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Effectiveness of Laser Therapy in Perimenopausal and Postmenopausal Stress Urinary Incontinence: A case series study

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ABSTRACT

Background: stress urinary Incontinence (SUI) is a prevalent condition affecting both perimenopausal and postmenopausal women and impacts all aspects of life. As estrogen level is reduced with advance of age , a secondary decrease in collagen occur leading to inadequate support of the urogenital tract.

Aim of the work: to evaluate the effect of laser in collagen regeneration amongst perimenopausal and postmenopausal women with stress urinary incontinence (SUI), its impact on quality of life, and its safety profile.

Patients and methods: Fifty-three women, aged from 45-67 years, with various grades of SUI (pure & mixed) were recruited. Patients received treatment with Er: YAG laser (2940nm) in one, two, or three sessions according to the grades of incontinence and response of treatment. Urinary incontinence (UI) was evaluated using the international consultation on incontinence questionnaire urinary incontinence short form (ICIQ- UISF). Quality of life was assessed by ICIQ – urinary incontinence symptom quality of life (ICQ- UIQOL), sexually active patients were interviewed by ICIQ-Female Sexual Matters associated with lower urinary tract symptoms (ICIQ- FLUITS sex). The questionnaires were collected at baseline, 1, 3, 6, and 12 months after the procedures.

Results: There were statistically significant improvements in frequency, amount of leakage, and grades of SUI-especially mild and moderate grades (p=0.004). A statistically significant positive relation between climacteric phases and grades of SUI before laser (p<0.001), which turned into negative relation after laser treatment, which (P=0.040). A statistically significant improvement was observed in all questionnaires scores (P< 0.05). Minor side effects were detected, such as discomfort or burning sensation; which disappeared within 1-2 days post procedure.

Conclusion: Laser therapy is an effective treatment for mild and moderate SUI, with or without mild prolapse, in peri-menopause or post-menopause women; it improves quality of life of patients and their sexual matters, with minimal side effects.

Keywords: stress urinary incontinence; erbium: yatrium- aluminium-granet (Er: YAG); climacteric phases; perimenopausal; postmenopausal.

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INTRODUCTION

During perimenopause, estrogen levels, often with wide fluctuations, lead to a several physical changes that affect perimenopause and menopause. Some of these changes are "general as heart disease, metabolic disorders, osteoporosis, hot flashes and night sweats ¹ or "local as urogenital atrophy which includes urinary incontinence, overactive bladder, recurrent lower urinary tract infections and vaginal atrophy . ²

Stress urinary incontinence (SUI) is an embarrassing problem that affects women in all ages, especially postmenopausal women and it can cause withdrawal

From social lives, depression and limited activity . ³

SUI is defined according to the International Continence Society (ICS) as a complaint of involuntary loss of urine on effort or physical exertion as coughing, laughing, sneezing, and exercising or any movements that lead to increase the intra-abdominal pressure and so increase in the bladder pressure . ⁴

SUI is characterized by altered metabolism of connective tissue causing decreased collagen production leading to insufficient support of the urogenital tract. Collagen is a fibrous protein imparting tensile strength to tissue, which plays an important role in maintaining the continence of

urine, interdigitating of collagen fibers between the vaginal wall, para urethral tissue and medial portion of levator ani allows the later to control the position of urethra .⁵

The effects of lasers are established in terms of biochemical, ablative and thermal effects. Thermal energy from the laser beam, especially in moist milieu, enhances collagen structure, stimulates neocollagenesis and modulates the activation of metalloproteinase at molecular level .⁶ This study is done to evaluate the effect of laser therapy in collagen regeneration in treatment of perimenopausal and postmenopausal SUI women and its impact on quality of life and to detect any potential side effects.

PATIENTS AND METHODS

A prospective intervention therapeutic clinical trial study was conducted on 65 women suffering from urinary incontinence, three of them were excluded because they had urge urinary incontinence (detrusor overactivity detected by urodynamic), and 9 patients were lost (dropped out) from follow-up, leaving 53 patients suffering from stress urinary incontinence (pure & mixed) who underwent to follow-up and analysis post treatment. Patients were recruited from the outpatient Gynecology and Urology clinics at Al-Zahraa University Hospital from January 2015 to January 2017. An approval of the ethical committee of Al-Zahraa University authority, and a written informed consent from all patients were obtained.

