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Original Article

Effect of non-ablative laser treatment on overactive bladder symptoms, urinary incontinence and sexual function in women with urodynamic stress incontinence

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ABSTRACT

Objective: To investigate the effects of non-ablative laser treatment on overactive bladder (OAB) syndromes, stress urinary incontinence and sexual function in women with urodynamic stress incontinence (USI).

Materials and methods: Between April 2015 and June 2015, consecutive patients with USI with OAB syndromes underwent two sessions of Erbium:YAG laser treatment in a tertiary hospital. Patients received validated urological questionnaires, urodynamic studies, 1-h pad test and measurement of vaginal pressure before, one and three months after laser treatment. Questionnaires at 12 months were completed by telephone interview. Adverse effects and patients' satisfaction were also assessed.

Results: We included 30 patients with a mean age of 52.6 ± 8.8 years. Three months after therapy, mean 1-h pad test significantly decreased (P = 0.039). Significant improvement in OAB symptoms in four questionnaires were noted at three months post treatment, but not sustained for 12 months in two of them. Three months after therapy, mean vaginal pressure significantly improved (P = 0.009). Of 24 (82.7%) sexually active patients, 62.5% (15/24) and 54.2% (13/24) of their sexual partners reported improved sexual gratification three months later. No major adverse effects were noticed.

Conclusions: Erbium:YAG laser treatment can resolve USI and coexistent OAB symptoms three months after therapy. Sexual experience is also improved. However, repeated laser therapy may be necessary after six months.

Introduction

Urinary incontinence (UI) is a common disorder that affects women of various ages and impacts all aspects of life. Overactive bladder (OAB) symptoms may coexist in 21.6–46.9% of patients with UI [1]. To date, one of the most effective and popular procedures for the surgical treatment of stress urinary incontinence (SUI) is the tension-free midurethral slings (TVT). However, TVT is not without complications. Hemorrhage, bladder injury, urethral injury, vascular injury, pelvic hematoma, urinary retention, de novo OAB, vaginal erosion, or bladder/urethral erosion after surgery have all been reported [2]. Another drawback is the lack of effectiveness in women with stress-predominant mixed UI. Some of these patients may not experience significant improvement in OAB symptoms after incontinence surgery. It has been reported that only 50–71% of patients have improved symptoms after one year [3].

Laser therapy is a relatively minimally invasive procedure and has been utilized in stimulation of wound healing since 1973 [4]. After treatment of lesions in lower genital tract by laser ablation, many patients reported an unexpected side effect: vaginal tightening. This situation improved their sexual experience. Salvatore S. et al. reported significant improvement of sexual function and quality of life after laser pulsation [5]. SMOOTH-mode Erbium:Yttrium–Aluminum-Garnet (Erbium:YAG) laser was proven to shrink the vaginal wall by stimulating neocollagenesis [6,7]. The IncontiLase protocol was reported to be efficacious and safe for SUI in women. Using the proper dosage of Smooth Mode

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(250 ms) the temperature at the vaginal mucosa reaches 60–63 °C, the optimal temperature for the process of shortening collagen fibers and stimulating neocollagenesis and angiogenesis [7].

Although there have been publications on the efficacy of laser therapy in stress incontinence, to our knowledge, none have discussed its effects on OAB symptoms in SUI patients [8,9]. We hypothesize that laser therapy may slightly increase the entire urethral pressure, including proximal urethral pressure, and in turn resolve OAB symptoms due to reduction of the bladder reflex response in SUI patients [10]. Thus we aimed to evaluate the efficacy of the non-invasive Erbium:YAG laser in the treatment of OAB symptoms and urinary incontinence in women with urodynamic stress incontinence (USI).

Subjects and methods

Between April, 2015 and July 2015, 30 consecutive women with OAB symptoms with UI diagnosed with USI were invited to undergo Erbium:YAG laser treatment in a tertiary hospital, and signed informed consent. We performed general and obstetric history taking, urinalysis, pelvic examination applying the Pelvic Organ Prolapse (POP) – Quantification system, and a voiding diary. Patients with a urinary tract infection, pelvic organ prolapse greater than ICS (International Continence Society) stage II, pregnancy, hematuria, childbirth within one year, abnormal vaginal bleeding, damage of vaginal fascia, history of spinal cord injury, post radical hysterectomy, stroke, autoimmune disease, and 1-h pad test greater than 50 g were all excluded from the study. All included patients received evaluations, including six validated urological questionnaires, pelvic examination, 1-h pad test, urodynamic testing (including stress test), and measurement of vaginal pressure with a perineometer before, one month, and three months after laser treatment. At 12 months post-laser follow-up, the same questionnaires were completed by a telephone interview.

