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Original Article

Preliminary outcome of non-ablative vaginal Erbium laser treatment for female stress and mixed urinary incontinence

Chi-Feng Su ^{a,*}, Gin-Den Chen ^b, Horng-Jyh Tsai ^a^a Department of Obstetrics and Gynecology, Kuang Tien General Hospital, Taichung, Taiwan^b Department of Obstetrics and Gynecology, Chung Shang Medical University Hospital, Taichung, Taiwan

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ABSTRACT

Objective: This prospective study presents a preliminary result to compare the clinical efficacy of patients with stress urinary incontinence and mixed urinary incontinence using minimal invasive Er:YAG vaginal laser.

Materials and methods: A total of 20 patients were included, in which were 10 patients with SUI and 10 patients with MUI (stress and urge incontinence), and underwent a 2940 nm Er:YAG laser with a special SMOOTH mode in an outpatient office without anesthesia or postoperative medications. All patients completed two sessions of treatment with an interval time of 28 days. At three months after treatment, all patients were asked to a clinical visit for evaluate the clinical outcome by pre-treatment and post-treatment ICIQ-SF questionnaire. At pretreatment and 3 months after the completion of two therapy sessions, patients were asked to answer the ICIQ-SF questionnaire. The questionnaire consists of three scales for assessment of the treatment outcome of urinary incontinence as: no change (no change score), improvement (decrease score 1–5), and strong improvement (decrease score >5) for two groups of patients with SUI and MUI. All the results were compared by Student's t test with two way analysis of variance between the two groups.

Results: A total of 20 patients presented with SUI symptom relief and improvement with treatment satisfaction. All 10 patients with SUI reported improvement after vaginal laser treatment, 70% with marked improvement and 30% with improvement. All 10 patients with MUI also had improvement, 40% with marked improvement and 60% with improvement. There was no statistically significant difference in the treatment outcome between the two groups.

Conclusions: Vaginal Erbium laser produce provides vaginal collagen remodeling and synthesis that may repair and restore the pelvic floor function. Despite of sample limitation and short follow up, this treating procedure presented a good and a safe clinical outcome in patients with SUI and with MUI by assessment of ICIQ-SF questionnaire.

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Introduction

Stress urinary incontinence (SUI) is the most common form of urinary incontinence and is defined as the involuntary leakage of urine during increased abdominal pressure (e.g a sneeze, a cough or sudden exertion) by the International Continence Society [1,2]. Mixed urinary incontinence (MUI) is the coexistence of stress (SUI) and urge urinary incontinence (UUI) and is defined as involuntary loss of urine associated with the sensation of urgency and

associated with exertion effort, sneezing, or coughing [3]. The etiology of urge urinary incontinence (UUI) is not well known. Urine leakage caused by abnormal bladder contractions maybe due to aging, bladder inflammation, infection or outlet obstruction. Approximately 63% of all women with urinary incontinence are diagnosed with stress urinary incontinence (SUI), 19%–25% have urge incontinence (UI), and 12–19% have mixed incontinence (MI) [4]. In the past two decades, the use of mid-urethral slings for treating SUI has achieved an 85–95% success rate [5], but it has also been associated with some adverse effects such as vaginal erosion, infection, pain, and recurrence [6]. However, there is great variability in treatment outcomes for MUI following mid-urethral sling or other anti-incontinence surgery for both the stress and urge

* Corresponding author. No.117, Shatian Road Shalu District, Taichung City, 433, Taiwan. Fax: +4 26653500.

E-mail address: kurrysu@yahoo.com.tw (C.-F. Su).

components. The urge component may be resolved, persist or worsen after surgery [7].

Some literature has revealed that SUI and pelvic floor dysfunction are associated with decreased collagen content and production of pre-urethral or pelvic connective tissue and ligaments [8–10]. Recently, lasers have been widely used in the field of dermatology and aesthetic medicine because lasers not only enhance collagen structures but also stimulate neocollagenesis. Fistonc et al. used the Er:YAG vaginal laser to treat women with SUI and found that the thermal energy effects of the Er:YAG vaginal laser can enable collagen remodeling and neocollagenesis within vaginal mucosa [11–13]. They have recommended non-ablative Er:YAG laser treatment as an effective, safe and comfortable treatment option for symptom relief in patients with SUI.

