Effect of the type of urinary incontinence in the Outcome of laser Therapy for Treatment of Female Stress Urinary Incontinence

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Background: Female stress urinary incontinence (SUI) is common lower urinary tract symptom. It affect many women especially middle and elderlywomen and about 40% of them have mixed Urinary incontinence (MUI).There are surgical and non-surgical options for treatment of stress urinary incontinence. Laser therapy is seemed to be a promising minimally invasive option for treatment of female SUI.

Objective:To determine the effect of the type of urinary incontinence in laser therapy outcomes.

Patients and method(s): A prospective non-randomized study for female patients with SUI who were referred to the Urology Department, Sohag University Hospital from March 2017 to June 2018. The study was approved from Sohag University ethics committee. Patients were treated by the clinical protocol for SUI with non-ablative 2940 nm Er: YAG laser. Patients were evaluated at the baseline and every 3 months for 1 year by Validated International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) Arabic version and the number of daily pads usage .The patients were classified according to their type into a pure SUI group and MUI group.

Result(s): Our results included 32female patients. 20 patients (63 %) had pure SUI while 12 patients (37%) had mixed incontinence. the median duration of symptoms 3 years. There was a significant reduction in daily pads usage and ICIQ-UISF score (p value<0001) for both groups with more significant for pure SUI group. No serious side effects were reported.

Conclusion: There was a statistically significant effect of the type of UI on laser therapy outcomes with better results related to pure SUI.On the other hand, No effect of type ofurinary incontinence on number of laser sessions needed by patients to achieve improvement of their incontinence.

Keywords: Stress Urinary Incontinence (SUI), Mixed urinary incontinence (MUI),andEr: YAG laser

Introduction:

Female stress urinary incontinence (SUI) is an important and common lower urinary tract symptom, middle-aged and elderly women are most commonly affected **(Luber, 2004**). It is known as "the symptom of involuntary urinary leakage related to effort or exercise, laughing, coughing or sneezing **(Abrams et al., 2003)**.Urine loss can also occur during the sexual act and lead to significant distress **(Temml et al., 2000**).

The prevalence of urinary incontinence is 16% for women younger than 30 years and 29% for older women **(Hunskaar et al., 2003**).About50% of thesewomen have purestress urinary incontinence (SUI). Ten percent of women have urge urinary incontinence (UUI) and a further 40% of women have mixed incontinence **(Hampel et al., 1997**).Risk factors of SUI and other pelvic floor dysfunctions are aging, pregnancy, route of delivery, smoking, obesity, and diabetes **(Patel et al., 2006)**.SUI may be due to the relaxation of the anatomical structure that supports the periurethral tissue or impairment of the function of the urethral sphincter. Women with SUI have an altered connective tissue characterized by decrease collagen production, which may result in inadequate support of the urogenital tract **(Wong et al., 2003).**

Nonsurgical options for SUI include weight loss for obese patients, stop smoking, pelvic floor muscle exercise, Electrical stimulation, weighted vaginal cones and medication **(Gustaf, 2015**).

Surgical procedures such as Burch colposuspension are effective than nonsurgical options But they are associated with side effects

and operative complications, for example bleeding, perforation of the bladder, injury of urethra, infection and chronic pelvic pain (**Novara et al., 2010**).

The medical effects of lasers are well established. Thermal energy from the laser stimulates new collagen formation in addition to the immediate tightening of collagen fibrils by two-thirds of their length in comparison to the pretreatment state. A minimally-invasive, non-ablative Er: YAG laser vaginal tightening procedure can be used for this purpose **(Thomsen, 1991)**.

Subjects and Methods: A prospective non-randomized study for all female patients with SUI who were referred to the Urology Department; Sohag University Hospital during the period from March 2017 to June 2018. The study was performed after approval from Sohag University Hospital's ethics committee. The inclusion criteria of the study included Mild to moderate stress urinary incontinence by clinical evaluation then all patients were re-evaluated according to ICIQ-UI SF score, any number of parity and with or without mild prolapse (stage 1 and stage 2 by POP-Q system). The exclusion criteria were; neurogenic bladder, Pregnancy, active genitourinary tract infection, previous incontinence surgery, and severe pelvic organ prolapse. According to previous criteria, the study included 32 female patients of which 20 patients had pure SUI and 12 patients had MUI.

The protocol of management:

All patients underwent a detailed medical history including, duration and severity of incontinence episodes, number of pads usage, menstrual and obstetric history, medical and drug history and any previous treatment modalities. The degree of SUI and its impact on the quality of life was assessed using the (ICIQ-UI SF), this questionnaire has been validated in Arabic. (10) The ICIQ-UI SF scorewasclassified into four-degree: mild degree (1–5), moderate degree (6–12), severe degree (13–18) and very severe degree (19–21), as reported by **Klovning et al (2009).**

The full gynecological examination was done to determine the suitability of the patient for the vaginal laser therapy and we assessed the presence of urine leaks by cough test, POP, vaginal mucosal atrophy and any sign of infection or vaginal lesions. Patients were advised to perform a pregnancy test the day before the session to exclude pregnancy. Patients fulfilled the inclusion criteria were managed with at least one session of laser with time interval at least one month between sessions.

