



Vaginal therapy of mild and moderate stress urinary incontinence using Er:YAG laser: a real treatment option

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Abstract

Purpose To evaluate the effectiveness of vaginal Er:YAG laser as treatment in patients with mild or moderate stress urinary incontinence.

Methods The study was a prospective, non-randomised, single center study of 33 women treated with two Er:YAG laser applications on an interval of four weeks. Follow-up evaluations were performed 4 and 8 weeks and 6 months after the first vaginal Er:YAG laser application (4 weeks and 5 months after the second vaginal Er:YAG laser application, respectively). The subjective outcomes were assessed using the International Consultation of Incontinence Modular Questionnaire Short Form (ICIQ-SF) and medical history. Patients rated their quality of life on a scale from 0 to 10.

Results The average quality of life (QoL) showed a significant improvement 5 months after both Er:YAG laser applications. The mean QoL score was 6.0 (SD 2.4) and improved to a mean of 7.6 (SD 1.8) ($p = 0.004$). The mean ICIQ-SF score changed significantly from 12.3 (SD 3.2, median 13, range 8–18) before treatment to 6.8 (SD 4.0, median 7, range 0–15) 6 months after treatment ($p < 0.001$). 24 patients out of 32 (75%) would again choose to have this therapy performed and 25 patients of 32 (78%) would recommend the vaginal Er:YAG laser therapy to a friend. The rate of side effects was low and none of the patients needed a medical treatment.

Conclusions This study confirms that vaginal Er:YAG therapy can improve clinical and quality of life outcomes in patients with SUI.

Introduction

Stress urinary incontinence (SUI) prevents women from enjoying a full and active life. SUI is caused by deterioration of the muscles, nerves and connective tissue that support and control pelvic organ function. The urethra and the anterior vaginal wall arise from the urogenital sinus, and are intimately connected. A stable anterior vaginal wall, against which the urethra is compressed during increases in abdominal pressure, is a component of the urinary continence mechanism [1]. Thus, the majority of therapeutical approaches aim at strengthening the pelvic floor, either conservatively or surgically.

The pubocervical fascia in stress incontinent women shows a diminished content of collagen [2, 3]. In recent

years, Er:YAG laser (so-called because it uses an erbium yttrium-aluminium-garnet medium) has been proposed for treating SUI. The treatment induces collagen reconstruction, thus improving the support of pelvic floor structures to, e.g. urethra and anterior vaginal wall. Specifically, erbium laser therapy results in controlled heating of the vaginal mucosa and consequently leads to collagen remodelling and neocollagenesis [4]. In biopsies collected from the anterior vaginal wall of women with SUI aged 37–62, before and 1.5–2 months after the second and last Er:YAG laser therapy session, Lapii et al. observed a significant thickening of the vaginal epithelium, a significantly improved density of capillaries and of numerous fibroblasts in vaginal stoma as well as a pronounced growth of elastic fibres in vaginal mucosa [5].

The aim of our study was to evaluate if the Er:YAG laser treatment improves SUI, since women are increasingly interested in non-surgical treatment modalities for SUI.

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Materials and methods

This prospective, single centre, non-randomized study was conducted at the Department of Obstetrics and Gynecology Tübingen in the period from February 2017 to April 2018.

33 women diagnosed with mild and moderate SUI and those with mixed urinary incontinence (MUI) with dominant SUI were included in the study. All of them had been scheduled for a surgical therapy, a tension-free vaginal tape (TVT) procedure and to all of them we offered the vaginal therapy using Er:YAG laser treatment. They had the option of a TVT procedure at the end of the study, in case the Er:YAG laser treatment did not lead to a sufficient therapeutical success.

Inclusion criteria were legal age, written informed consent, mild and moderate SUI and MUI with dominant SUI (grade I and grade II according to the Ingelmann–Sundberg classification). SUI grade I (mild) is defined as loss of urine with severe stress, such as coughing or sneezing. SUI grade II (moderate) is incontinence with minimal stress including walking or running or lifting objects from the floor [6, 7]. Exclusion criteria were pregnancy, previous radiotherapy of the small pelvis, previous malignant diseases of the uterus, ovaries, vagina and vulva, connective tissue disorders, previous surgery for SUI, a pelvic organ prolapse (POP) greater than stage I according to the Pelvic Organ Prolapse Quantification POP-Q system classification, and previous POP surgery with vaginal mesh.