In this study, we reported the preliminary results of the vaginal Er:YAG laser in treating women with pure SUI and women with MUI.

Materials and methods

From April 2014 to January 2015, 10 patients with mild-to-moderate SUI and 10 patients with MUI were recruited into this study. All patients underwent treatment with a 2940 nm Er:YAG vaginal laser (XS Dynamis, Fotona, Slovenia). The study protocol and the use of the International Consultation on Incontinence Questionnaire - Short Form" (ICIQ-SF)" questionnaire [14] for the outcome measurement were approved by the Institutional Review Boards of Kuang Tien General Hospital.

The inclusion criteria were: no active vaginal bleeding and infection, normal cell cytology (PAP smear), normal urinalysis, average age about 34–60 years old, body mass index about 18–23 kg/m², SUI (positive cough test, 1–10 g of pad test) with or without mild prolapse (pelvic organ prolapse stage I to II) according to POP-Q system [15], or MUI (positive cough test, 1–10 g of pad test, urgency and frequency, urge form and stress form UI) with or without mild prolapse (pelvic organ prolapse stage I to II). All of the patients had at least one parous status (delivered vaginally or abdominally) and had no prior pelvic surgery, medical treatment, and physical therapy for incontinence and prolapse.

The treatment is performed using a non-invasive and non-ablative Er:YAG vaginal laser in an outpatient clinical setting. Before the procedure the patient is placed in the lithotomy position, and the patient's vagina is thoroughly washed with disinfectant solution and dried off with a swab. No general anesthesia is used. Xylocaine (lidocaine HCl) 2% Jelly is applied to the vestibule and introitus for 3–5 minutes as a topical anesthesia before treatment, if the patients fear of pain.

A specially designed speculum is inserted into the patient's vagina and well positioned. The laser beam delivery probe (R11 circular handpiece) is then introduced into the vagina and enables 360° laser irradiation of the vaginal canal. Laser energy is applied on the vaginal wall, at the spot size of 7 mm, a frequency of 1.6 Hz, and a fluence of 10 J/cm², in circular belt-shaped patterns, and deposits four pulses on the vaginal canal without overlapping via every 5 mm withdrawal of the R11 handpiece outwards from the laser speculum. The four pulses of energy can reach the treatment depth of 500–700 μm in vaginal mucosa [12]. The procedure is repeated three times rotating the speculum by 45° each time, ensuring the optimal distribution of laser energy to vaginal mucosa. This first phase designed for vaginal tightness produces a thermal effect on the whole vaginal canal that causes immediate tissue shrinkage, collagen remodeling and new collagen synthesis in the vaginal mucosa. The second phase is uses a different probe (PSO3 angular handpiece) and enables 90° laser irradiation of the anterior vaginal wall. The laser energy is the same as the R11 probe

procedure, but is applied along the anterior vaginal wall in five longitudinal passes, at 10, 11, 12, 1, and 2 o'clock directions. This second phase designed for urinary incontinence produces a thermal effect on the anterior vaginal wall that causes mid-urethral tissue lifting by shrinkage of collagen and new collagen synthesis. At the final phase (only for vaginal tightness), after removing the speculum, the vestibule and introitus are irradiated by the PSO3 straight-shooting handpiece at the same laser energy for the thermal impact to vaginal collagen. Patients are requested to restrain from sexual activities for a period of 72 hours. After every treatment session, patients went home without any medication.

The absorbing chromophore of Erbium is water with a wavelength of 2940 nm. The technique SMOOTH mode is at the spot size (diameter of the laser beam on the target) of 7 mm, a frequency of 1.6 Hz, and a fluence (laser energy delivered per unit area) of 10 J/cm². This specific mode distributes the heat several hundred micrometers into the vaginal mucosa (epithelium and lamina propria), and achieves a controlled deep thermal effect (the treating depth reaching 500–700 μm). The thickness of vaginal mucosa varies and is normally several hundred micrometers. Therefore, the SMOOTH mode pulses allow controlled tissue heating, in a safe and harmless ambulatory procedure without ablation and carbonization of the mucosa tissue, practically avoiding the risk of perforation with accidental lesions of the urethra, bladder or rectum [16]. Patients were treated in two sessions with an interval time of 28 days, avoiding the menstrual period.