Detailed history was taken from all patients included in the study. Postmenopausal and perimenopausal women having mild, moderate and severe SUI (pure & mixed) with and without mild prolapse were included in this study, while patients with moderate to severe prolapse, SUI mainly related to obstetric causes, uncontrolled diabetes, history of surgical repair of prolapse, undiagnosed vaginal bleeding and injury or active infection in the treated area were excluded .

All patients were subjected to Interviewed International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form (ICIQ-UI SF) [7-8] was assessed degree and type of incontinence and its impact on the quality of life (total score=21 as 0 mean no incontinence and 21 means severe incontinence. (ICIQ-UI SF) include three questions items: How often do you leak urine?(never=0,once a week=1,two or three a week=2,once a day=3,several time a day=4,all the time =5).How much urine do you usually leak? (None =0, a small amount=2, a moderate amount=4, a large amount=6). Overall, how much does leaking urine interfere with your everyday life? (Not at all=0, a great deal=10).

ICIQ-Urinary Incontinence Symptoms Quality of Life (ICIQ-UI QOL) was assessed quality of life. Total score of UIQOL=10. Zero means no impact of UI on daily work and quality of life, 1-3 mild, 4-6.moderate, 7-9 severe and 10 means great extent impact of UI on daily work and quality of life .⁸

Sexually active patients were interviewed by (ICIQ-Female Sexual Matters associated with lower urinary tract symptom) (ICIQ-FLUTS sex).Scoring system: 0-14 overall score with greater values indicating increasing problems with sexual matters as 0 means

no effect of UI on sexual matters while 14 means severe impact of UI on sexual matters .⁹

)ICIQ- FLUTS sex) include 4 questions items: Do you have pain or discomfort because of a dry vagina? (Not at all= 0, a little=1, somewhat=2, a lot =3). To what extent do you feel that your sex life has been spoiled by your UI? (Not at all= 0, a little =1, somewhat =2, a lot = 3). Do you have pain when you have sexual intercourse? (Not at all =0, a little=1, somewhat=2, a lot=3, I don't have sexual intercourse=4). Do you leak urine when you have sexual intercourse? (Not at all=0, a little=1, somewhat=2, a lot=3, I don't have sexual intercourse =4)

Then, all patients were subject to; General& abdominal examination, vaginal examination was done to detect prolapse and tone of levator ani , cough stress test which was done to all patients to diagnose SUI, perineometer to measure muscle strength and the vaginal pelvic diaphragm, the average contraction pressure of the vagina (30-37 mm Hg),¹⁰ urine culture and sensitivity,¹¹ and urodynamic study was requested for all patients before laser treatment to aid and to insure the diagnosis of SUI and to determine the different types of SUI either intrinsic sphincter deficiency (ISD) or hyper mobility urethra (HMU) or mixed of them and whether it is pure (SUT) or mixed (stress and urge). The subcategories of female SUI were ascertained by evaluating the abdominal leak point pressure (ALPP), which also was determined as the valsalva or stress leak point pressure, it is defined as the least abdominal pressure need to cause leakage of urine. ALPP < 60 cm H2O meaning the diagnostic value of type III SUI (ISD), an ALPP between (90-120) cm H2O is considered diagnostic of type II SUI (HMU), while ALPP between (60-90) cm H2O indicate the presence of both type II and type III .¹² Detrusor instability is diagnosed when the true detrusor pressure increased or even when smaller increases cause urgency or incontinence during urodynamic.¹³ Mixed urinary incontinence" (stress and urge) is a combination of urodynamic conditions (urodynamic stress incontinence and detrusor over activity) in the same individual .¹⁴

All patients were subjected to treatment by Er-YAG laser (2940 nm) causing a controlled, nonablative thermal effect on the tissue .¹⁵ The laser therapy achievement a photo thermal effect of a laser beam on vaginal mucosal tissue in order to produce shrinking without any damage of tissue, to produce shrinkage of the collagen while preserve its structure without any damage need a temperature around 60-65 c.

