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Treatment of female stress urinary incontinence with Erbium-YAG laser in non-ablative mode

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ABSTRACT

Objective: To evaluate the efficacy of laser photothermal therapy in a group of Chilean women with SUI.
Material and methods: Longitudinal prospective study based on 42 women with mild-to-severe SUI, intervened with non ablative Er:YAG laser, between July 2014 and October 2015, in Santiago, Chile. The therapy efficacy was evaluated through the difference between every patient's scores obtained, before and after treatment, with the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-SF), at a confidence level of 95%. Also, the patient satisfaction with treatment was reported through an ordinal scale.
Results: ICIQ-SF median score was 11 before treatment and 3 after 6 months, with a significant difference per patient ($p < 0.001$). 78.6% ($n = 33$) reported improvement and 38.1% ($n = 16$), a complete healing of SUI at follow up. 66.7% ($n = 28$) reported high satisfaction and 81.8% ($n = 27$) of sexually active women, also reported improvement of sexual gratification. Only mild pain during the procedure was reported as adverse effect.
Conclusions: Based on this short-term pilot study, non-ablative Er:YAG laser procedure seems to be a safe and efficacious alternative for patients with SUI. Further controlled studies will help to validate the use of non-ablative Er:YAG for treatment of SUI.

Introduction

Female stress urinary incontinence (SUI) is a highly prevalent lower urinary tract dysfunction, most commonly affecting middle-aged and elderly women [1,2]. Although the etiology of SUI is not fully understood, the risk factors for the condition include congenital factors, pregnancy, childbirth, hipoestrogenism, cognitive impairment, obesity, and advanced age [2]. Because of increased awareness about SUI, more and more physically active younger women, mostly with mild and moderate SUI, are seeking professional help for their condition.

There are many possible nonsurgical and surgical therapies for SUI; however, TVT (tension-free vaginal tape) has been considered like gold standard in SUI [3,4]. Initial therapy involves nonsurgical options such as behavioral changes in terms of diet reduction for overweight patients, smoking cessation and pelvic floor muscle training (PFMT) [5]. Although good results can be achieved with PFMT, the long-term improvement is hard to maintain due to lack of training and poor patient persistence [6]. Drug therapy also may reduce SUI [7].

Surgical procedures are more effective for SUI than nonsurgical therapies, but are sometimes associated with adverse effects and complications, such as bleeding, bladder perforation, urethral injury, infection, groin pain and a sexual abstinence period of 6 weeks after surgery [7]. In TVT, that can be retropubic or transobturator, slings are used in order to prevent urethral descent at the time of increased intrabdominal pressure [8–10]. In recent years, less invasive single incision mini-slings have been introduced and have become very attractive; however, they have been associated with unwanted side effects as obstruction and voiding dysfunction [10,11].

Many researchers are looking for a non-invasive and safer treatment options, and recently surgical treatment is often replaced by non-invasive therapies, such as electrical stimulation,

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radiofrequency and laser photothermal therapy [6,7,12]. Studies have demonstrated remodeling and *de novo* synthesis due to photothermal effect of laser irradiation [13,14]. Since synthesis of collagen, an important component of pelvic floor supportive structures, slows down due to aging, laser-mediated heating of pelvic floor tissue could represent an effective non-surgical method for treating disorders associated to diminish pelvic floor support. In fact, Er:YAG laser therapy have been previously described as an effective and safe option for different gynecological applications, such as SUI, vaginal relaxation syndrome and vaginal atrophy [15–18].

The aim of the present study is to evaluate the short term effectiveness and safety of minimally invasive non ablative Er:YAG laser therapy for female SUI, using a validate questionnaire.

Materials and methods

Pilot prospective study was performed between July 2014 and October 2015 in Clinica Sara Moncada, a private health center in Santiago, Chile.

The inclusion criteria for this study were a mild-to-severe SUI, to complete the interviews and to provide a written informed consent, voluntarily. The exclusion criteria were: exclusive urge incontinence, severe prolapse, pregnancy, previous surgery due to treated condition, patients with severe neurological conditions, vaginal lesions, genitourinary tract infections, abnormal vaginal bleeding, history of photosensitivity disorder or use of photosensitizing drugs and hematuria. According to these criteria, 42 female patients were included in the study.

The degree of SUI, and its impact on quality of life, was assessed using the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) [23], applied in person by a unique medical doctor. This questionnaire has been validated in Spanish [20] and, recently, to be used in the Chilean population [21]. The results of the ICIQ-UI SF were divided into the following four severity stages: slight (1–5), moderate (6–12), severe (13–18) and very severe (19–21) [19], as suggested by Klovning et al. [22].