Each patient had a detailed medical history, a urogynecological examination with measurement of vaginal length, urodynamics, a vaginal, abdominal and introital sonography before the enrolment in the study. After the patients had given their informed consent, they were asked to fulfil the ICIQ-SF questionnaire [8].

All women enrolled in the study were treated with two vaginal Er:YAG laser applications at an interval of 4 weeks. Every laser application consisted of two phases. The first, ablative phase, was performed with a fluence of 25 J/cm² (fluence – laser energy delivered per unit area) and a pulse length of 300 µs. The goal of this phase is to drill microchannels in the tissue up to the lamina propria of the vaginal wall and to stimulate collagen production in a mechanical way. The second, thermal phase, was performed with a fluence of 9 J/cm² and a pulse length of 1000 µs. The goal of this phase is to generate controlled heat in the superficial layers of the tissue that spreads to the deeper ones in order to have collagen shrinking as a result of a thermal effect. First the vagina was cleaned with disinfectant solution (Octenisept®) and dried with a swab. Afterwards the laser delivery handpiece was inserted into the vagina. The laser therapy was performed according to

the manufacturer's guide and was administered circularly at designated intervals from the apex of the vagina toward the introitus while the handpiece was withdrawn. During the two phases the full circumference of the vaginal canal was treated. The duration of each Er:YAG laser application was about 20 minutes and the therapy was performed in an outpatient surgery approved for laser therapy by local authorities. Er:YAG-Laser–Juliet, Asclepion Laser Technologies GmbH Jena Germany was used for treatment.

All procedures were performed by the same gynaecologist (CR). During the intervention, patients were placed in lithotomy position without anaesthesia and any medication. After treatment, patients were told to avoid sexual intercourse and not to bathe for 3 days.

Follow-up evaluations were performed 4 and 8 weeks and 6 months after the first vaginal Er:YAG laser application (4 weeks and 5 months after the second vaginal Er:YAG laser application respectively). At each follow-up visit the patients had a detailed medical history and completed the ICIQ-SF questionnaire and rated their quality of life on a scale from 0 to 10. Furthermore adverse events in relation to the laser treatment were recorded. At their last visit patients were asked to answer the following questions: “Would you again choose to have this therapy performed?” and “Would you recommend the treatment to a friend?”. Table 1 shows an overview of the study design.

For the study Asclepion Laser Technologies GmbH Jena Germany provided us with the Juliet Laser and the single use handpiece adapters. For the patients included in the study the therapy was charge free.

Statistical analyses

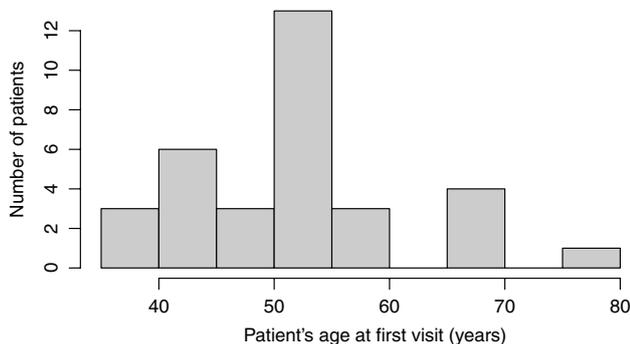
The aim of the study was to evaluate the effectiveness of the Er:YAG laser therapy in women with mild and moderate SUI on the basis of the improvement of the quality of life (on a scale 0 to 10 and the medical history) and of the ICIQ-SF score based on the before-and-after effect on urinary incontinence. Continuous variables were characterized by mean and standard deviation (SD) with median and range. The change in quality of life and ICIQ-SF score between the first and last visit was assessed by the paired Wilcoxon rank test. A significance level of 5% was chosen. All statistical analysis was done using R, version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria).

Ethical approval

The study protocol was approved by the Clinical Ethics Committee at the University Hospital of Tübingen (192/2017BO1) and was registered with ClinicalTrials.gov (NCT 03267719).