The six validated objective questionnaires were as following: the Overactive Bladder Symptom Score (OABSS) for assessment of OAB, the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF) for assessment of UI, the short form of the Urogenital Distress Inventory (UDI-6) for assessment of UI, the short form of the Incontinence Impact Questionnaire (IIQ-7) for assessment of quality of life related to UI, Pelvic Organ Prolapse Distress Inventory (POPDI-6) for assessment of symptoms related to POP, and A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) for assessment of sexual matters related to urinary symptoms. Patients also rated vaginal loosening or desiccation from a scale of 0–4, respectively from no loosening/desiccation, mild, moderate, severe, and very severe. Visual analog scale (VAS) for pain was recorded during therapy. Adverse effects and patients' satisfaction were also assessed. The ethics committee of our university hospital approved the study protocol (No. 201600739B0).

Treatment consisted of two sessions, four weeks apart using the Erbium:YAG laser. After adequate antiseptic procedure, the patients were placed in the lithotomy position. A specially designed laser speculum was introduced into patient's vagina as a guide. Circular and angular adapters were used to project 2940-nm Erbium:YAG laser (XS Dynamis, Fotona, Slovenia) beam to the full circumference of the vaginal wall and to the anterior vaginal wall. The laser was set in Smooth Mode, and was used from distal vagina to proximal vagina with 5 mm intervals. The laser speculum was rotated 10° twice during the procedure to avoid wire masking of the Erbium:YAG laser beam. The angular adapter was then used for sub-vesicle and sub-urethral tissue. The laser speculum was rotated 10° again and then the angular adapter was rotated five degrees twice bilaterally. Finally, urethral and vaginal outlets were treated with another adapter in a figure of eight. During the laser intervention, patient discomfort and treatment tolerability, as well as potential adverse events, were monitored. No anesthesia was used before or during the session. Patients were instructed to avoid intercourse the first three days after each session of Erbium:YAG laser treatment. Outpatient follow-ups were performed at one week, four weeks, and three months after first treatment.

Statistical analysis was completed using SPSS version 20. Fisher's exact test was used to assess categorical data, and Student's *t* test was applied to evaluate continuous variables. Mann–Whitney test was performed to assess continuous variables. To compare preoperative and postoperative responses to individual questions, generalized McNemar's test was performed. A p value of <0.05 was considered statistically significant.

Results

30 patients were included in this study. The mean age was 52.6 ± 8.8 years. Patient characteristics are shown in Table 1. Twelve months after completing two sessions of Erbium:YAG laser treatment for SUI, 2 (6.8%) patients were very satisfied with the efficacy, 16 (55.2%) patients were satisfied, 8 (26%) remained unchanged, and 4 (13.8%) patients were dissatisfied [Fig. 1]. Three months after laser therapy, mean 1-h pad test decreased from 13.2 ± 17.7 g to 6.1 ± 11.6 g (P = 0.039) [Table 2], indicating that Erbium:YAG laser could improve the severity of UI. OABSS symptom scores were significantly improved at three months follow-up (P = 0.027), especially in the symptom of urinary frequency (Q1, P = 0.001). However, the symptom scores were not sustained at 12 months follow-up [Table 2]. When compared with ICIQ-SF and UDI-6 symptom scores before laser therapy, the symptom scores all showed significant improvement at three

Table 1
Patient characteristics.

	N = 30	
	Mean ± SD	Range
Age	52.6 ± 8.8	(38–69)
BH (cm)	158.4 ± 6.2	(147–170)
BW (kg)	61.6 ± 9.8	(44.1–88.5)
BMI	24.5 ± 3.3	(18.9–33.5)
Parity	2.5 ± 0.9	(1–5)
1-hr Pad test (gm)	13.2 ± 17.7	(1.9–34.0)
Urodynamic measurements N = 30 (100%)		
MFR (mL/s)	20.2 ± 8.3	(9.2–40.0)
Voided volume (mL)	485.3 ± 108.6	(313–753)
RU (mL)	17.8 ± 19.4	(0–81)
MCC (mL)	416.2 ± 70.5	(302–552)
MUCP (cmH_2O)	56.2 ± 20.2	(23–99)
FL (mm)	22.8 ± 5.7	(14–36)
Pdet Qmax (cm H_2O)	20.95 ± 9.5	(10–41)
Sexual activity N = 24 (80.0%)		
Vaginal Pressure	26.6 ± 11.0	(3–53)
Vaginal Loosening	1.2 ± 1.2	(0–4)
Vaginal Desiccation	1.6 ± 1.5	(0–4)

