point numerical scale. Long-term follow-ups were performed via telephone interviews, at which an additional questionnaire was used to assess the duration of SUI improvement and the patient's willingness to repeat the treatment. Adverse events were registered at each follow-up.

Results

132 patients with SUI were included in this study. The average age was 50.3 years (range 23-75) and average parity 1.9 (range 0-4). Average ICIQ-UI SF score at baseline was 12.3, which decreased to 5.19 at the 3-month follow-up (improvement of 7.1 points). At the 3-month follow-up, 19% of the patients were dry and 96.8% had improved ICIQ-UI SF scores. 75% of the patients had the full effect lasting at least 12 months and 24% for at least 18 months. The average duration of improvement was 12.0 months. 85% of the patients were not disappointed when the symptoms started to come back and 97% were satisfied with the treatment (average score at 18 months was 7.9/10; 67% with grades 8-10). 98% of the patients would repeat the therapy. All reported adverse effects were mild and transient.

Conclusions

Erbium laser treatment showed efficacy in the improvement of female SUI with no major adverse effects noted. Patient discomfort during the treatment was minimal and satisfaction was very high.

Key words: Stress urinary incontinence, vaginal Er:YAG laser therapy, long-term efficacy.

Article: J. LA&HA, Vol. 2022, No.1; onlineFirst.
Received: December 24, 2021; Accepted: September 5, 2022

I. INTRODUCTION

Stress urinary incontinence, usually defined as involuntary urinary leakage during physical efforts that cause increased abdominal strain, is a common condition affecting between 3% to 35% of women in their reproductive period and significantly influencing their quality of life [1,2].

It is recommended to treat stress urinary incontinence initially with nonsurgical therapies, such as weight reduction, hormonal substitution, physiotherapy, pelvic floor exercise or the use of pessaries. [3] If non-invasive treatments do not result in improvement within 3–6 months, surgical treatments such as mid-urethral sling procedures and single-incision polypropylene mesh mini-slings (SIMS) can be considered. Surgical therapies are very effective but are associated with serious and long-term adverse events and complications. [4,5] Alternative treatment options are requested especially by younger, active women seeking non-invasive therapies.

In the past decade, vaginal Er:YAG laser therapy has been established as a minimally invasive treatment option for stress urinary incontinence. Several studies have reported that the non-ablative Fotona

SMOOTH® Er:YAG laser procedure seems to be an effective and safe alternative to existing SUI therapies [6-12]. The mechanism of action relies on the thermal effects of the Fotona SMOOTH® technology, which targets the connective tissue of the vaginal mucosa, resulting in thermal stimulation of new collagen formation and promotion of existing collagen remodeling [13-15].

In this study we focused on evaluating the long-term efficacy and safety as well as durability of the results of erbium laser treatment for female stress urinary incontinence (SUI).

II. MATERIALS AND METHODS

Our prospective clinical study included female patients (age range 23-75) suffering from stress urinary incontinence who visited Poliklinika Novakov et al. between April 2014 and January 2016. The study was approved by the local Ethics Committee (No. 1/2014). Diagnosis of stress urinary incontinence was established based on subjective complaint of stress urinary incontinence and ICIQ SF, combined with medical history and objective gynecological examination, during which the Valsalva maneuver as well as coughing test were done. Inclusion criteria were non-pregnant women aged between 18 and 85 years, with subjective complaints of stress urinary incontinence, but lacking malignancy, autoimmune disease, local vaginal wound, infection, and bleeding. If pregnancy, infection, local disruption of tissue, or any malignancy was diagnosed during the study, the patents were excluded. 132 women with a diagnosis of SUI who signed informed consent were included in this study. The patients were informed about the laser procedure and its potential adverse effects. Expectations were also discussed before the treatment. All the participants completed an ICIQ-UI SF before treatment. Non-ablative Fotona SMOOTH® Er:YAG laser therapy was conducted according to the three-step IncontiLase® protocol described by the manufacturer. Patients received two consecutive non-ablative Er:YAG laser therapies with a 4 to 6 week interval between sessions. No anesthesia was used before or during any of the laser therapies. Patient discomfort and potential adverse events were monitored during and after each treatment. No special post-op therapy was needed, and patients were instructed to avoid physical straining and sexual intercourse for 7 days after each treatment.