Some precautions were done immediately before the treatment: 1- the patient's vagina (Vestibule, introitus and the vaginal canal) was cleaned with disinfecting solution, and dried off carefully from the mucous. 2- Whole area which treated should be thoroughly inspected and checked to be sure there are no injuries or bleedings.

All patients received laser treatment by both IncontiLase for urinary incontinence and IntimaLaseTM for vaginal tightening. The IncontiLase procedure was consisted of two phases: First phase, a specified fractional Er: YAG hand

piece with an angular adapter which give a precise irradiation was introduced inside the vaginal canal which act as a guide for the laser beam delivery system in which nearby 30J laser beam was delivered to each irradiation location producing thermal effect on the mucosa tissue and endopelvic fascia of the vaginal that causes shrinkage of collagen in the vaginal mucosa.¹⁰

The secondary phase of the IncontiLase TM was done on the vestibule and introitus using a straight shooting fractional laser hand piece.¹⁰ All area had to be included with the energy of laser to produce an optimal thermal effect on collagen of the treated mucosa. The average time of treatment was 25 minutes.

Also, the IntimaLaseTM had two phases. In the first phase, all vaginal length was exposed to laser beam, and in the second phase the introitus and vestibule were irradiated as well. In the first phase, a specific designed laser speculum and a circular beam delivery adapter were used, which produce rapid and easily irradiation of the vagina in its entire circumference. The second phase was done by a fractional straight-shooting hand piece which was used to fix the urethra in the anatomical position and consolidate the ligaments and connective tissue around the urethra. The laser action involved three components; a photo thermal effect Penetrating up to 0.5 mm inside the vaginal wall causing immediate shrinkage of the tissue, photo thermally processed tissue layers; and neo-collagenases following heat treatment which generates new collagen fibers that further improve thickness, elasticity and firmness of the vaginal tissue[16]. During session of laser, we must observe any associated pain, erythema or any other side effects.

After laser treatment, women were asked to avoid any efforts producing pressure on the bladder, especially in first month because the neocollagenesis and remodeling were occurring which make the tissue more strength, abstain from sexual activities for at least one week following the treatment, report and check-up the appearance of any adverse effects or complications, patients should carry a diary to record changes in incontinence behavior and events of leakage.

The patients asked to come after 4 weeks for check-up of the treated area and for possible additional treatment session. The second laser treatment was performed after 4-6 weeks and the third session was performed 3-6 months after the first procedure.

All women underwent follow up at 1, 3, 6, 12 months post treatment. In each visit the patients were assessed by; History included Urinary Incontinence questionnaires; examination (general, abdominal, vaginal and cough stress test); urine culture and sensitivity; perineometer. Urodynamic Study was asked if indicated (the symptoms has been exaggerated or developed other new symptoms).

RESULTS

Fifty three perimenopausal and postmenopausal women suffered from stress urinary incontinence (mixed & pure) were included in the study; the mean age of study group was (50 Y). Thirty one (58%) of

patients was perimenopausal and 22 (42%) were postmenopausal. Forty five (85%) were married, 2 (4%) were divorced and 6 (11%) were widow. The mean number of children was 2. As regard their occupation 35 (66%) of patients were housewife, 9 (17%) were nurses, 6 (11%) were clerk and 3 (6%) were workers. As regard BMI of patients 19 (36%) were overweight, 16 (30%) were class1 obesity while 10 (19%) were class 2 obesity, 8 (15%) were normal weight. Three woman (5%) were had asthma, 3(5%) had hypertension and 2 (4%) had thyroidectomy (table1).

In the current study, 12 (23%) of patients had pure SUI, 41 (77%) had mixed UI (SUI & UUI), (all of them were diagnosed by history, examination and confirmed by urodynamic, which defined the types of SUI as seven (13%) of patients had hypermobile urethra (type2 HMU), while six (11%) had intrinsic sphincter deficiency (type 3 ISD), and 40(76%) of patients had mixed SUI (combination of type2 and 3). As regard grades of SUI, seven (13%) of patients had grade1 SUI (leakage of urine occur with severe stress as cough or laugh), 40(76%) of patients had grade 2 moderate SUI (leakage of urine with effort and walking) and 6 (11%) had severe SUI (leakage of urine occur at rest). The mean duration of UI among patients was 5±5 years. Forty four (83%) of patients had no prolapse, while 9 (17%) had mild prolapse. Thirty three (62%) of patients were sexually active (table2).