SD = standard deviation; BH = Body High; BW = Body weight; BMI = Body Mass Index; 1-hr Pad test = 1 h Pad test; MFR = maximal flow rate; RU = residual urine; MCC = maximal cystometric capacity; MUCP = maximal urethral closure pressure; FL = functional length; PdetQmax = detrusor pressure at maximum flow. The Loosening(L) and Desiccation(D) are: 0 = no L/D; 1 = mild L/D; 2 = moderate L/D; 3 = severe L/D; 4 = very severe L/D; These scores were obtained by patients statements.

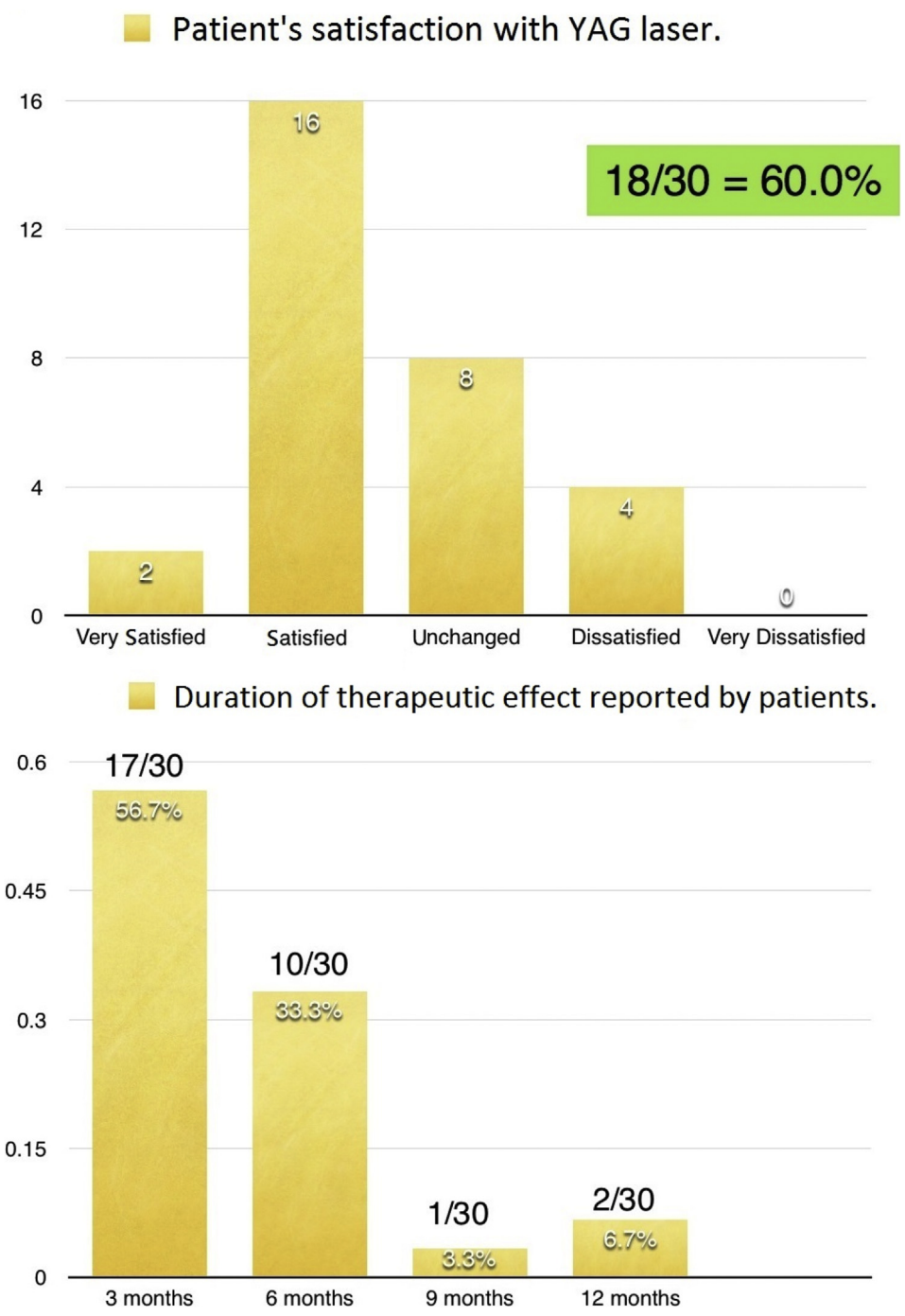

Fig. 1. Patients' satisfaction of Er:YAG laser treatment 12 months later.