All patients were treated according to the clinical protocol using Er: YAG (2940 nm) laser using the thermal only mode through a three-step protocol. The treatment was performed in the outpatient clinic with neither pre-operative anesthesia nor analgesia or post-procedure medications. The procedure consisted of three phases. In the first step, the whole vaginal wall using the R11 full-field headpiece with a circular adaptor. In the second step, the anterior vaginal wall was irradiated using the PS03 headpiece with an angular adaptor. Then the speculum was removed and the third step was done by the PS03 hand piece with a straight adaptor to irradiate both the mucosa of the vestibule and the introitus.

LASER TYPE:Er: YAG (2940 nm) laser system (XS Dynamis, Fotona, Slovenia). **Mode** non-ablative thermal only SMOOTH mode" (energy 10.0 J/cm2; four pulses per packet, pulse duration 250 ms with spot size 7 mm and rate 1.6 Hz..

The improvement was defined as any reduction in The ICIQ-UI SF score and any reduction in the number of pads usage by the patients at 1,3,6 months and one year. However, the cure was defined as (ICIQ-UI SF) equal zero and failure was defined as no change in (ICIQ-UI SF) or the number of pads usage. Patient's satisfaction with the treatment was also reported, using an ordinal scale: high satisfaction, moderate, low or no satisfaction.

Following the procedure, patients were observed for complications such as infection, pain, vaginal burn, and urinary retention, loss of efficacy or complete failure. All patients were consulted to avoid sexual activity for at least one week.

Results:

The study included 32 female patients. With the median age of 38years (range 26-62 years) the

median BMI per patient was 24 (range: 19–29.5). The median delivery number was 4 per patient (range: 2–8). Most of the patients were in premenopausal state 87% (28 patients). Twenty patients (63 %) had SUI while twelve patients (37%) had mixed incontinence with a predominance of SUI. the median duration of symptom 3 years (range 1-5 year). the median baseline of pads usage was three pads per day (rang 0-5)

Table (1): Demographic data, Obstetric and gynecological history of the study participants:

		All patients (N= 32)		
		Mean ± SD	Median	Range
Age		38.81 ± 7.59	38	26-62
BMI		23.95 ± 2.78	24	19-29.5
Parity			4	2-8
Normal vaginal delivery		3.66 ± 1.45	4	0-7
Abortion		0.22 ± 0.49	0	0-2
Duration (years)		2.28 ± 1.28	2	1-5
Number of daily pads		2.84 ± 1.53	3	0-5
Post menopause		13% (4)		
Complaint	**SUI**	63% (20)		
	Mixed UI	37% (12)		
POP stage	**0**	9% (3)		
	1	47% (15)		
	2	44% (14)		

Standard Deviation(SD), Body Mass Index(BMI), Pelvic Organ Prolapse(POP),Stress Urinary Incontinence (SUI), Mixed urinary incontinence (MUI).Number(N)

All patients were treated by laser therapy with a median number of the session was 2 sessions there was a significant reduction in the number of daily pads usage and the ICQI-UI SF score after the first session and as well as the number of session increase. However, this was obvious until the third session with no more reduction was seen after the third session. There was a significant reduction in the median of daily pads usage from a median of 3pads per day (rang 0-5) at baseline to a median of one pad per day at both 6 months and one year (rang 0-3 pads per day) for both group with more significant in pure SUI group.

ICIQ-UI SF median score before treatment was 12 (range: 5–16).The post-operativemedian score of ICIQ-UI SF was 7 (range: 5– 16) at 3rd month, 5 (rang 0-16) at 6 months and 5.5(rang 0-14) at one year (Figure 1). The difference between the two scores (pre and post-treatment) per patient was significantly different (p-value < 0.001).and we reported a cure (no SUI symptoms and ICIQ-UI SF= 0) in five patients (16%) and improvement in overall score in 26 patients (81%)(Table 2).

There was no significant effect of the type of UI on the number of sessions needed by patients to achieve clinical improvement. However, there was a statistically significant effect of the type of UI on laser therapy outcomes (Table 3).On the other hand, there was a significant correlation between the type of UI and predictor of the success of laser therapy such as daily pads usage, duration of symptoms, parity, and the number of vaginal delivery .