In the current study, eighteen (34%) of patients needed only one session of laser (Seven of them had mild SUI and 11 had moderate SUI (pure & mixed). While 29 (55%) of patients [all of them had moderate SUI (pure & mixed)] were required 2nd session (it was done one month after the first session), six women (11%) of patients (all of them had severe mixed SUI) were needed 3rd session of laser (6 months after the first session).

| Variables | Studied group (53) |
|--------------------------------|--------------------|
| Age | 50 ± 7 |
| Stage of climacteric: | |
| Perimenopause | 31 (58%) |
| Post menopause | 22 (42%) |
| Marital status | |
| Married | 45 (85%) |
| Divorced | 2 (4%) |
| Widow | 6 (11%) |
| Number of child | 2 ± 2 |
| Occupation | |
| - Housewife | 35 (66%) |
| - Nurse | 9 (17%) |
| - Clerk | 6 (11%) |
| - Worker | 3 (6%) |
| (body mass index (BMI) | |
| -normal weight=18.5--24.9 | 8 (15%) |
| -overweight = BMI=25-29.9 | 19 (36%) |
| - obesity (class 1)=BMI =30-35 | 16 (30%) |
| -obesity (class2)=BMI=35-39.9 | 10 (19%) |
| Comorbidity | |
| -Hypertension | 3 (5%) |
| -asthma | 3 (5%) |
| -thyroidectomy | 2 (4%) |

Table 1: Demographic data of study group.

| Variables | Studied group (53) |
|--|------------------------------|
| Type of urinary incontinence diagnosed by UDS: • Stress urinary incontinence(SUI): 1. Type 2 (HMU) 2. Type 3 (ISD) 3. type2+type3(Mixed SUI) | 7(13%) 6 (11%) 40(71%) |
| Grade of stress: 4. Mild stress (with cough) 5. Moderate stress (with effort) 6. Severe stress (with rest) | 7(13%) 40(71%) 6(11%) |
| Duration of UI: | 5 ± 5 (1-10) years |
| Associated prolapse No prolapse Mild prolapse | 44 (83%) 9 (17%) |
| Sexual active: | 33 (59%) |

Table 2: Urogynecological finding of study group.

| Variable* | before laser | after laser treatment | Test of significance | P |
|--|--|--|------------------------|------------|
| frequency of incontinence: No once per week 2-3 per week 2-4 once per day many times per day all the time | 0 (0%) 0 (0%) 0 (0%) 7(13%) 36(68%) 10(19%) | 23(43%) 8(16%) 9(17%) 7(13%) 6(11%) 0(0%) | X ² =71.429 | <0.0001 HS |
| Amount of leak: No leak(continent) Small amount Moderate amount Large amount | 0(0%) 7(13%) 35(66%) 11(21%) | 23(43%) 19(36%) 11(21%) 0(0%) | X ² =52.060 | <0.0001 HS |

Table 3: Comparison between amount and frequency of incontinence before and after laser.

There was statistically significant improvement in frequency of incontinence and amount of leakage after laser therapy (table3).

| phases of climacteric (53)*: | Grade of SUI before laser | | | | Test of significance | p-value |
|--|---------------------------|----------|--------------|------------|------------------------|----------|
| | No SUI | Mild SUI | Moderate SUI | Severe SUI | | |
| Perimenopause =34 (64%) | 0(0%) | 4(7.5%) | 29 (55%) | 1(2%) | X ² =19.137 | 0.0007 S |
| Post-menopause <5 years =9(17%) | 0 (0%) | 2(3.7%) | 7(13%) | 0(0%) | | |
| Post-menopause >5years=10(19%) | 0(0%) | 1(1.8%) | 4(8%) | 5(9%) | | |

Table (4a): Relation between phases of climacteric and grades of SUI before laser therapy.

