The Role of Diode Laser in Urinary Incontinence

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Aim: The aim of our study is to assess efficacy of Non-Invasive Gallium Aluminium Arsenide laser (Diode laser) for female Stress Urinary incontinence (SUI).

Materials and Methods: Forty-Seven women with SUI were included in the study and scheduled for Solid State vaginal Diode laser treatment. The procedure was performed with a 1470 nm, Diode laser (Sabrina Solid State Diode Laser from Heager GmbH Germany) designed to heat up the vaginal mucosa to around 60°C. All subjects had a baseline and 6 months' post treatment assessment that included perineal sonography and lower urinary tract symptoms.

Results. Significant improvements in both urinary frequency and incontinence were found 6 months after Diode laser treatment when compared to the baseline ($p<0.001$). The battery of questionnaires administered to patients, including the UDI-6, IIQ-7, OABSS, and POPDI-6, all showed significant improvement posttreatment ($P < 0.001$). The treatment efficacy for the vaginal Diode laser for SUI at 6 months posttreatment was 80.85% (31/41). Bladder neck mobility by perineal ultrasonography decreased significantly (16.4 ± 6.2 mm to 10.34 ± 4.4 mm) after treatment ($p=0.039$). No permanent adverse events were found.

Conclusions. The Diode vaginal laser seems to be a safe and efficacious treatment for women with mild to moderate SUI, this being partly related to the decrease of bladder neck mobility following laser treatment.

Introduction

Urinary Incontinence in Women: Urinary incontinence is the accidental loss of urine.

- Over 50% adult female experience temporary or chronic urinary incontinence.
- This condition can occur at any age, but it is more common in women over the age of 50.
- There are four types of urinary incontinence: urgency, stress, functional and overflow incontinence.
- Behavioural therapies, medications, nerve stimulation and surgery are some of the treatments available for managing urinary incontinence.

What is urinary incontinence?

Urinary incontinence (UI) is the accidental loss of urine. UI can occur at any age, but it is more common among women over 50. Urinary incontinence may be a temporary condition that results from an underlying medical condition. It can range from the discomfort of slight losses of urine to severe, frequent wetting.

What causes urinary incontinence?

Urinary incontinence is not an inevitable result of aging, but it is particularly common in older people. It is often caused by specific changes in body function that may result from diseases, use of medications and/or the onset of an illness. Sometimes it is the first and only symptom of a urinary tract infection. Women are most likely to develop urinary incontinence during pregnancy and after childbirth, or after the hormonal changes of menopause.

What are some of the different types of urinary incontinence?

The following are some of the different types of urinary incontinence:

- Urgency incontinence**:** This is the inability to hold urine long enough to reach a restroom. It can be associated with having to urinate often and feeling a strong, sudden urge to urinate. It can be a separate condition, but it may also be an indication of other diseases or conditions that would also warrant medical attention.
- Stress incontinence**:** This is the leakage of urine during exercise, coughing, sneezing, laughing, lifting heavy objects or performing other body movements that put pressure on the bladder.
- Functional incontinence**:** This is urine leakage due to a difficulty reaching a restroom in time because of physical conditions, such as arthritis, injury or other disabilities.
- Overflow incontinence: Leakage occurs when the quantity of urine produced exceeds the bladder's capacity to hold it.

What are the symptoms of urinary incontinence?

The following are common symptoms of urinary incontinence. However, each individual may experience symptoms differently. Symptoms may include:

- Needing to rush to the restroom and/or losing urine if you do not get to the restroom in time
- Urine leakage with movements or exercise
- Leakage of urine that prevents activities
- Urine leakage with coughing, sneezing or laughing
- Leakage of urine that began or continued after surgery
- Leakage of urine that causes embarrassment
- Constant feeling of wetness without sensation of urine leakage

- Feeling of incomplete bladder emptying

The treatment of SUI includes conservative treatment and surgical intervention. The conservative treatment methods focus on lifestyle modification, bladder and pelvic muscle training, and electronic stimulation of pelvic floor muscles. Although conservative treatment can attain results,many patients experience poor outcomes due to low persistence and compliance rates. Regarding surgical intervention for SUI, the middle urethral sling procedure is the standard surgery and is regarded as an effective treatment, however, the adverse effects of transvaginal sling surgery may occur, including mesh extrusion, voiding dysfunction, dyspareunia, and pain. Due to these possible complications, patients are often reluctant to undergo surgical intervention. Furthermore, the American Food and Drug Administration (FDA) has announced warnings regarding their use.Therefore, the risks of these devices should be evaluated, and patients should be informed prior to use.