To assess the improvement of SUI symptoms and the improvement of quality of life after the treatment, follow up was performed at 3–6 months using ICIQ-SF questionnaire, by telephone interviews performed by a non-medical assistant. We consider as an improvement of SUI, an ICIQ-SF score after treatment lower than that reported prior to treatment, without consider the change in the severity stage. The differences between both scores and severity stages per patient were tested for statistical significance with the Wilcoxon signed-rank test, at a confidence level of 95%. A possible association of improvement of SUI to age and the number of vaginal deliveries was evaluated through a multiple logistic regression model, at a confidence level of 95%.

Although it was not the main objective of this study, patient's satisfaction with the treatment and sexual life improvement were also reported, across an ordinal scale: no satisfaction, low, moderate or high satisfaction.

All information was gathered on a database, which was created and analyzed with the statistical software program Stata® 12.1, licensed for one of the author.

Ethics Committee of the Clinica Sara Moncada approved the research protocol on June 20, 2014, by resolution number 3.

All patients were treated according the three-step protocol using 2940 nm Er:YAG laser (Fotona Smooth™ XS, Fotona, Ljubljana, Slovenia) in non-ablative thermal only mode, equipment owned by one of the authors. The treatment was performed using outpatient clinical setting and no specific preparations or post treatment medications were needed. Although no regional or general anesthesia was required, we used topic anesthesia (1% procaine, 1% benzocaine, 1% lidocaine), which was applied with a vaginal gauze impregnated 20 min prior the procedure. All the postmenopausal women with vaginal atrophy, and no hormonal replacement therapy, were treated with local estrogen (estriol) before treatment.

Regarding the treatment protocol, this includes three steps. In the first, irradiation of the whole vaginal wall was performed, using the full beam handpiece with circular adapter. Four passes were performed with fluence of 3 J/cm^2 rotating the speculum by 45° each pass. In the second step, the anterior vaginal wall was irradiated from the most distal point toward the introitus using patented handpiece with angular adapter, which was introduced to the vagina using specially designed speculum. Laser energy, with fluence of 6 J/cm^2 in burst of 4 consecutive smooth pulses at frequency of 1.6 Hz, was applied along anterior vaginal wall in 10 longitudinal passes, avoiding overlapping. In the final step, irradiation of the vestibule and the introitus was performed with straight shooting patterned handpiece and fluence of 10 J/cm^2.

No anesthesia was used during the treatment. The patient discomfort and treatment tolerability as well as adverse effects were monitored during and after the treatment. No special post-operative therapy was needed; patients were only advised to avoid increased intra-abdominal pressure, as well as, sexual intercourse at least 3 days after the treatment. They were discharged immediately after the procedure.

The therapy consisted of two treatment sessions with 21–28 days interval between sessions.

Results

All 42 patients completed the study. The age range was 30 and 79 years (median: 46.5, IQR: 17 years). The median delivery per patient was 2 (IQR: 1, range: 0–5) (Table 1). 81.1% ($n = 86$) of all births ($n = 106$) were vaginal deliveries.

ICIQ-SF median score before treatment was 11 (IQR: 6, range: 3–20). 9.5% ($n = 4$) of all patients had a slight SUI, 47.6% ($n = 20$) moderate, 40.5% ($n = 17$) severe and 2.4% ($n = 1$) had a very severe SUI (Fig. 1a).

Follow-up was performed at a median of 5 months (IQR: 2, range: 3–6) after treatment.

The post-operative ICIQ median score was 3 (IQR: 10, range: 0–18). The difference between the two scores per patient was significantly different and lower than zero ($p < 0.001$; $z = -5.038$). 26.2% ($n = 11$) were considered as slight SUI, 23.8% ($n = 10$) moderate and 11.9% ($n = 5$) severe SUI after treatment (Fig. 1b). 38.1% ($n = 16$) of all patients reported a complete healing of SUI at follow up (no SUI symptoms); among which, 18.8% ($n = 3$) described a slight SUI before treatment, 37.5% ($n = 6$) a moderate SUI and 37.5% ($n = 6$) a severe SUI and included the woman with very severe SUI (ICIQ score 20) before treatment.

Among 42 patients, the improvement was reported in 78.6% ($n = 33$), which was not related to age ($p = 0.091$) or the number of vaginal deliveries ($p = 0.550$) in multiple logistic regression

Table 1
Patient features and ICIQ-SF score before the therapy and at follow up.

	p50 (p25–p75)	Range
Age (years)	46.5 (42–57)	30–79
Deliveries	2 (2–3)	0–5
Vaginal	2 (1–3)	0–5
Cesarean	0 (0–1)	0–2
ICIQ score before	11 (8–14)	3–20
ICIQ score after	3 (0–10)	0–18
Follow up (months)	5 (4–6)	3–6