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Prospective study of safety and objective improvement in sysmptoms of GSM (Genitourinary syndrome of menopause) with Er:YAG vaginal /urethral laser treatment

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ABSTRACT

Background: Genitourinary syndrome of menopause (GSM) is the condition which combines the conditions of vulvovaginal atrophy (VVA) and urinary tract dysfunction which are associated with oestrogen deficiency. GSM is treated using vaginal laser therapy by using non-ablative Er: YAG laser therapy to evaluate the effectiveness and safety of this therapy. The present study was planned to evaluate the safety and objective improvement in symptoms of GSM with Er:yag vaginal / urethral laser treatment in sextual and urinary symptoms of post / peri menopausal women on long term basis.

Materials and Methods: A prospective study was conducted at V care laser centre from 2020 on words to till date. Total sample population enrolled was 74 among them 53 completed 1^{st} follow up and 29 had completed 2^{nd} follow up. Data were collected before and subsequent 2 follow ups over next 12 months on parameters like dryness, dyspareunia, itching/ burning and lower urinary tract symptoms, data were collected using VLQ (vaginal laxity questionnaire), VHIS (vaginal health index score), FSDS-R (The female sexual distress scale – revised)and Satisfaction questionnaire (0-3) assessed on FSFI.

Result: The study showed symptomatic improvement among patients with GSM like no pain or mild pain among 79.31% and 20.39% respectively, no itching (72.41%) at the end of 2^{nd} follow up. There was an improvement in vaginal condition (normal – 93.10%) at the end of 2^{nd} follow up. Majority of patients reported no sexual distress (82.7%).

Conclusion: The non-ablative Er: YAG laser therapy is efficacious and safe modality for treatment of symptoms in cases of genitourinary syndrome of menopause. It also offers a promising, minimally invasive safe treatment for SUI.

1. Introduction

The genitourinary syndrome of menopause (GSM) occurs due to hypoestrogenism and affects the vulvar, vaginal and urological tissues.[1] It affects about 50% of women who undergo menopause. Urological symptoms include urinary tract infections; while vulvovaginal symptoms include dyspareunia, pain, dryness, itching, and tissue friability.[2] For genitourinary syndrome of menopause (GSM), the recommended treatment includes hormonal therapies such as estrogen-based medications, as well as non-hormonal therapies such as vaginal lubricants, and moisturizers.[3,4] Ospemifene is currently a non-estrogen

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selective estrogen receptor modulator, the only approved, effective and safe non-hormonal treatment option for GSM; however, it has been found associated with estrogenic effects on endometrial tissue as well as systemic hot flush symptoms.[5,6]

As a non-hormonal option for the treatment of GSM, laser therapy was introduced. It works by stimulating the body's mechanism to repair, grow, and heal tissue, thereby facilitating regenerating tissues. There are two types of lasers most thoroughly evaluated for their use in GSM treatment are the microablative fractional co_2 laser and the Erbium: YAG (Er:YAG) laser.[7] The treatment with a co_2 laser or an Er:YAG laser for the GSM usually consists of three procedures spaced 4 to 6 weeks apart.[8] In the co_2 laser therapy, a gaseous medium at wavelength of 10,600 nm is used, which when absorbed by tissue water results in various depths of penetration and ablation.[9,10] While the Er:YAG laser therapy uses a solid medium with a wavelength of 2,940 nm, in which more focused ablation is allowed and there are deeper thermal secondary effects due to its approximation of the peak of water absorption.[11,12]

For evaluation of laser therapy in GSM, the last systemic review (SR) concluded that laser therapy for post-menopausal women with GSM appears promising as it can reduce severity of symptoms, improve quality of life, and restore the vaginal mucosa to its pre- menopausal state; however, the authors claimed that the quality of the body of evidence is low or very low. Thus, the evidence-based modifications of the current clinical practice cannot be suggested.[2]

Recently, in women with breast cancer and GSM, another meta-analysis evaluated the effects of laser therapy, the study concluded that prospective, large-scale, randomized controlled trials were necessary to fully explore the benefits of vaginal laser therapy for treatment of atrophy of vagina, such as reducing severity of symptoms and improving the quality of life of post-menopausal women.[1,13]