Method & Material: In this study all patients were treated with the non-ablative SSVL (Sabrina – Heager GmbH Germany) with a wavelength of 1470 nm using a fluence (laser energy emitted per unit area) of 10-15 J/cm^2. The handpiece of the Solid-State Vaginal Laser (SSVL) (SABRINA) used to perform the treatment is a vaginal internal probe developed for gentle introduction with a radial light emission in continuous mode working at 360° on the vaginal channel. Its spot size it's larger than the spot size of the other vaginal laser (CO2, Er: Yag spot size 150-300 micron) and this characteristic enables greater depth of penetration improving the absorption of energy at the target. Particularly this laser uses a laser wavelength with a proper mix between water absorption and tissue penetration without creating ablation which enables heat to the vaginal wall to shorten the intermolecular cross-links of collagen, shrinking the collagen fibers & enhancing collagen production (16,17), the thermal effect of the vaginal laser seems to strengthen the support of the vaginal wall via neo collagenases & subsequently helps to treat SUI.

The procedure was performed in the outpatient clinic and did not require any specific preparation (e.g., analgesia/anesthesia). After each treatment the patients were advised not to have sexual activity and not to wear tight clothing and/or play sports that would rub the treated area for 1 week.

It included 47 Women for this study and these women were classified using the Ingelman-Sundbergmethod of stress incontinence classification (18). They were classified into three grades based upon their clinical severity. Grade I: urinary incontinence when coughing or sneezing. Grade II: urinary incontinence when running or lifting objects off the floor. Grade III: urinary incontinence when walking or climbing stairs. The grades of Ingelman-Sundberg are in accordance with Stamey as grade I: Mild (SUI only with severe stress, such as coughing or sneezing), grade II:Moderate (incontinence with minimal stress, including walking or running), and grade III:severe (incontinence at bed rest)(19) . All patients underwent three treatments, usingthe Solid-State Diode vaginal laser (Sabrina from Heager GmbH Germany) with a wavelength of 1470 nm, every 2 weeks.

Before and 6 months after treatment, each patient's base- line characteristic data was collected and a personal interview was conducted using the following battery of questionnaires: Incontinence Questionnaire–Short Form (ICIQ-SF)(20) , Urogenital Distress Inventory 6 (UDI-6), Incontinence Impact Questionnaire 7 (IIQ-7)(21) , Overactive Bladder Symptom Score (OABSS)(22) , and Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6)(23) . The information gained was used to assess each patient's degree of urinary incontinence and its impact on their quality of life.

Table 1: Demographic data (n=47) are given as mean ± standard deviation or n (%).

Mean age (years)	47.5 ± 5.2
Mean parity	2.3 ± 0.7
Mean BMI (kg/m2)	21.7 ± 3.5
Maximal birth weight (kg)	3.1 ± 0.3
Pad test	5.5 ± 2.3
Menopause 30 (63.8)	
SUI grade	
grade 1	10 (19.5)
grade 2	30 (65.0)
grade 3	7 (15.0%)
Follow up (months)	6

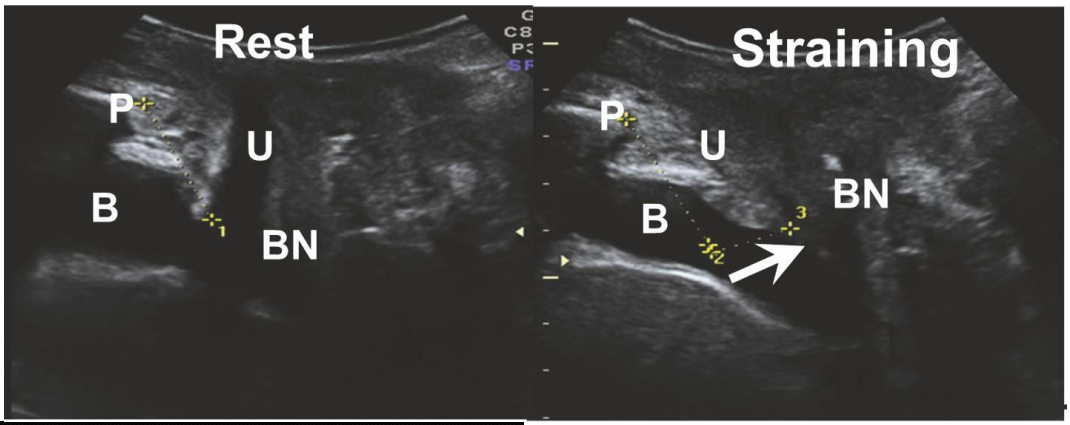
BMI, body mass index.