Follow-ups were scheduled within one week after each session via telephone interview with the patients. At pretreatment and 3 months after the completion of two therapy sessions, patients were asked to answer the ICIQ-SF questionnaire. The questionnaire consists of three scales for assessment of the treatment outcome of urinary incontinence as: no change (no change of ICIQ-SF score), improvement (decrease of ICIQ-SF score 1–5), and strong improvement (decrease of ICIQ-SF score >5) for two groups of patients with SUI and MUI.

All the results were compared by Student's t test with two way analysis of variance between the two groups. The statistical significance level was set at 0.05. The Sigma Stat View software (SPSS Science, Chicago, IL, USA) was used for statistical analysis.

Results

A total of 20 patients (10 patients with SUI and 10 patients with MUI) underwent the Er:YAG vaginal laser treatment successfully in an outpatient office. The average treatment time was 30 minutes. All 20 patients returned for a clinical 3-month follow-up. Most patients reported the vaginal treatment as totally painless. Only mild pain and a burning sensation were noted during the treatment of the introitus area with the PSO3 straight-shooting probe. Patients returned to their daily activities immediately after treatment and no adverse effects were reported.

Table 1

Characteristics of patients with stress urinary incontinence or mixed urinary incontinence and outcomes of the vaginal Er: YAG laser treatment after three month follow-up.

	SUI (n = 10)	Mixed UI(n = 10)
Age, years (range)	46.5 (36–59)	45.5 (34–54)
Parity, median (range)	2 (1–3)	2 (1–3)
BMI, kg/m ² (range)	20.97 (18.8–23.4)	20.36 (18.3–23)
Outcome *		
No change	0	0
Improvement, n (%)	3 (30%)	6 (60%)
Marked improvement, n (%)	7 (70%)	4 (40%)

*P > 0.05.

There were no significant differences in age and parity in the two treatment groups in our study (Table 1). A total of 20 patients presented with SUI symptom relief and improvement with treatment satisfaction. All 10 patients with SUI reported improvement after vaginal laser treatment, 70% with marked improvement and 30% with improvement. All 10 patients with MUI also had improvement, 40% with marked improvement and 60% with improvement. Patient distributions (in percentage) based on improvement at the 3-month follow up are shown in Fig. 1. There was no statistically significant difference in the treatment outcome between the two groups.

Discussion

Our preliminary results show 70% with marked improvement in patients with mild to moderate SUI and 40% in patients with mixed UI at the three month follow-up. These results imply that the Er:YAG vaginal laser can be a possible future option in treating mild to moderate SUI and mixed UI, although there is a need of more randomized, controlled and prospective data, with a larger number of patients and longer follow-up.

This novel Eb:YAG laser technology was used in urogynecology for the treatment of vaginal laxity, stress urinary incontinence, pelvic organ prolapse and vaginal atrophy during the period from 2010 to 2014. The results have shown SMOOTH-mode laser procedures to be an effective and safe method for treating all four indications [11,17,18]. The laser-generated thermal energy has been applied to produce vaginal collagen hyperthermia, followed by collagen remodeling and the synthesis of new collagen fibers, resulting in improved vaginal tissue tightness and elasticity [17,19,20]. The Er:YAG laser in SMOOTH mode used in gynecology is based on a concept of controlled heating of the vaginal mucous tissue up to approximately 65 °C i.e. to the optimal temperature range, without exceeding the temperature threshold for surface ablation or irreversible denaturation of collagen [17,21,22]. The thickness of vaginal mucosa typically varies several hundred micrometers or several millimeters [23]. Studies have shown that laser energy achieves a mucosal depth of 100–700 micrometers [13,23]. A precisely controlled pulse duration by the Er:YAG laser delivered to the mucosal tissue can achieve a controlled heating of the collagen in the deeper mucosal layers without overheating the vaginal mucosa. Vaginal laser energy is safe without any resulting