Therefore, there is need of new studies to assess the safety and effectiveness of lasers in the treatment of GSM. The protocol for this proposes a SR with meta-analysis of randomized clinical trials that assess new high-quality evidence supporting laser therapy as a therapeutic option in menopausal with the genitourinary syndrome of menopause (GSM) limited data were available on long term effect of such treatment hence the present study was planned to assess the safety and objective improvement in symptoms of GSM with Er:yag vaginal / urethral laser treatment in sextual and urinary symptoms of post / peri menopausal women on long term basis.[14]

2. Materials and Methods

2.1. Study design, setting and duration

The study was a prospective, longitudinal in nature; planned at V care laser centre for Cosmetic Gynaecology, Indore, Madhya Pradesh from 2020 onward to till date.

2.2. Sample size and sample population

The patient came with symptoms of GSM were enrolled as study population and till date 74 were participated in the study. Out of total 53 had completed 1^{st} follow up and 29 had completed 2^{nd} follow up of the treatment.

2.3. Treatment protocol

Inclusion criteria 1. Normal cell cytology (PAP smear) 2. Negative urine culture 3. Vaginal canal, introitus and vestibule free of injuries, 4. Sexual active and non-active women. Exclusion criteria: 1. Pregnancy, 2. Intake of photosensitive drugs 3. Injury or/and active infection in the treatment area, 4. Undiagnosed vaginal bleeding, 5. Active menstruation.

2.4. Data collection tools used for this study

1. VLQ (vaginal laxity questionnaire)
2. VHIS (vaginal health index score)
3. FSDS-R (The female sexual distress scale – revised)
4. Satisfaction questionnaire (0-3).

2.5. Treatment procedure

Renovalase® Treatment Protocol with using SClear and MClear speculum. Total duration of Treatment: 20-30 minutes.

2.6. Post treatment guidelines

1. The patient does not require any special aftercare, such as medications or special equipment.
2. It is advised to follow standard precautions associated with stress urinary incontinence, such as avoiding efforts that may put pressure on the bladder. This is especially important during the first month after the treatment, i.e. during the period of most intensive neocollagenesis and further collagen remodelling.
3. It is also advised that the patient refrain from sexual activity for at least one week following treatment.
4. The patient should report and return for check-up at an occurrence of any adverse effects aside from transient mild erythema and oedema.
5. The patient should keep a diary to record changes in behaviours and any incidents related to GSM.

2.6.1. Repetition

1. The subsequent visits was being scheduled as per the treatment protocol.
2. Usually, Two to three sessions are administered in a year followed by a single maintenance session in subsequent year
3. The measurements were performed before, at subsequent 2 follow up visits.

2.6.2. Renovalase treatment protocol with G-runner robotic scanner

Total treatment time: 20-30 minutes

2.7. Step 1

2.7.1. Configuring laser parameters and the G-runner adapter

G-runner laser treatments can be performed with speculums of two different sizes: the larger GClear30 or the smaller GClear25. Choose a speculum that is appropriate for the size of the vaginal opening and the elasticity of the vaginal walls—the speculum should make contact with the vaginal walls while not overstretching them.

Clean and disinfect or sterilize the speculum prior to use. Refer to the cleaning, disinfection, and sterilization section in the G-runner operator manual.

Note that disinfected single-use speculums can be used in contact only with intact mucous tissue.

Set the laser system to the Renovalase 1 mode and the Top Pixel 30 or Top Pixel 25 handpiece, according to the selected speculum. Use the preset parameters, as presented on the laser system's touchscreen (Figure 1).

Figure 1: Applications library screen for the first step of the G-runner Treatment protocol with the GClear25 speculum. The image at the centre of the screen shows the correct configuration of the components needed for this step

Attach the yellow GRA-PY adapter to the G-runner and insert it into the speculum. Start the forward movement of the G-runner by pressing the forward-pointing arrow on the G-runner control panel and wait until the adapter reaches the final position. At this point, the G-runner will stop and switch directions automatically.

Moisten the speculum with distilled water and, while it is attached to the G-runner adapter, insert it into the patient's vagina. Keep the orientation of the G-runner in the upright position (control panel up).