There was statistically significant direct relation between phases of climacteric and grades of SUI before laser (p=0.0007) (table 4a).

| Phases of climacteric (53)*: | Grade of SUI after laser | | | | Test of significance | p-value |
|--|--------------------------|----------|--------------|------------|------------------------|---------|
| | No SUI | Mild SUI | Moderate SUI | Severe SUI | | |
| Perimenopause =34 (64%) | 13(24%) | 16(30%) | 5 (9.5%) | 0 (0%) | X ² =10.004 | 0.040 S |
| Post menopause <5 years =9 (17%) | 6 (11%) | 2 (4%) | 1 (2%) | 0 (0%) | | |
| Post menopause > 5 years=10 (19%) | 4 (8%) | 1 (2%) | 5 (9.5%) | 0 (0%) | | |

Table (4b): Relation between phases of climacteric and grades of SUI after laser therapy.

There was statistically significant inverse relationship between phases of climacteric, duration of menopause and grades of SUI after laser therapy (p =0.040) (table 4b).

| Variable* | before laser | after laser treatment | Test of significance | P |
|--|--------------------------------------|---|------------------------|------------|
| SUI(grade) 7. No SUI 8. Grade 1 mild SUI 9. Grade 2 moderate SUI 10. Grade 3 severe SUI | 0 (0%) 7(13%) 40(71%) 6(11) | 23 (43%) 19 (36%) 11 (21%) 0(0%) | X ² =51.029 | <0.0001 HS |

Statistically significant at p- value <0.05

X² means chi-square value

Table 5: Comparison among grades of SUI of study group before and after laser.

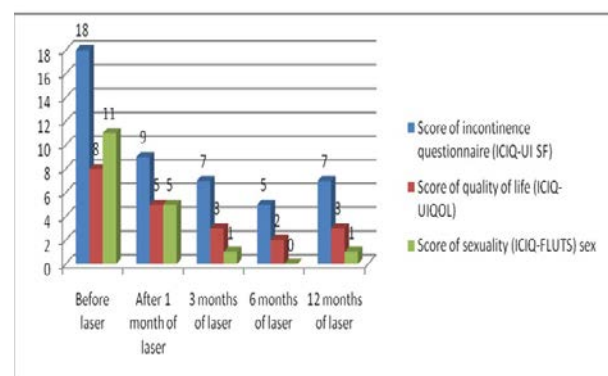


Fig. 1: Comparison between scores of incontinence questionnaire, quality of life and sexuality before and after laser.

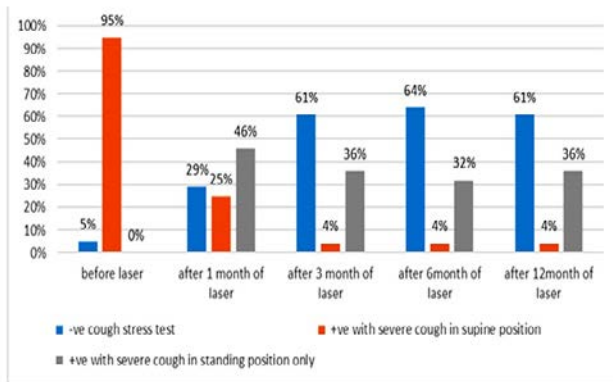


Fig. 2: Comparison between cough stress test before and after laser.

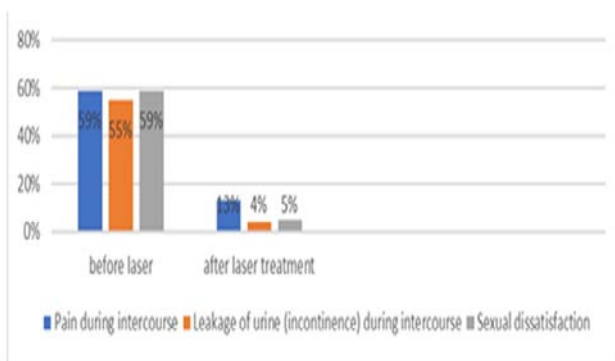


Fig. (3): Comparison of sexual history as regard pain, leakage of urine during intercourse and sexual dissatisfaction of study group before and after laser. There was statistically significant improvement as regard pain, leakage of urine and sexual dissatisfaction during intercourse in sexually active women of study group after laser ($p < 0.05$) at 1, 3, 6, 12 months (figure3).