months follow-up. The improvements in UDI-6 symptom scores were also not sustained at 12 months follow-up [Table 2]. POPDI-6 symptom scores showed significant improved at three and twelve months follow-up, indicating Erbium:YAG laser could treat vaginal relaxation syndrome (VRS) effectively [Table 2]. Three months after laser therapy, mean vaginal pressure increased from 26.6 ± 11.0 mmHg to 36.3 ± 15.4 mmHg ($P = 0.009$) [Table 3]. The improvement of POPDI-6 symptom scores were compatible with the increase in vaginal pressure. As shown in Table 2 and 3, IIQ-7 and PISQ-12 symptom scores improved at three months follow-up, but the improvement was not statistically significant. 24 (82.7%) patients were sexually active prior to treatment. Three months after laser therapy, 62.5% (15/24) patients reported an increase in sexual gratification and 54.2% (13/24) of patients' sexual partners reported improved sexual sensation after treatment. However, only 8.3% (2/24) patients reported persistently improved sexual gratification at 12 months after laser therapy [Fig. 2]. During laser therapy, most patients described mild but tolerable pain and burning sensation. The average VAS pain score during laser treatment was 4.2 ± 2.0 [Table 4]. After laser therapy, only few patients found increased vaginal discharge or vaginal spotting [Table 4]. These side effects

Table 2
Outcomes of urinary incontinence and OAB symptoms before and after laser treatment (before Tx, 1 m, 3 ms, and 12 ms).

(n = 30)	Mean ± SD				*P0vs3*	*P0vs12*
	Before Tx	1 m Later	3 ms After Tx	12 ms After Tx		
1-hr Pad test (g)	13.2 ± 17.7	9.7 ± 15.1	6.1 ± 11.6		0.039	
OABSS	8.2 ± 5.0	7.1 ± 2.1	6.1 ± 4.3	7.9 ± 6.0	0.027	0.576
Q1	1.7 ± 0.8	1.3 ± 0.7	0.7 ± 0.5	1.5 ± 1.0	0.001	0.465
Q2	1.8 ± 1.1	1.4 ± 0.9	1.3 ± 1.0	1.6 ± 1.1	0.214	0.778
Q3	2.8 ± 2.1	2.7 ± 1.8	2.4 ± 1.9	2.7 ± 2.1	0.682	0.504
Q4	1.9 ± 1.8	1.7 ± 1.5	1.7 ± 1.4	2.1 ± 1.9	0.471	0.679
ICIQ-SF	10.0 ± 3.7	7.1 ± 4.0	6.8 ± 4.0	5.5 ± 4.2	0.002	0.001
UDI-6	8.9 ± 4.3	6.6 ± 3.7	5.4 ± 3.6	7.3 ± 4.6	0.001	0.763
POPDI-6	5.1 ± 3.6	3.8 ± 3.0	2.2 ± 2.1	2.2 ± 2.6	0.001	0.001
IIQ-7	6.9 ± 6.0	6.9 ± 5.9	5.1 ± 5.2	6.5 ± 8.3	0.227	0.429

SD = standard deviation; OABSS = the overactive bladder symptom score (Q1: How many times do you typically urinate from waking in the morning until sleeping at night? Q2: How many times do you typically wake up to urinate from sleeping at night until waking in the morning? Q3: How often do you have a sudden desire to urinate, which is difficult to defer? Q4: How often do you leak urine because you cannot defer the sudden desire to urinate?); ICIQ-SF =0International Consultation on Incontinence Questionnaire - Short Form; UDI-6 = urogenital distress inventory-6; POPDI-6 = Pelvic Organ Prolapse Distress Inventory-6; IIQ-7 = incontinence impact questionnaire-7.

Table 3
Outcome of sexual function before and after laser treatment (before Tx, 1 m, and 3 ms).