Position the speculum so that the observing groove is in the upright position

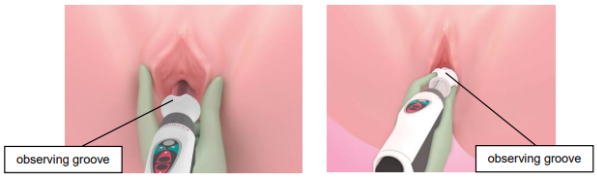

Figure 2: Insertion and initial positioning of the G-runner

Table 1: Suggested treatment parameters for Step 1 of the RenovaLase procedure with GClear25 or GClear30 speculums

RenovaLase Procedure Step 1		
User Interface Mode	Er:YAG Pulse	
Handpiece	G-runner with yellow GRA-PY adapter	
Pulse width	SMOOTH	
Pulse number	4	
Frequency	2 Hz	
Speculum	GCIear25	GClear3O
Fluence	10 J/ cm^2	11 J/ cm^2

2.7.2. Laser action: angular treatment of the anterior vaginal wall

Press your foot on the footswitch. This simultaneously initiates laser emission and the G-runner's rotation. Laser treatment of the anterior vaginal wall begins at the proximal end of the vaginal canal and moves automatically toward the vaginal opening. At first, laser energy is delivered in bursts of four SMOOTH pulses per each position along the anterior vaginal wall.

Be sure to hold the base of the speculum with one hand and to support the G-runner with your other hand during the treatment. The speculum should not rotate during the treatment.

Proceed with the treatment until the vaginal opening is reached. If at any time the patient shows discomfort, stop the treatment by lifting your foot off the footswitch. Wait for a few seconds before continuing the procedure or decreasing the laser fluence. Normally, the patient starts feeling discomfort when the scanner reaches the sensitive area, one or two centimetres from the vaginal canal opening. At this point, it is recommended to stop the laser emission and take out the G-runner adapter by pressing the backward button on the Grunner control board.

Keep the speculum in the vagina while making sure it doesn't fall out during the next step.

Figure 3: Application screen for the G-runner Renovalase 1 treatment showing a burst of four SMOOTH pulses per each position

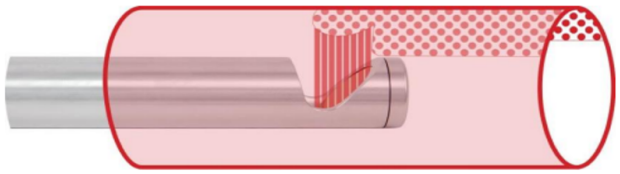

Figure 4: Deposition of laser energy along the anterior vaginal wall during the RenovaLase1 procedure

2.8. Step 2

2.8.1. Setting the laser parameters and the G-runner adapter

Set the laser system to the RenovaLase2 mode and the ContFull 30 or ContFull 25 handpiece according to the selected speculum. Use the preset parameters as presented on the laser system's touchscreen. Attach the green GRA-FG adapter to the G-runner and insert it into the speculum. Start the forward movement and wait until the adapter reaches the final position. Set the backward direction of G-runner.

2.8.2. Laser action: continuous vaginal canal treatment-first pass

Press your foot on the footswitch. This simultaneously initiates laser emission and the G-runner's rotation. The laser treatment begins at the proximal end of the vaginal canal and automatically moves toward the vaginal opening. Laser energy is delivered homogeneously in continuous SMOOTH pulses across the entire vaginal canal.

During the treatment, make sure to hold the speculum with one hand and support the G-runner with the other. The speculum should not rotate during the treatment.

Figure 5: Screen from the applications library for the second step of the G-runner RenovaLase Treatment protocol with the GClear25 speculum. The image at the centre of the screen shows the correct configuration of the components needed for this step

Proceed with the treatment until the entrance to the vaginal canal is reached. If the patient appears to be in pain, turn off the laser by removing your foot from the footswitch. Wait for a few seconds before continuing the procedure, or continue after decreasing the laser fluence on the laser system touchscreen. Normally, the patient starts feeling discomfort when the scanner reaches the sensitive area, one or two centimetres from the vaginal canal opening. At this point, it is recommended to stop the laser emission along the first pass and begin the second pass (step 2.3).