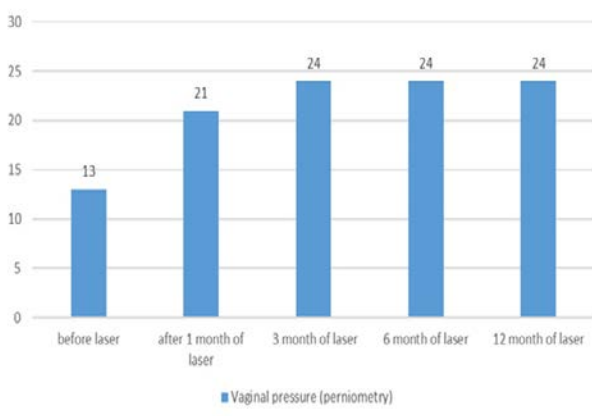


Fig. 4: Comparison between vaginal pressure measurements (perniometer) of study group before and after laser at 1, 3, 6, 12 months. There was statistically significant difference in the mean of vaginal pressure measurement in study group before and after laser treatment ($p < 0.05$) (fig4).

| Adverse effect of laser therapy | No (%) |
|---|---------|
| Discomfort & burning sensation during session | 25(47%) |
| Mild pain for 1 day after laser | 9(17%) |
| Mild pain for 2 days | 5(9%) |
| Bleeding | 0(0%) |
| Affecting activities of patients | 0 (0%) |
| Superficial burn or scarring | 0(0%) |
| Hyper pigmentation or hypo pigmentation | 0(0%) |
| Infection | 0(0%) |
| Recurrence | 7 (13%) |

Table 6: Adverse effect of laser therapy.

DISCUSSION

All patients in this study underwent treatment by Er: YAG laser (2940nm) in a nonablative photo thermal stimulation of collagen neogenesis, shrinking and tightening of vaginal mucosa tissue and collagen-rich endopelvic fascia, and subsequently greater support of bladder.

Our study revealed a significant improvement in both frequency & amount of incontinence ($p < 0.05$) after laser treatment (table3). These results were not far from Fistoncic et al [16], they detected a significant improvement of frequency and amount of incontinence in patients treated by IntimaLase™ for vaginal tightening.

Our study showed a significant direct relation between phases of climacteric and grades of SUI before laser therapy ($p\text{-value} < 0.001$) (table 4a). It means that with increasing the age there was increasing in grades of SUI. Also with lengthened the duration of post menopause the grades of SUI was increased. While there was significant inverse relation between phases of climacteric and grade of SUI after laser therapy ($p\text{-value} < 0.05$) (table 4b). Moreover there was improvement in grades of SUI with increase the duration of menopause after laser therapy, this indicate that, the laser therapy is effective in collagen regeneration in postmenopausal patients especially with long duration > 5 years, so we emphasis that the laser mainly act on collagen deprived tissues which happened with menopause and the advanced age.

Our study detected a statistically significant improvement in grades of SUI after laser treatment ($p\text{-value} = 0.0001$). Before laser treatment, 7(13%) of patients had grade 1(mild SUI) (leakage of urine occur with severe stress as cough), 40 (76%) of patients had grade 2 (moderate SUI) (leakage of urine with effort as walking), and 6(11%) had grade 3 (severe SUI) (leakage of urine occur at rest). After first session of laser treatment, most of patients showed improvement as follows: all patients of mild SUI 7(13%) and 11(21%) patients of moderate SUI were completely relived while the rest of patients with moderate SUI showed improvement in frequency and amount of incontinence, the patients with severe SUI showed no response. After 2nd session of laser, the rest of moderate SUI 29 (55%) were nearly normal (only leakage one drop with severe cough), patients with severe SUI 6(11%) showed improvement in frequency and amount of leakage but need another session, so 3rd session were

done for them, and they got better to become moderate to mild SUI (table 5). These results were not far from Rivera,¹⁷ who used IncontiLase protocol in treatment of 115 patients suffering from (SUI). They found improvement of mild and some moderate patients after the first session, and more improvement was observed in the rest of moderate SUI after second session, with no improvement in cases with severe SUI.