Table 1 Study design: vaginal therapy of mild and moderate SUI using Er:YAG laser

Data and time of collection	Baseline visit (day –14 to –1)	Visit 1 Laser therapy 1 (day 1)	Visit 2 Follow-up 1 (approx. 1 month after visit 1) Laser therapy 2 (approx. 1 month after laser therapy 1)	Visit 3 Follow up 2 (approx. 1 month after visit 2)	Visit 4 Follow up 3 (approx. 4 months after visit 3)
Age, height, weight, deliveries, stress incontinence severity, length of the vagina	×				
ICIQ-SF questionnaire		×	×	×	×
Quality of life (on a scale 0 to 10)		×	×	×	×
Medical history		×	×	×	×
Questions concerning side effects of the therapy			×	×	×
Questions regarding recommendation of the therapy					×

**Fig. 1** Patient's age at first visit

Results

33 women diagnosed with mild and moderate SUI and MUI with dominant SUI, respectively, scheduled for a surgical therapy with a tension-free vaginal tape (TVT) procedure, were enrolled in the study after they had given their written informed consent.

At the time of the first vaginal Er:YAG laser application the patients were 51.9 years old (SD 9.8 years, median 51.8 years, range 35.1–75.9 years) (Fig. 1). Their mean body mass index (BMI) ranged from 16.9 kg/m² to 38.1 kg/m² with a mean of 26.0 kg/m² (SD 5.1 kg/m², median 24.7 kg/m²). Two out of 33 women (6%) were uniparous and 31 out of 33 women (94%) were multiparous. Six patients (18%) had no vaginal delivery, 29 (88%) had one or more vaginal deliveries, of which four (12%) had an operative delivery (vacuum extraction or forceps).

23 out of 33 patients (70%) suffered from SUI and 10 out of 33 patients (30%) suffered from MUI with dominant SUI. Seven out of 33 women (21%) had grade I and 26

Table 2 Side effects after vaginal therapy of mild and moderate stress urinary incontinence using Er:YAG laser

Side effect	Number of patients	Period of time
Vaginal discharge, spotting	7	1 day to 3 weeks
Burning sensation and irritation	4	3 days to 4 weeks

patients (79%) had grade II SUI according to Ingelman-Sundberg classification.

The mean vaginal length was 7.8 cm (SD 1.1 cm, median 8.0 cm, range 5.5–10.0 cm).

During the procedure patients reported minimal discomfort described as a sensation of warmth or irritation. Following the first Er:YAG laser application 10 women (30%) experienced vaginal discharge, spotting, burning sensation and/or irritation for some days up to 4 weeks (Table 2). After the second Er:YAG laser application eight (24%) patients reported the same side effects as after the first application. None of the patients who reported side effects needed medical treatment. Patients were able to return to normal activities on the same day.

The average quality of life (QoL) showed a significant improvement 5 months after both Er:YAG laser applications (follow-up 3). The mean QoL score was 6.0 (SD 2.4, median 7, range 0–10) before treatment and improved to a mean of 7.6 (SD 1.8, median 8, range 4–10) ($p = 0.004$) (Fig. 2). While the QoL improved for 22 patients, seven women had a lower QoL at the end of the study and for four women QoL remained unchanged.

The mean ICIQ-SF score, which assesses the frequency and severity of incontinence, changed significantly from 12.3 (SD 3.2, median 13, range 8–18) before treatment to 6.8 (SD 4.0, median 7, range 0–15) 6 months after treatment (p

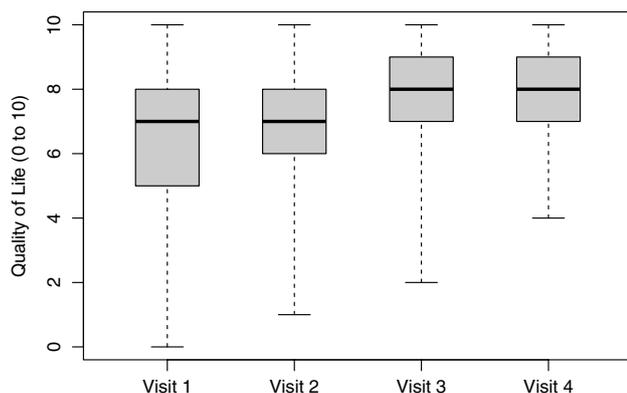


Fig. 2 The effect of Er:YAG laser therapy on the Quality of life of the patients during the study