ablation or injury as the separation pulses are longer than the thermal relaxation time of the mucosal tissue in order to provide sufficient time for cooling [23]. The thermal effect on collagen is momentary in collagen remodeling and synthesis during the procedure, and neocollagenesis can continue up to 6 months to reach its full completion [17]. Some published data have shown the well established facts of using Er:YAG laser in treating female vaginal relaxation, urinary incontinence, and vaginal atrophy [11–13,17,23]. Their treatment protocols are mentioned as follows: The IntimaLase (indicated for vaginal relaxation) and IncontiLase (indicated for urinary incontinence) protocols include two treatment sessions with a 4–6-week interval. The time needed to execute the IntimaLase protocol is approximately 8 minutes and for IncontiLase around 15 minutes. The ProlapLase protocol for treatment of pelvic organ prolapses is based on the protocols for vaginal tightening and incontinence, and requires three to five sessions at 4–6-week intervals. The number of sessions is dependent on the severity of the prolapse. Therefore, we combined the protocols of IntimaLase and ProlapLase for treating our patients with SUI and MUI with or without mild prolapse.

To the best of our knowledge, Ogrinc UB et al. [24] first reported of using the Er:YAG laser for treating patients with MUI. In their patients with SUI as assessed before the treatment urinary incontinence significantly improved in 77% of the cases while the patients diagnosed with MUI prior to the treatment only improved in 34% of the cases. In their conclusion, vaginal Erbium laser could be regarded as a promising additional treatment strategy for SUI with at least one year lasting positive effects. But, it does not seem appropriate for treating MUI. In our study, we found this procedure for treating patients with MUI also showed good efficacy, improvement (60%) and marked improvement (40%) after a three month follow up. Women with MUI experience symptoms of both urge incontinence and stress incontinence and have a poor response to conservative or surgical interventions [6]. However, in our study, we found similar treatment outcomes in patients with SUI and MUI.

Possible mechanisms of effects of the Eb:YAG vaginal laser in treating SUI and MUI might be as follows: The Eb:YAG vaginal laser triggers collagen remodeling and synthesis of vaginal mucosa, which may strengthen the elasticity and tissue density underneath the urethra to repair the structure and restore its function. Recently, Gaspar et al. showed that non-ablative intraurethral (a

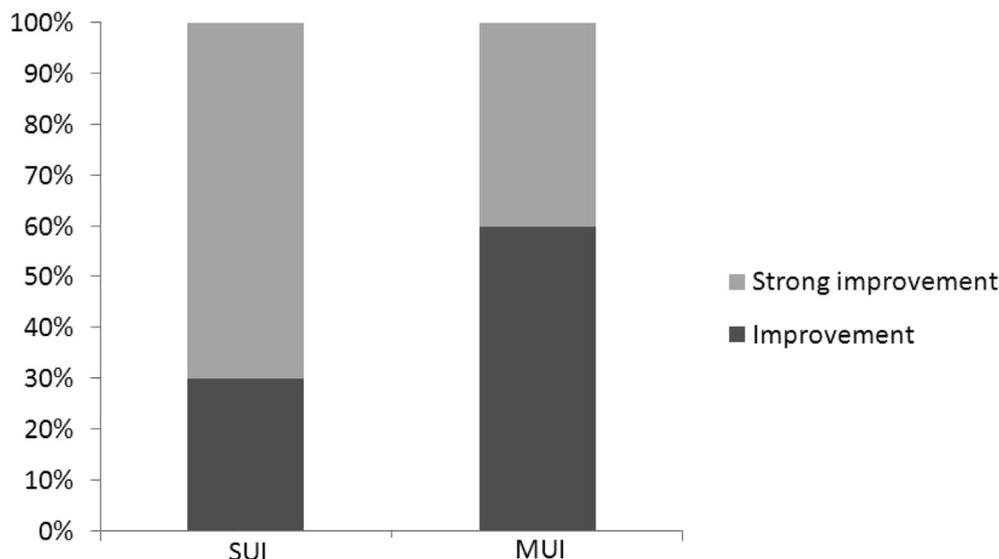


Fig. 1. Patient distribution in percentage (%) based on improvement in 3 months follow up.

specially designed cannula) Er:YAG laser also has a safe and efficacious outcome in treating patients with intrinsic sphincter deficiency [25].

The small sample size and short term follow-up are limitations in our study. Our preliminary results revealed equal treatment outcome between SUI and MUI groups by assessment of ICIQ-SF questionnaire. However, the mechanism of vaginal Er:YAG laser in treating MUI, long term follow-up and large sample size still require the further study.

Conflict of interest

None declared.

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