Our results showed a significant improvement in the mean of ICIQ-UI SF score at 1,3,6, and 12 months post treatment (9,7,5 and 7 points, respectively) when compared to before treatment (18 points), (figure 1) ($p < 0.05$). Our result was in agreement of Ivan et al [18]. In a study of laser procedure for early stages of SUI, where all patients responded to the ICIQ-UI questionnaire, the average ICIQ-UI score before and at 1,3, and 6 months post treatment was, 11, 7.4, 7.6, 8.0 points respectively and this was statistically significant ($p < 0.05$).

There were statistically significant improvement in all questionnaires scores after laser treatment at 1, 3, 6, 12 months (figures 1).

The present study revealed a significant improvement of the mean score of QOL after treatment at 1, 3, 6 and 12 months when compared to before treatment, it was 5, 3, 2 and 3 points versus 8 points respectively. This consistent with Majaron et al [19], who found a significant improvement in QOL that was evaluated by ICIQ-UIQOL score, after IncontiLase treatment by > 3 points at 6-weeks.

Our study revealed a significant improvement in cough stress test following laser therapy (p -value < 0.05) (fig 2).

There was a statistically significant difference in cough stress test ($p < 0.05$) after laser therapy at 1, 3, 6, 12 months (figure 2).

Our study revealed improvement in sexual function after laser treatment, which assessed by ICIQ-FLUTS scoring system (p value < 0.05) (fig 3). This result was correlated with Garcia et al [20], they conducted a study on twenty-nine patients treated by (IntimaLaseTM) for vaginal tightening, which revealed a 96.6% subjective improvement of sexual history.

Regarding the result of perineometer, our study showed significant improvement in perineal muscle tone in all patients after laser treatment at 1, 3, 6, 12 months follow-up compared to before treatment as follows: 21, 24, 24, 24 mmHg respectively versus 13 mmHg before treatment. (p -value = 0.001) (fig 4). The results were in keeping with Saracoglu [21], who treating SUI and laser vaginal tightening using a one session of the IncontiLase, that all patients were done perineometer before and at 6 weeks of the laser therapy, perineometric measurements showed increases of maximal pressure from 18.0 to 23.8 mm Hg.

Our patients didn't need to repeat the urodynamic study after laser therapy because there was no indication for it.

We detected minor side effects such as, mild pain & burning sensation which occurred in 39 patients (73%) and disappeared within 1-2 days post procedure (table 6). Those results were consistent with Rivera (17), using the IntimaLaseTM protocol, which revealed no adverse effects after one month from the first session. Recurrence occurred in seven patients (13%), which may be attributed to decrease in the immunity of the patients with presence of predisposing factors of SUI as constipation, and cough.

CONCLUSION

This study concluded that minimally invasive non-surgical laser treatment offered efficacious treatment for mild and moderate postmenopausal pure or mixed SUI with or without mild prolapse. Also, it improved severe SUI as regard amount and frequency. It improved quality of life of patients and their sexual matters with increased safety and a short period of recovery.

LIMITATION

This study does not prove that laser therapy can rejuvenate the deficient collagen in urogenital tissues, because most of reported information are based on patient questionnaires (suggestive method) so we need to other studies used confirmatory method to evaluate the collagen tissue rejuvenation as biopsy and histological examination (before & after treatment). Other limitations; this study is a one arm study (involved one group only). It may be precise the benefits and side effects of laser treatment in cases of SUI but it prefers to clarify the pros and cons of laser in comparison to other treatment modalities. So we recommend RCTs studies to compare the effectiveness and side effects of laser (including the cost) with other treatment modalities. In addition, we only examine the efficacy of laser treatment up to one year, we recommend more studies to evaluate; the need of booster dose or not, to maintain the sound result, and the long term complications if present.

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