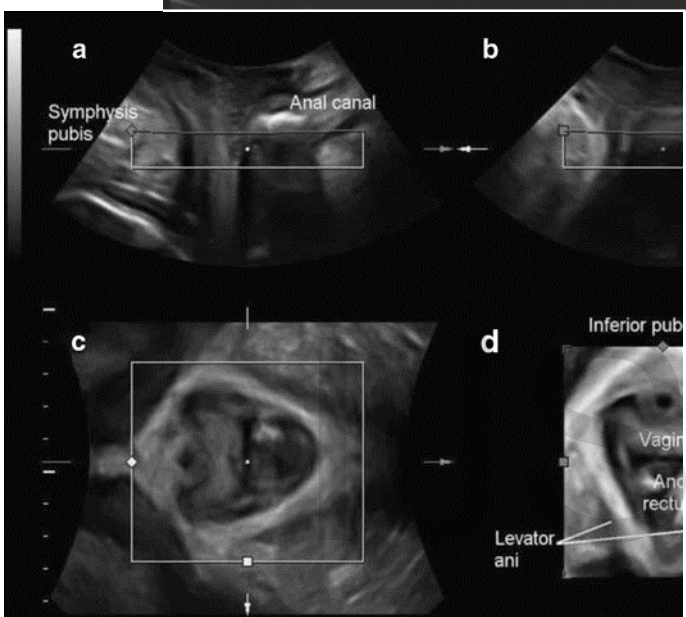
Values are expressed as mean ± standard deviation or numbers.

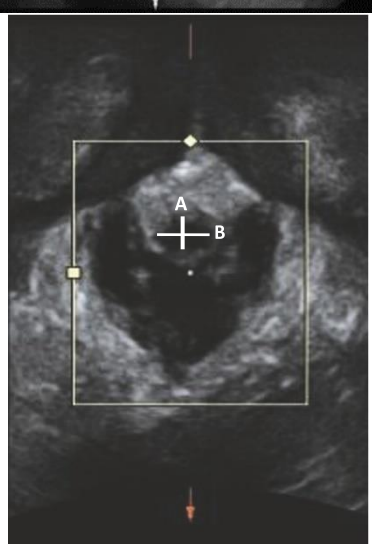
Perineal ultrasound was performed and the transducer was placed between the major labia and underneath the external urethral orifice. The assessments included calculation of the hypoechoic area of the proximal, middle, and distal urethra by multiplying π by the lengths of the short (A) and long (B) axes of the urethral core at rest and during Valsalva maneuver using three-dimensional mode (Figure 1). The sagittal view was used to measure bladder neck mobility at rest and during Valsalva maneuver at baseline and three months after treatment (Figure 2).

The vaginal pressure was measured at rest and during contraction prior to initial treatment and repeated 6 months after laser treatment. The average and maximal pressures and the period of time during contraction were also calculated. If patients did not adhere to their scheduled follow-up appointments, their recordings were excluded from the study. For normal distribution, data was reported as mean and standard deviations. Statistical significance was set to $p < 0.05$. Confidence intervals were set at 95%. Two-way analysis of variance for repeated measures and factorial analysis of variance were used to test the differences within and between the groups.

The ethics committee of our hospital approved the study protocol.







(a)

Figure 1: (a) **Perineal sonography**. Lower urinary tract on three-dimensional trans perineal ultrasound imaging in a woman. The top left image shows the mid-sagittal view (A-plane). The top right image is a coronal view (B-plane); the bottom left is the axial or C-plane, showing hypoechogenic area of urethra. The bottom right image is the resulting rendered volume. (b) **Axial view of the urethral hypoechoic core**. Ultrasound image (axial plane) of the mid-urethral hypoechoic core in a woman with SUI, showing the measurements made for this study: the shortest (A) and longest (B) diameters of the urethral hypoechoic core.

Figure 2: The sagittal view of perineal sonography. The pubic bone marked as P. The urethra marked as U. The bladder marked as B. The bladder neck marked as BN. The pubic bone is set as basic point and makes a line from the pubic bone to BN at rest and during straining. The maximal distance of two lines is calculated as bladder mobility.