Table (3): effect of UI typeon the number of sessions and post-treatment outcome in the studied patients:

	SUI	**Mixed UI**	**P value**
Number of sessions	1.90 ± 0.72	2.75 ± 1.42	0.09
Daily Pads after 6 months	0.70 ± 0.92	2.00 ± 1.91	**0.036**
Daily Pad reduction	1.65 ± 1.42	1.67 ± 1.30	0.95
ICIQ –UI SF at 6 months	3.15 ± 3.41	7.25 ± 5.26	**0.026**
ICIQ-UI SF reduction	9.25 ± 2.95	7.17 ± 4.76	0.35

Data are expressed as mean and standard deviation. P value

is significant when < 0.05.Stress Urinary Incontinence (SUI), Mixed urinary incontinence (MUI), International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF)

Table2. Laser therapy outcomes.

	Total Improvement Including cure	Cure	Failure	missed
Number (%)	26 (81%)	5 (16%)	3 (9.5%)	3(9.5 %)
Type of incontinence	18 SUI 8 MUI	4 SUI 1 MUI	1 SUI 2 MUI	1 SUI 2 MUI
Degree of incontinence by Score	3 mild 11 moderate 12 severe	3 mild 2 moderate	3 severe	3 moderate
Median ICUQ UI-SF score	12	5	15	11
Median N. of Pads	3	2	4	3
Median N. of deliveries	4	2	4	4
POP Stage	2	0	2	1
Median Duration of symptom	2 years	1year	4year	2year
Menopausal state	One premenopausal	All cases premenopausal	2 post-menopausal	One post-menopausal

Stress Urinary Incontinence (SUI), Mixed urinary incontinence (MUI). Number (N),International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF), Pelvic Organ Prolapse(POP).

Discussion:

Surgical options are effective than nonsurgical options for treatment of SUI But they are associated with side effects and operative complications, for example bleeding, perforation of the bladder, injury of urethra, infection and chronic pelvic, tape erosion, urethral injury, infection, and chronic pelvic pain *(***Novara et al., 2010**). As laser therapy offers patients' quality of life improvement, because it is minimally invasive and associated with no serious complications compared to mid-urethral slings so, it is considered a promising alternative option. However, there is a deficiency in randomized clinical trials (RCT) and studies comparing any laser procedure to the other well-established UI treatment options, such as pelvic floor exercises or mid-urethral slings.

In our study we used a validated questionnaire ICIQ-UI SF (Arabic version) and the number of daily pads usage per patient to report our results of Er: YAG laser therapy. The Arabic version is simple, easily applicable by Arabic patients and it was the first time to use an Arabic version for this purpose. This validated questionnaire was used to compare pre and post-treatment patient's status which revealed a significant improvement in SUI not only in terms of frequency and quantity but also the degree of patients' quality of life affection. Moreover, we used the number of daily pads usage for evaluation of improvement of SUI symptom which also the first time to be used for this purpose as an easy and applicable subjective method. Other studies report their results using other validated questionnaires, pad weight test, Q-tip test, urodynamics parameter or histological character of tissue which are objective methods but invasive and were time-consumingOverall, the clinical benefit of calculating the amount of urinary leak was not established to be used as a predictive value for treatment outcomes*(***Al Afraa et al., 2012**).

The results of our study showed that laser effectively reduces the symptoms of SUI. And the improvement was evident after the first

session, as reported by the patients before doing the second session and durable for at least 6 months. However, the efficacy decrease as duration increase post-treatment mainly after one year and may need another booster session as suggested by **Gasper et al . (2016**) who reported that Treatment effects of laser sessions for at least three sessions with monthly intervals last about one year after these time the effect begins to decrease.

We reported 16% cure rate (patients were dry (ICIQ-UI SF = 0) at one year which is comparable to **Mija Blaganjea et al.(2018)** who reported 21% cure rate in patient treated with laser in randomized controlled trial with follow up only for 3month .and also to Tien et al 2017 who reported a 21.9% cure rate and 12.5% improvement rate based on various questionnaires and scales at 6 months follow-up.

Improvement of SUI symptoms in our study was observed in 81 %(n=26) of all patient which is comparable to the study did by ***Ogrinc et al.(2015)*** who reported an improvement in 77% of patients after follow up of his patients for one year after the laser procedure.

In our study, there was no significant effect of the type of UI (63%SUI vs. 37%MUI) on the number of sessions needed by patients to achieve clinical improvement. However, there was a statistically significant effect of the type of UI on laser therapy outcomes. Which was comparable to A prospective non-randomized study followed 175 patients suffering from SUI (66%) and MUI (34%) reported by **Ogrinc et al .(2015**) and Follow-up was arranged at 2, 6, and 12 months. Who reported results at 1-year-followup, (62%) from both SUI and MUI groups reported no incontinence. In patients with SUI, the treatment statistically significantly improved in 77% of the cases, while the patients diagnosed with MUI before the treatment only improved in 34%of his patients.

Our study has some limitations, for example the short follow up period, the absence of control group or randomization, the small sample size and the absence of objective outcome measures.

Conclusion:

There was a statistically significant effect of the type of UI on laser therapy outcomes with better results related to pure SUI.On the other hand, No effect of type of urinary incontinence on number of laser sessions needed by patients to achieve improvement of their incontinence.

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