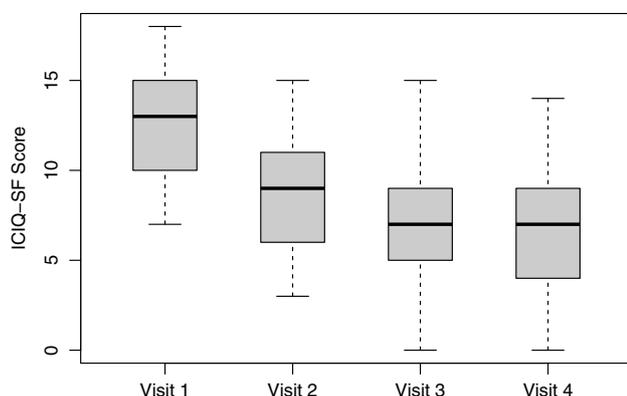


Fig. 3 The effect of Er:YAG laser therapy on the ICIQ-SF score during the study

<0.001) (Fig. 3). The ICIQ-SF score improved for 31 out of 33 women, it remained unchanged for one and deteriorated for one woman. According to the medical history 5 months after both vaginal Er:YAG laser applications, 12 out of 33 women (36%) were continent, 11 (33%) reported a considerable improvement of SUI, 2 (6%) had a mild improvement, 3 (9%) had a temporary improvement but 5 patients (15%) did not feel any improvement. At the end of the study, 8 out of 33 women (24%) underwent a TVT operation. The TVT operation was performed in those women who were not satisfied with the therapeutical success (mild or temporary or no improvement) after the Er:YAG laser treatment. The TVT operation was performed by the same surgeon (CR). Intra-operatively, dissection was not different from that in patients who did not have a vaginal Er:YAG laser therapy before.

24 patients out of 32 (75%) stated that they would again choose to have this therapy performed and 25 patients of 32 (78%) would recommend the vaginal Er:YAG laser therapy to a friend. One patient out of 33 did not answer the questions. 25% of the patients would not again choose to have

the therapy performed because of the side effects experienced and the therapeutical success which was lower than expected.

Discussion

Five months after the two vaginal Er:YAG laser applications at an interval of 4 weeks, 12 out of 33 (36.3%) women were subjectively continent, 11 (33.3%) women had considerably improved and 10 (30.3%) women reported mild or no improvement of their SUI. All patients included in the study had been scheduled for a TVT procedure. Five months after the pre-switched vaginal Er:YAG laser therapy, only 8 out of 33 continued to wish a TVT and were scheduled for surgery.

The effect of the Er:YAG laser therapy in women with SUI was proven by Blaganie et al. 114 premenopausal parous women with SUI were randomized in two groups of 57 women: a laser intervention group (Er:YAG laser) and a sham group (no energy output). Three months after a single session Er:YAG laser therapy of the vaginal canal, the mucosa of the vestibule and the introitus, 21.4% (12/56) of the patients in the laser group were dry (ICIQ-SF score 0), whereas only 3.6% (2/56) of patients in the sham control group were dry [9].

Gambacciani et al. treated 114 postmenopausal women suffering from SUI with three Er:YAG laser applications (vaginal wall, vestibule and introitus and anterior vaginal wall) at 30-day intervals (L1, L2, L3). The laser treatment induced a significant decrease in the ICIQ-SF scores from basal values of 12.2 ± 2.5 to 8.0 ± 1.4 at L1 to 4.7 ± 1.8 at L2, and 5.1 ± 2.0 at L3. Follow-up evaluations were performed after 1 (T1), 3 (T3), 6 (T6), 12 (T12), 18 (T18) and 24 (T24) months after the last laser application. The ICIQ-SF scores remained significantly lower than basal values after 1 (4.8 ± 1.8), 3 (6.2 ± 1.9), 6 (7.0 ± 2.3) and 12 (8.0 ± 1.8) months after the last Er:YAG laser application. The values measured 18 (9.3 ± 2.7) and 24 (9.9 ± 2.8) months after the last Er:YAG laser application were, however, not significantly different from the basal values [10]. The results of this study suggest that, on one hand, one-third Er:YAG laser application did not improve SUI more than the first two applications and, on the other hand, that the improvement of SUI diminished continuously so that the ICIQ-SF scores at the follow-up visit 18 and 24 months after the last Er:YAG laser therapy did not differ significantly from the basal values.