Results

All 47 patients completed the study. The demographic characteristics of the patients are presented in Table 1. The mean age of the patients was 47.5 ± 5.2 years. Thirty women were menopausal. The median parities were 2.3 ± 0.7. The distribution among the grade levels of severity of SUI is as follows: grade I, 10 patients; grade II, 30 patients; and grade III, 7 patients. The ICIQ-SF median score, which assessed the frequency and severity of incontinence, before treatment was 9.2 ± 3.7 and significantly decreased to 3.5 ± 3.6 post treatment ($p<0.001$) (Table 2). The UDI-6 and IID-7 were used to assess the symptoms of distress and the impact of urinary incontinence on the subjects' daily life; both were significantly decreased after treatment ($p < 0.01$). The OABSS significantly improved with scores from 6.9 ± 4.0 to 2.7 ± 2.2 ($p=0.001$). The scores of POPDI-6, which measured distress and discomfort of pelvic organ prolapse or vaginal relaxation, were significantly decreased from 7.06 ± 3.5 to 1.5 ± 1.6 ($p< 0.001$).

At 6 months after treatment, 44.68% (21/47) of patients were cured of SUI, with 36.17% (17/47) of patients reporting improvement. In nine patients (19.14%), there was no improvement. The treatment efficacy of Diode laser 6 months post treatment was 80.85% (38/47) (Table 3).

After Heager GmbH Germany Sabrina Solid State Diode laser treatment, measurements of the middle urethral short axes (A), long axes (B), and middle urethra areas showed an obvious decrease at rest (A: 5.4 ± 1.2 mm to 4.7 ± 1.0 mm, $p=0.033$; B: 7.4 ± 2.1 mm to 6.4 ± 1.7 mm, $p=0.024$; area: 130 ± 58 mm^2 to 93.5 ± 42.7 mm^2, $p=0.001$). The proximal urethral short axes (A) and the distal

Table 2: Questionnaires from baseline before the intervention and 6 months posttreatment.

n=41	Baseline	6 months post laser	P value∗
ICIQ-SF	9.2 ± 3.7	3.5 ± 1.4	<0.001∗
UDI-6	36.7 ± 15.4	13.9 ± 12.8	<0.001∗
IID-7	29.2 ± 18.5	11.8 ± 18.7	<0.001∗
OABSS	6.9 ± 4.0	2.7 ± 2.1	0.001∗
POPDI-6	7.06 ± 3.5	1.5 ± 1.6	<0.001∗

Values are expressed as mean ± standard deviation or numbers.

∗Statistical significance; paired t-test.

Table 3: Efficacy of Diode laser.

N=47	6 months post treatment: n(%)
Cure	21 (44.68)
Improved	17 (36.17)
Failure	9 (19.14)
Efficacy of laser	38/47 (80.85%)

urethral long axes (B) were also significantly decreased (A: 5.6 ± 1.9 mm, p=0.028; B: 7.0 ± 2.0, p= 0.001) (Table 4).

During straining, the measurements of the mid-urethral areas and short axes (A) were significantly decreased (area: 90.0 ± 57.4mm to 80.0 ± 30.9 mm, p=0.048; A: 2.2 ± 3.3 mm

to 2.3 ± 3.4, p=0.006) (Table 5). Bladder neck mobility from resting to straining via perineal sonography showed significant decrease after laser treatment (16.1 ± 6.4 mm to 10.5 ± 4.6 mm, p=0.039) (Figure 2).

Discussion

As previous studies have reported, there are no long-term complications when using minimally invasive, nonsurgical, or non-ablative laser therapy [12, 16, 17]. The most commonly reported adverse effects from the Diode vaginal laser, in our study, were a burning sensation felt by the patient when vaginal probe tip touches labia while it's coming out from vagina and less vaginal bleeding during the first week post treatment.

The efficacy of our treatment using the Heager GmbH Sabrina Solid State Diode Laser was approximately 80.85%, The 90% of women who underwent the Diode vaginal laser treatment in our study were classified as either grade I or grade II SUI; therefore, the efficacy for treatment for severe SUI (grade III) should be further investigated.