Telephone follow-ups were performed at 3 and 18 months after the last treatment. For assessment of the symptoms of stress urinary incontinence, ICIQ-UI SF was used before and at the 3-month follow up. The ICIQ-UI SF was divided into the following four severity categories: mild (1–5), moderate (6–12), severe (13–18) and very severe (19–21) [16]. The Incontinence Severity Scale (ISI score), consisting of questions Q3 and Q4 of the ICIQ-UI SF questionnaire and excluding the QoL question (Q5), was calculated at baseline and at the 3 and 18 months follow up to obtain more objective results [16]. The ISI scale was divided into the following four severity categories: mild (1–3), moderate (4–5), severe (6–9) and very severe (10–11) [16]. The ICIQ and ISI improvement scales were divided into 5 categories: dry (no symptoms of SUI), significantly improved (ISI and ICIQ scores decreased by 50% or more), improved (decrease of ISI and ICIQ scores between 1- 49%), not improved (no change in ISI or ICIQ scores) and worse (increase in ISI or ICIQ scores).

Patient satisfaction was also measured with an 11-point numerical scale. At the 18-month follow up, an additional questionnaire was introduced to the patients for evaluating the duration of the results and the patients' willingness to repeat the treatment. The questionnaire consisted of three questions Q1: How long after the IncontiLase® treatment did you feel that the symptoms of SUI started to come back?; Q2: When were the symptoms bothersome enough that it was necessary to repeat the treatment?; Q3: Assess your satisfaction with the treatment result 18 months after the treatment on a scale from 0 to 10.

SPSS version 18.0 (SPSS Science, Chicago, IL) was used for statistical analysis of the collected data. Numeric values were expressed as mean and standard deviation. Statistical analysis was performed on the data before and after the laser treatment by using Generalized Linear Model Repeated Measures with covariates of age and delivery. P values less than 0.05 were accepted as significant.

III. RESULTS

126/132 patients with stress urinary incontinence completed the study. The average age of the patients was 50.2 years (range between 23-75) and average parity was 1.9 (range between 0-4) (Table 1).

Based on the ICIQ-UI SF, 52% of the patients had mild to moderate SUI and 48% had severe to very severe SUI symptoms (Fig. 1). Based on ISI score, mild to moderate SUI was diagnosed in 40% of the patients and severe to very severe in 60% of the patients (Fig. 1). At baseline, the average ICIQ-UI SF score was 12.29 and the average ISI score was 5.99 (Table 2). In addition to SUI, cystocele was observed in 23 patients, vaginal laxity in 7 patients, vaginal dryness in 5 patients and 1 patient had both cystocele and vaginal laxity (Table 1).

Table 1: Patients characteristic data:

Age (years)	No. of patients (%)	
20-30 years	2 (1.6%)	
30-45	50 (39.7%)	
45-60	43 (34.1%)	
> 60	31 (24.6%)	
No. of deliveries	**Vaginal**	**Cesarean**
0	1 (0.8%)	
1	21 (16.67%)	1 (0.8%)
2	87 (69%)	6* (4.8%)
>2	12 (9.5%)	1 (0.8%)
Symptoms		
SUI	90 (71.4%)	
SUI+Dryness	5 (4%)	
SUI Cystocele	23 (18.2%)	
SUI +LVT**	7 (5.6%)	
SUI +LVT+cystocele	1 (0.8%)	

* 3 of the patients with two deliveries had 1 vaginal and 1 cesarean delivery
** LVT – Laser Vaginal Tightening

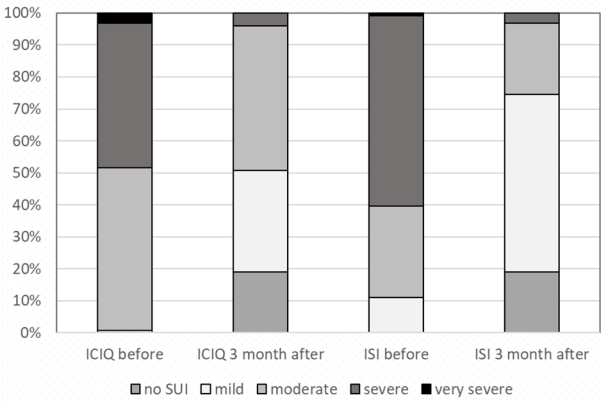

Fig.1: Comparison of the severity of SUI symptoms improvement based on ICIQ-UI SF and ISI scores.