Table 2: Suggested treatment parameters for Step 2 of the RenovaLase procedure with GClear25 or GClear30 speculums

RenovaLase Procedure Step 2		
User Interface Mode	Er:YAG Pulse	
Handpiece	G-runner with green GRA-FG adapter	
Pulse width	Smooth	
Frequency	3.3 Hz	
Speculum	GClear25	GClear30
Fluence	3.5 J/ cm2	4.5 J/ cm2

2.8.3. Laser action: continuous treatment of the entire vaginal canal - second pass

Move the GRA-FG adapter to the final position by pressing the forward-pointing arrow on the G-runner control panel and waiting until the adapter reaches the final position. At this point, the G-runner will stop and switch directions automatically.

Press your foot on the laser footswitch and start the treatment as described in the previous section 2.2. Be sure to hold the base of the speculum with one hand and to support the Grunner with your other hand during the treatment. The

speculum should not rotate during the treatment.

If you stopped the treatment before reaching the vaginal opening due to discomfort, remove the adapter from the speculum by pressing the downward arrowhead on the G-runner control panel. Wait for 10 seconds and slowly remove the speculum.

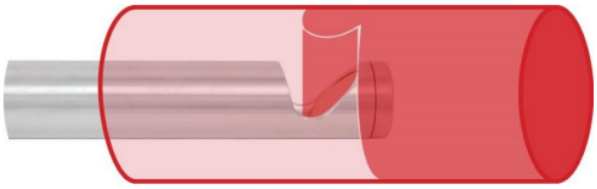

Figure 6: Continuous coverage of the whole vaginal canal

2.9. Step 3

2.9.1. Laser parameter setup and the G-runner adapter

First set the laser system to the IncontiLase3 mode and the direct Pixel handpiece, then use the preset parameters as presented on the laser system's touchscreen (Figure 7).

Then attach the red GRD-PR adapter to the G-runner. On the control panel, two red indicator lights should illuminate and remain lit. In this mode, the rotation of the G-runner is blocked and it can be used as a manual handpiece.

Figure 7: Applications library screen for the third step of the G-runner RenovaLase Treatment. At the centre of the screen the image shows the G-runner configuration

Apply laser pulses to the exposed vestibule, excluding the urethra meatus, by depositing a patterned laser beam across the whole vestibule and introitus area. At each spot location, 2-3 Smooth pulses should be delivered before moving to the next spot. Overlap the spots slightly (by approx. 10%). The three full passes across the introitus and vestibule area should be performed.

Table 3: Suggested treatment parameters for Step 3 of the RenovaLase procedure

RenovaLase Procedure Step 3	
User Interface Mode	Er:YAG Pulse
Headpiece	G-runner with green GRD-PG adapter
Pulse width	Smooth
Frequency	1.6 Hz
Fluence	10 J/ cm2

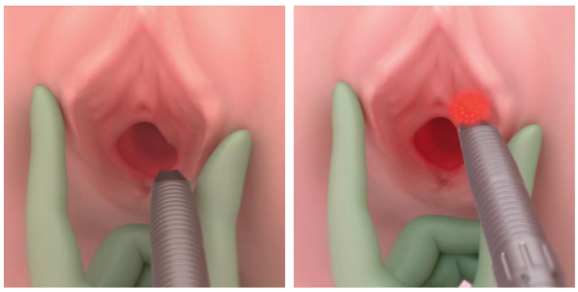

Figure 8: The treatment of the vestibule and introitus

2.10. Post-treatment guidelines

1. In the way of medications or special accessories, the patient does not require any special after care. 97258_AM_Gynecology G-runner_CE_ENG_7 Page 90/119
2. It is advised to follow standard precautions associated with GSM. This is especially important during the first month after treatment, when neocollagenesis and collagen remodelling are at their peak.
3. The patient should abstain from sexual activities for at least one week after the treatment is also recommended.
4. The patient should report and return for check-up upon any occurrence of adverse effects, aside from transient mild erythema and oedema.
5. The patient should note the changes in and any events related to GSM.