	Mean ± SD			*P0vs3* value
	Before Tx (n = 30)	1 m Later	3 ms After Tx	
PISQ-12(N = 24)	33.4 ± 7.0	33.7 ± 6.5	31.7 ± 6.3	0.402
Vag. P	26.6 ± 11.0	27.4 ± 10.4	36.3 ± 15.4	0.009
Vag. Loosening	1.2 ± 1.2	1.4 ± 1.0	0.6 ± 0.8	0.042
Vag. Desiccation	1.6 ± 1.5	1.3 ± 1.2	1.0 ± 0.9	0.094

PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; Vag. P = Vaginal pressure; Vag. Loosening = Vaginal lossening; Vag. Desiccation = Vaginal Desiccation.

only persisted for several days, and most patients did not find the side effects bothersome. No major adverse effects were noticed.

Discussion

Majaron et al. reported the first study of Erbium:YAG laser on human soft tissue in 2000, and in gynecology, was used to treat human papilloma virus infections, cervical ectropion, vulva intraepithelial neoplasia, etc [7,11]. The side effect of vaginal tightening then initiated the use of laser effect as a treatment for VRS in 2008 [12]. Fistonic et al. first published the use of laser for treatment in the early stages of SUI in 2012 [8,9]. The Erbium:YAG laser was then used to treat POP and vaginal atrophy [13], showing that laser treatment was effective without major adverse effects. We recruited these patients based on the hypothesis that OAB symptoms could be improved with Erbium:YAG laser treatments, and to our knowledge, no articles related to this hypothesis has been published.

In patients with SUI, leakage of urine into the proximal urethra may stimulate urethral afferents and facilitate the voiding reflex. Although TVT incontinence surgery improves incontinence symptoms, OAB symptoms often persists after surgery. In fact, 15–70% of patients reported unresolved symptoms [3,14–17]. However, according to the results of our study, Erbium:YAG laser could improve OAB symptoms. The SMOOTH mode setting was designed to stimulate neocollagenesis without ablation [8]. Neocollagenesis can change the composition of the pelvic floor structures, and thus an increase pressure over the entire length of urethra, while TVT increases dynamic middle urethral pressure [18]. Increased proximal urethral pressure may resolve OAB symptoms by reducing the bladder reflex response in SUI patients [10]. OABSS, ICIQ-SF, and UDI-6 symptom scores all showed significant improvement of OAB symptoms at three months follow-up when compared with scores prior to treatment. However, the OAB symptoms seemed to relapse at 12 months in OABSS and UDI-6 symptom scores compared with pre-treatment sores [Table 2]. By most patient's report, the optimal therapeutic effect was maintained for the duration of three to six months [Fig. 1]. This indicates that patients may need repeated treatment six months after the initial treatment. In addition, patients' partners reported persistently improved sexual gratification 12 months after laser therapy, but our patients reported a decrease in sexual gratification. This could be explained by the fact that when assessing sexual gratification, men and women considered different parameters. The tightness of the vagina may be a more significant factor for the partners, while in contrast, women considered factors other than vaginal tightness when evaluating sexual function, such as vaginal desiccation, urine leakage during sexual intercourse, etc.

Limitations of the present study include its retrospective study design, small case number and lack of face to face visit at 12 months follow-up. Many objective parameters such as post-therapy pad test or vaginal pressure are lacking, because most patients did not want to return to the clinic. With only subjective questionnaires at 12 months after laser therapy, further studies are required for confirmation of our preliminary findings.

In conclusion, the results have shown that Erbium:YAG laser could improve the severity of USI and the OAB symptoms. It could also enhance both patient and partner's sexual experience by increasing vaginal pressure. Therefore, Erbium:YAG laser is a good alternative treatment for patients who prefer minimally invasive therapy, or are unsuitable for surgery. In our study, minimal complications were recorded, concluding the Erbium:YAG laser a safe method of treatment. The duration of therapeutic effect was approximately three to six months after two sessions. Repeated sessions may be necessary after six months. We chose to administer two treatment sessions in this study, similar to a previously published study by Fistionic et al. [8], though three treatment sessions may better improve OAB symptoms and patients satisfaction.