In literature neither number and phases of laser applications nor the area of the vagina which is irradiated are standardized so far.

The effect of the Er:YAG laser therapy on SUI is demonstrated by subjective and objective outcome parameters. In their study, Ogrinc et al. treated 175 women with SUI

and MUI by Er:YAG laser, performing on average 2.5 ± 0.5 applications in each woman, separated by a 2-month period. After one year follow-up, SUI significantly improved in 77% women while in patients diagnosed with MUI only 34% of the patients improved. The subjective outcomes were assessed by ICIQ and ISI (Incontinence severity index) questionnaires. Furthermore they showed that age (49.7 ± 10 years) did not affect the outcome of urinary incontinence treatment using vaginal Er:YAG laser [11].

Most of the studies evaluated SUI after Er:YAG laser therapy based on subjective outcomes. Objective success rate (cure and improvement rate) of SUI after Er:YAG laser therapy reported by Tien et al. was 78.6%. An objective cure was defined by pad weight ≤ 1 g after 20-min pad test at 6 months after treatment, and improvement was indicated by a $> 50\%$ decrease in pad weight at 6 months, compared with the preoperative data. However, urodynamic values did not differ along the timeline [12].

In his study Okui compared the effect of TVT, TOT and Er:YAG laser therapy on SUI using the 1-h pad test and ICIQ-SF score before and 12 months after treatment. The sample included 50 patients who underwent the TVT procedure in 2014 (TVT group), 50 who underwent the TOT procedure in 2015 (TOT group), and 50 who underwent the ER:YAG laser therapy in 2016 (laser group therapy) by numerical order of their medical charts. Laser therapy was first performed for 10 min on the entire anterior wall of the vagina, then 5 min for the entire vagina, and 5 min around the urethra for three times every alternative month. The 1-h pad test and ICIQ-SF score significantly improved in all three groups [13].

In our prospective study, the selection of the patients has been unique so far, as 33 women diagnosed with mild and moderate SUI and MUI with dominant SUI, scheduled for surgical therapy with tension-free vaginal tape (TVT) procedure were enrolled in the study. According to medical history 23 out of 33 patients showed a cure or improvement of SUI. The average quality of life (QoL) showed a significant improvement and the mean ICIQ-SF score changed significantly 5 months after the second Er:YAG laser therapy. Only 8 (24%) of 33 women needed a TVT procedure at the end of the study.

The TVT surgery was performed by the same surgeon (CR). Intraoperatively, neither macroscopical changes nor differences during the tissue preparation were observed compared to those patients who did not have a vaginal Er:YAG laser therapy before. Undoubtedly our study has limitations due to the relatively short follow-up. The side effects were mild and needed no treatment. They coincide with those reported in literature. 75% of the patients would again choose to have this therapy performed and 78% of the women would recommend the vaginal Er:YAG laser therapy to a friend.

Conclusion

The vaginal Er:YAG laser application is a new, promising, minimally invasive therapy in the treatment of mild and moderate female SUI. Furthermore, women are increasingly interested in non-surgical treatment modalities for SUI. Nevertheless, further studies are needed to show long-term results of vaginal Er:YAG laser therapy in comparison to the efficacy of conventional treatments of SUI.

Authors' contribution CR: Protocol/ project development, data collection and management, data analysis, manuscript writing and editing. SH: Protocol development, data collection and management, data analysis, manuscript editing. BS: Protocol development, statistical analysis, manuscript editing. SYB: Data analysis, manuscript editing. FN: Project administration, supervision, data writing.

Compliance with ethical standards

Conflicts of interest For the study Asclepion Laser Technologies GmbH Jena Germany provided us with the Juliet Laser and the single use handpiece adapters. Our research did not involve animals.

Informed consent From all human participants Informed consent was obtained.

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