2.10.1. Repetition

1. The follow up treatment is advised as per the protocol.
2. Usually, two to three sessions are administered per year, followed by a single maintenance session the following year.

3. Results

A total of 74 (100%) women had Genitourinary Syndrome of Menopause. They underwent treatment with an Er:YAG (2940 nm) laser in non-ablative fractional mode at Vcare laser centre, a state-of-the-art centre for cosmetic gynaecology, Indore, Madhyapradesh. The enrolment of study participants started in 2020 onwards and followed

them prospectively. Informed consent from the patient was taken as per the study protocol.

The age of the patients ranges from 22 to 74 years of age with mean ± SD is 42.40 ± 13.85 years. Age wise distribution of patients was mentioned in below given Table 4.

Table 4 shows, more than half of the patients were in age group 31 – 50years (59.46%).

A total of 74 patients were treated with the IncontiLase protocol, which requires 2-3 sessions with a schedual interval.

1. 74 patients were enrolled and data were collected before treatment.
2. 53 patients completed 1st sessions
3. 29 patients completed 2nd sessions

Table 5 shows vaginal condition before treatment and its improvement over period of time visible on follow ups. Scores are used to describe vaginal laxity. A score of 1-3 indicates vaginal laxity, a score of 4 represents normal vagina (neither loose nor tight), and a score of 5-7 indicates no laxity. Out of the total 74 participants, more than three fourth (81.08%) participants were having laxity in their vagina, 12.16% had normal vagina and only 6.76% had no laxity in their vagina before receiving any treatment. Out of total, 53 had completed first follow up. Among those who had 1^{st} follow up nearly half (50.94%) had laxity in their vagina, and remaining half (47.17%) had normal vagina except one participant. On second follow up, out of 29 participants almost all participants (93.10%) had normal vagina except two patients.

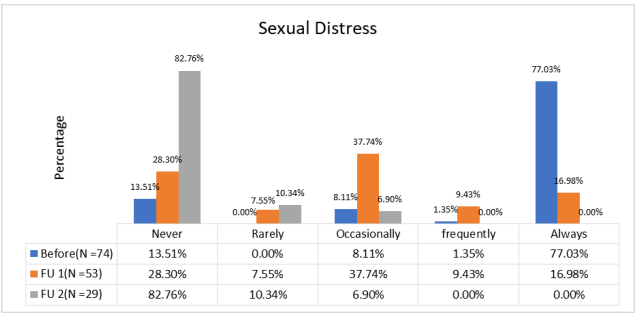

Figure 9: Sexual distress among study participants before treatment and during follow up

Figure 9 shows the data on sexual distress due to vaginal condition. Initially before treatment majority participants (77.03%) always had sexual distress, 1.35% frequently had sexual distress, 8.11% occasionally had sexual distress and 13.51% never had sexual distress. On first follow up majority participants (37.74%) had occasionally sexual distress, more than one fourth (28.30%) never had sexual distress, nearly 10% frequently had distress and 7.55% rarely had sexual distress. On second follow up majority participants (82.76%) never had sexual distress, 10.34% rarely had sexual distress and 6.9% occasionally had sexual distress. Not a single participant had regular and frequent sexual distress.