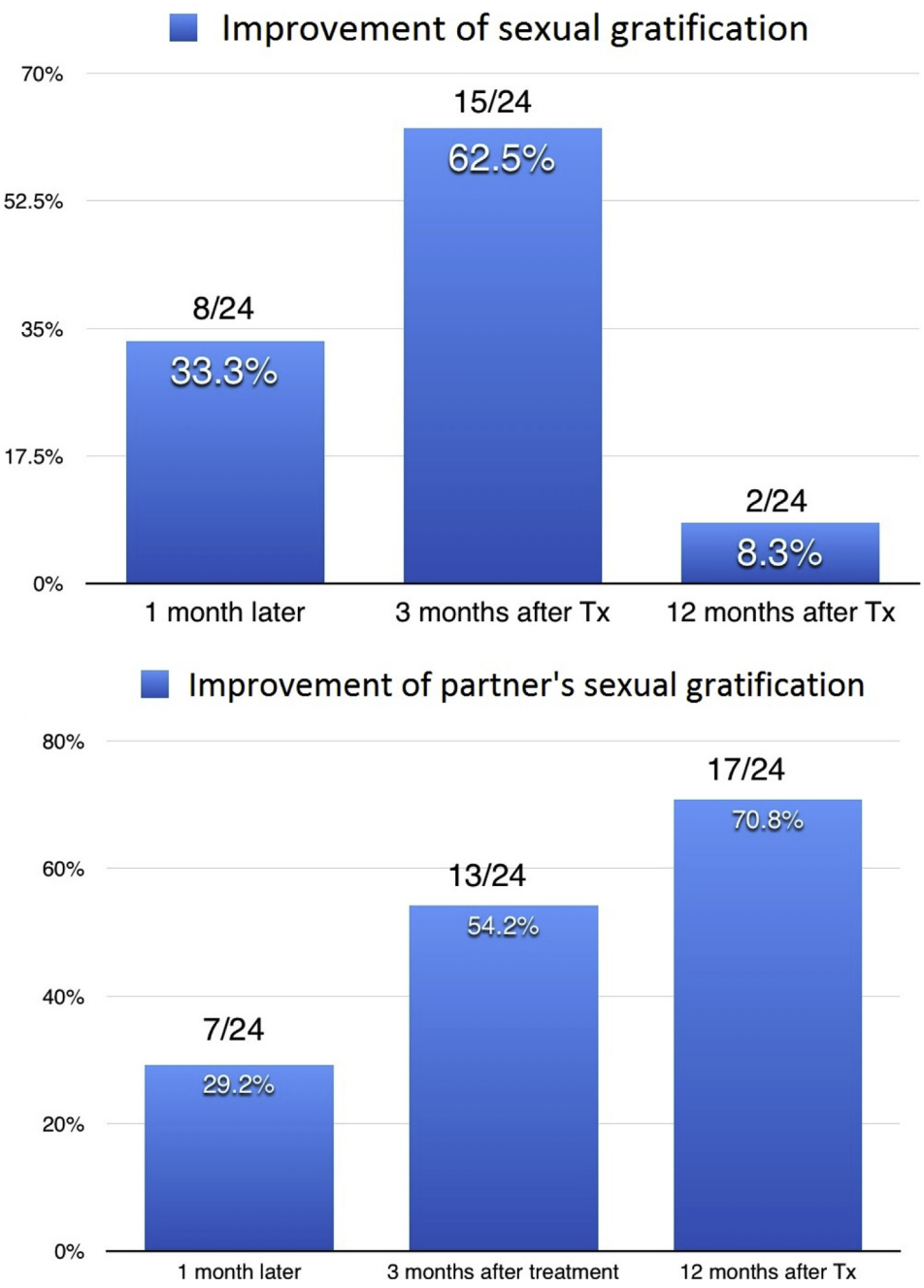

Fig. 2. Patients' and their partners' assessment of sexual gratification improvement after Er:YAG laser treatment (total N = 24).

Table 4
Complications during/after laser therapy (total number = 30).

	Mean ± SD	
	1st Cycle of Tx	2nd Cycle of Tx
Pain (VAS)	4.2 ± 2.0	3.6 ± 2.1
Burning sensation (0–5)	1.6 ± 0.7	1.6 ± 0.8
Other		
Vag. itching	3/30 (10.0%)	1/30 (3.3%)
Increased Vag. discharge	3/30 (10.0%)	4/30 (13.3%)
Vulva discoloration	5/30 (16.7%)	2/30 (6.7%)
Abnormal Vag. bleeding	2/30 (6.7%)	0 (0.0%)

VAS = Visual Analog Score; Vag. = Vaginal.

Although Erbium:YAG laser cannot replace the TVT procedure for SUI; it can, however, be an alternative selection for those patients who are unwilling or are unable to undergo TVT surgery. Further studies to compare the Erbium:YAG laser with physiotherapy are required to exclude the placebo effect.

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None.

Ethical committee/institutional review board

The ethics committee of our university hospital approved the study protocol (No. 201600739B0).

Conflicts of interest

The authors declare that they have no conflict of interest.

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