At the 3-month follow-up, 96.8% of patients improved their ICIQ-UI SF score. In 78.5% of the patients, the improvement was at least 50%. 19% of the patients were dry based on the ICIQ-UI SF and ISI scores (Table 2). Improvement of cystocele was observed in 4/24 patients. Based on ICIQ-UI SF and ISI Klovning scores at the 3-month follow up, no or mild SUI symptoms were observed in 51% and 75%, comparing to the baseline where mild SUI symptoms were observed in 1% and 11%, respectively (Fig. 1).

The average decrease of ICIQ-UI SF score was 7.1, while ISI score decreased by 3.17 points, representing average improvements of 58% and 53%, respectively. There was a significant difference in ICIQ and ISI between baseline and 3 months after treatment ($p<0.001$). At the 18-month follow up, 88% of patients improved their ISI score with an average decrease of 3.5 points, representing an average improvement of 59%. The mean scores were statistically significantly different from the mean baseline scores throughout the entire study (Table 3). Age and delivery had no significant effect on the result as evidenced by non-significant interaction terms in the generalized linear model ($p>0.5$).

Table 2: Improvement in outcome measures comparing ICIQ-UI SF and ISI. Data is presented as the percentage of patients with a corresponding improvement rate. ***(n=number of patients)***

Outcome measurement	ICIQ-UI SF	ISI - Klovning	
Follow up	3-month (n=126)	3-month (n=126)	18-month (n=105)
Dry (%)	19	19	23.8
Significantly improved (%)	59.5	46.8	41
Improved (%)	18.3	29.4	24.7
Not improved (%)	3.2	4.8	9.5
Worse (%)	0	0	1

At the 18-month follow-up, 126 patients were interviewed. According to subjective questionnaire, only 3 patients did not observe any improvement after the laser therapy, while with 3 patients the results lasted less than 3 months. 5% of the patients reported that their SUI improvement lasted up to six months, 58% reported improvement of symptoms up to 12 months and 13% up to 18 months, while 20% of the patients had persistent improvement by the time of the interview (Fig. 2). The calculated average duration of the improvement was 12.0 months.

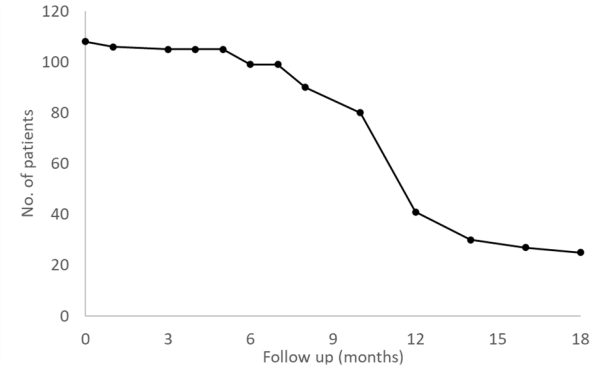

Fig. 2: Duration of improvement based on patients' evaluation (n = 111).

85% of the patients were not disappointed when the symptoms started to come back and 98% of them would repeat the therapy. 56% of the patients claimed that they felt a desire to repeat the procedure 12 months after the therapy or later, while 37% of patients felt no need to repeat the treatment at the 18-month follow up.

Table 3: Results of the ICIQ-UI SF and ISI scores. The results are presented as mean (SD). All follow up measures were statistically significantly different (a significance level was set to 0.05) from the baseline *(n=number of patients).*

	Pre-treatment (n =126)	3 months post treatment (n =126)	p-value	18 months post treatment (n =105)	p-value
ISI Klovning	**5.99** (4.14 to 7.84)	**2.82** (1.22 to 4.42)	0.0001	**2.44** (1.01 to 3.87)	0.0001
Q3	**3.01** (1.85 to 4.17)	**1.19** (0.3 to 2.08)	0.0001	**0.91** (0.25 to 1.57)	0.0001
Q4	**2.98** (1.96 to 4)	**1.63** (0.76 to 2.5)	0.0001	**1.52** (0.67 to 2.37)	0.0001
Q5	**6.29** (4.08 to 8.5	**2.34** (0.34 to 4.34)	0.0001	/	/
ICIQ-UI SF	**12.29** (8.86 to 15.72)	**5.19** (1.76 to 8.62)	0.0001	/	/

97% of the patients were satisfied with the treatment. The average satisfaction score at 18 months was 7.9/10, with 67% of the patients very satisfied with the results (grades 8-10). All patients expected diminishing of the results after time.