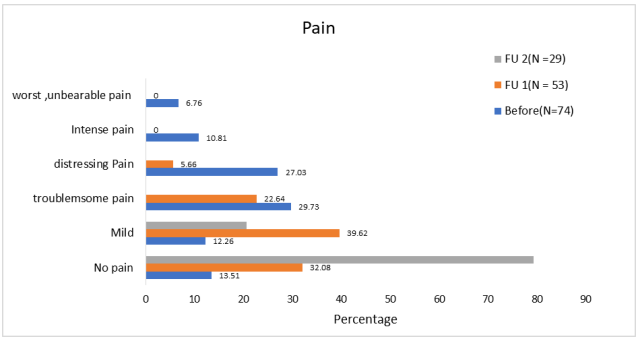

Figure 10: Pain before and during follow up among study participants

Figure 10 shows distribution of participants according to severity of pain. Severity of pain decided by scoring scale. No pain is assigned a score of 0, Mild pain is scored between 1 and 2, uncomfortable troublesome pain falls within the range of score 3 to 4, distressing pain is rated at score 5 to 6, intense pain is indicated by scores of 7 to 8 and the most severe, unbearable pain is represented by scores of 9 to 10. Before initiation of treatment, 13.51% participants reported no pain. Mild pain was reported by 12.16% of participants, while 29.73% experienced uncomfortable troublesome pain. Distressing pain was reported by 27.03% of participants. Intense pain was experienced by 10.81% of the group, and the highest level, worst and unbearable pain was reported by 6.76% of participants. On first follow up, out of 53 participants, 32.08% reported having no pain, while 39.62% experienced mild discomfort. A significant portion, 22.64% dealt with uncomfortable troublesome pain, and 5.66% faced distressing pain. Interestingly, none reported experiencing intense or worst unbearable pain. On second follow up, out of 29 participants, majority (79.31%) reported experiencing no pain. A smaller percentage of participants (20.69%) reported mild pain and none of the participants had reported uncomfortable troublesome pain, distressing pain, intense pain or worst, unbearable pain.

Figure 11 shows the distribution of participants according to itching scale. The data categorizes itching severity based on a scoring system. A score of 0 represents no itching, while a score of 1 to 7 indicates mild itching. The highest level of itching is represented by a score of 8 to 10, which is considered as maximum itching. Out of the total 74 participants, 64.86% participants experience mild itching and 35.14% participants reported maximum itching before treatment. On first follow up among the 53 participants, 5.66% experienced no itching, 92.45% had mild itching, and 1.89% reported experiencing the maximum level of itching. In the second follow up assessment with 29 participants, the

Table 4: Age distribution of sample population

Age group (years)	Number	Percentage
20-30	14	18.92%
31-40	20	27.03%
41-50	24	32.43%
51-60	10	13.51%
61-70	5	6.76%
71-75	1	1.35%

Table 5: Vaginal condition of patient before treatment and during subsequent follow up

Vagina Condition	Score	Before treatment (N = 74)		1st follow up (N = 53)		2nd follow up(N = 29)	
		Number	Percentage	Number	Percentage	Number	Percentage
Laxity	1 to 3	60	81.08%	27	50.94%	1	3.45%
Normal (neither loose not tight)	4	9	12.16%	25	47.17%	27	93.10%
No Laxity	5 to 7	5	6.76%	1	1.89%	1	3.45%

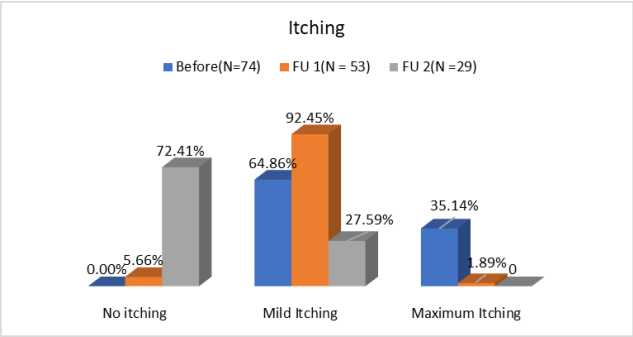

Figure 11: Itching before and during follow up among study participants

itching scale results were as follows: 72.41% of participants reported no itching, 27.59% experienced mild itching, and none reported experiencing maximum itching.

4. Discussion

The non-ablative Er:YAG laser therapy is recently introduced for the treatment of Genitourinary syndrome of menopause among pre and post menopausal women.[15] The present study revealed showed improvement among patient either by no complain or reduction of symptoms to tolerable level.

5. Conclusion

The non-ablative Er:YAG laser therapy by RenovaLase© improves the symptoms of GSM and affect quality of life and sexual function in pre and post menopausal women. The present study shows improvement in context to sexual function, vaginal condition reducing pain and itching with follow up visits. The treatment provides a promising minimally invasive, safe treatment alternative as per our study results, which, after further optimization, could reduce the need for surgery. It is a fast, simple and well tolerated procedure. It is associated with a high level of safety and a short recovery period.

6. Source of Funding

None.

7. Conflict of Interest

None.

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