the patients' quality of life and symptoms of incontinence, assessed using UDI- 6 and IID-7, improved after treatment with the Diode laser (25,26). and we also have noticed that the pure cure-rate is 44.68 % which is high in comparison to similar studies conducted with other laser CO2, Er Yag and Radio frequency devices. more so ever in comparison to other studies, our OABSS and POPDI scores were significantly decreased. Women with SUI usually have OAB problem and most parous women demonstrated some degree of cystocele. The mechanism has been investigated that funneling of the proximal urethra urine enters the proximal urethra and then produces sensory stimulation resulting in a reflex of bladder contraction with OAB (27). The Diode vaginal laser treatment has proven to have a supportive effect on the bladder; therefore, we expected that it could also improve symptoms of SUI, then with relatively less bladder contractions to improve OAB and also less prolapse associated disturbance. From our ultrasound data, we further demonstrated the supportive effect of Diode vaginal laser treatment on the bladder and urethra, as evidenced by a decrease in measured bladder neck mobility (16.1 ± 6.4 mm to 10.5 ± 4.6 mm). a woman with the bladder neck decent during straining over 13 mm is a predictor of SUI (28). The change in bladder neck mobility after Diode laser treatment explains not only the positive effect on bladder stability, but also the improvement of SUI symptoms in our study.

Due to SUI often being related to pelvic floor muscle dysfunction, we were inquisitive about a possible application using the Diode laser to increase pelvic muscle tone (29, 30). Surprisingly, the assessed muscle tone did show an increase after treatment, we took into consideration that the wave emitted by the Diode vaginal laser with a spot size of 6 mm could penetrate around 2 – 3 mm, so the laser's effectiveness on increasing pelvic muscle tone would be increased. More so ever, a

synergistic benefit may be achieved with a combined treatment regimen using the Diode laser in combination with pelvic muscle exercises, thereby allowing for a different mechanism for SUI improvement.

Table 4: Resting urethral topography at baseline and 6 months after treatment.

Rest	Baseline	6 months post laser	P-value*
Proximal (area)(mm^2)	120.4 ± 51.2	91 ± 51.2	0.097
A (mm)	5.7 ± 1.6	4.4 ± 1.5	0.026*
B (mm)	6.9 ± 1.6	6.0 ± 1.4	0.915
Middle (area)(mm^2)	134.6 ± 55	90.5 ± 41.6	0.001*
A (mm)	5.7 ± 1.3	4.8 ± 1.0	0.032*
B (mm)	7.7 ± 2.0	6.3 ± 1.6	0.025*
Distal (area)(mm^2)	111.3 ± 51.2	74.9 ± 60.8	0.003*
A (mm)	4.9 ± 1.2	4.0 ± 1.2	0.152
B (mm)	7.3 ± 2.0	5.7 ± 2.0	0.001*

Values are expressed as mean ± standard deviation or numbers.

*Statistical significance; paired t-test.

Table 5: Straning urethral topography at baseline and 6 months after treatment.

Straining	Baseline	6 months post laser	P-value*
Proximal (area)(mm^2)	107.1 ± 44.1	92.0 ± 53.9	0.543
A (mm)	5.1 ± 1.2	4.1 ± 3.7	0.318
B (mm)	6.9 ± 1.6	5.0 ± 4.6	0.203
Middle (area)(mm^2)	94.0 ± 54.4	79.0 ± 29.9	0.044*
A (mm)	2.5 ± 3.4	2.6 ± 3.3	0.006*
B (mm)	7.9 ± 4.1	6.1 ± 4.2	0.063
Distal (area)(mm^2)	78.0 ± 59.4	79.0 ± 44.3	0.001*
A (mm)	3.1 ± 3.5	1.3 ± 2.5	0.134
B (mm)	5.9 ± 4.4	6.8 ± 4.4	0.300
Bladder neck mobility (mm)	16.4 ± 6.2	10.3 ± 4.4	0.039*

Values are expressed as mean ± standard deviation or numbers.

*Statistical significance; paired t-test.

Table 6: Perineometry at baseline and 6months after treatment.

Perineometry	Baseline (n = 41)	6-month follow-up (n = 31)	P value*
Resting (mmHg)	32.9 ± 12.7	36 ± 18.5	0.134
Contraction			
Maximal (mmHg)	59.6 ± 20	61.3 ± 25.4	0.689
Average (mmHg)	43.4 ± 15.7	51.3 ± 21.0	0.161
Duration (seconds)	28.1 ± 16.0	30.1 ± 21.5	0.547

Values are expressed as mean ± standard deviation or numbers.

*Statistical significance; paired t-test.

Conclusion: Diode vaginal laser is an effective treatment for women with Mild to Moderate SUI. No severe or permanent side effects occurred during or after treatment. The bladder neck mobility from perineal sonography was significantly decreased after Diode vaginal laser treatment, which contributed to the improvement of SUI symptoms. More prospective studies and longer follow-up would be helpful to confirm our findings and realize the appropriate interval for repeat intervention.

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