During the procedure a majority of the patients reported a burning sensation at the entrance of vaginal canal near the introitus, but it passed immediately after the treatment moved towards the next area. All of the patients had increased vaginal secretion, but none complained about it. A couple of patients reported increased leakage of urine in the first ten days, which passed spontaneously. Capillary bleeding around the urethra was seen in some older patients, which subsided almost immediately. All reported adverse effects were mild and transient.

IV. DISCUSSION

Our prospective study was performed to investigate the long-term efficacy, safety and durability of the results of non-ablative Er:YAG laser treatment used for treating symptoms of SUI. Er:YAG laser treatment has become a well-recognized therapy for SUI with several studies confirming the safety and effectiveness [6-12,17-19]. Some studies suggests that Er:YAG laser can be effective for treatment of mixed urinary incontinence [7, 20]. A comparison study of urethral sling surgery and non-ablative vaginal Er:YAG laser treatment (VEL) in patients with SUI showed similar improvement in the1-h pad test and ICIQ-SF for the tension-free vaginal tape (TVT) and VEL group, while in the Overactive Bladder Symptom Score, the VEL group showed significantly greater improvement compared to the TVT group [21].

Despite several studies having demonstrated a short-term effect of Er:YAG treatment for SUI, only a few studies have evaluated the long-term effect of the non-ablative Er:YAG therapy [22-24]. The ICIQ-UI SF questionnaire was used as primary tool for assessing the efficacy of the Er:YAG laser treatment. The data from the ICIQ-UI SF showed a statistically significant improvement of the SUI symptoms. The results are consistent with those of other studies using the same protocol (IncontiLase®). These studies reported a cure or improvement in 21% to 91% of patients at follow-ups between 3 to 12 months [6-11]. The reports of other studies using multiple treatments showed that the results last even longer [12,19,20]. Gaspar showed that the effect of three initial laser treatments is sustainable for 12–18 months, which is consistent with our observation [18]. He also showed that subsequent treatments result in maintaining the effect over a period of three years [20].

To use a more objective evaluation of the results of the treatment, ISI score, which is calculated from Q3 (frequency) and Q4 (severity) of the ICIQ-UI SF, was assessed (Table 2). Q5 of the ICIQ-UI SF represented the subjective part of the questionnaire, asking to what extent urine leakage interferes with the everyday life of the patients. The results of analyses of question Q4 showed an improvement from 2.98 before the treatment to 1.63 at the 3-month follow up. The results of analyses of question Q3 showed an improvement from 3.01 before the treatment to 1.19 at the 3-month follow up. The ISI Klovning score was 5.99 at baseline and 2.82 at the 3-month follow up (Table 2).

When comparing both outcome measures, a high correlation between the ISI and ICIQ-UI SF scores can be observed, but there were still some differences in the distribution of SUI symptoms severity, suggesting that quality of life represents an important part of a patient's expected improvement. In some patients even a small improvement can make big difference to their quality of life, while in other cases, we can observe that even high clinical improvement brings only a small improvement in quality of life. The expectations of the patient can have an important role when evaluating the satisfaction rate, so it is very important to realistically present the expected result of the treatment to the patients beforehand. In several studies, patient age was shown to be a significant independent predictive factor for Er:YAG laser treatment of SUI [10,24,25], while the study of Ogrinc et al. could

not show any relationship between patient age and success of the Er:YAG laser treatment [7]. In this study, age as well as parity were not found to be predictors of success in the Er:YAG laser treatment of SUI.

Laser therapy for stress urinary incontinence is highly accepted among patients. In our study 98% of the patients claimed that they would be willing to repeat the treatment, which is also consistent with other studies [17,26]. Patients often seek minimally invasive therapies, and as can be seen from our results, the most important measure of effectiveness for the patient is improvement in their quality of life.

V. CONCLUSIONS

The nonablative Fotona SMOOTH® erbium laser treatment showed efficacy in the improvement of female SUI with no major adverse effects noted. Patient discomfort during the treatment was minimal and satisfaction was very high. Non-ablative Er:YAG laser could be considered as a first line treatment option, especially for younger patients in their reproductive period seeking to improve their quality of life.

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