

The effectiveness of intravaginal fractionated CO₂ laser therapy on premenopausal patients with stress urinary incontinence and urge incontinence



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ABSTRACT

Introduction: Urinary disorders in Asian women about 25-45% occur in premenopausal age, and it keeps increasing to 40% at the age of 70. This study aims to determine the sensitivity, specificity, and non-invasive laser therapy in the intervention of problematic stress urinary incontinence and urge incontinence.

Method: This study was a quasi-experimental study using Pre and Post-test design methods with inclusion criteria in the form of Stress Urinary Incontinence (SUI) and urge incontinence. The fractionated CO₂ laser non-invasive therapy was applied using the brand Femilift©. Univariate and bivariate data analyses were conducted by using STATA version 19.

Results: There was a significant improvement after three times of Femilift© CO₂ laser fractionated intravaginal therapy one month after the procedure, but the same malaise was completely recovered three months after having the therapy. By using the QUID questionnaire, it was found that the mean value of SUI after 1 and 3 after treatment was significantly lower (p-value < 0.05).

Conclusion: A Femilift© CO₂ fractionated laser is a minimally invasive therapy with relatively immediate results so that patients can immediately return to normal activities (no downtime). Femilift© CO₂ fractionated laser makes a very effective, efficient therapy and improves the patient's quality of life.

Keywords: Urinary incontinence, stress urinary incontinence, pressure urinary incontinence, Femilift© CO₂ laser fractionated, vaginal laxity.

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INTRODUCTION

Urinary disorders in premenopausal and menopausal women are like the tip of the iceberg; this is caused by the general public's assumption that this must happen with age. Urinary disorders are an 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 indicate other diseases or conditions that would warrant medical attention. Prolonged urinary problems will result in a decreased quality of life and health problems in general.^{1,2} This causes the prevalence of urinary incontinence to be very heterogeneous. It ranges from 10 to 58% in the world, while in Europe and America, the percentage is

around 29.4%. In Asian women, urinary disorders are 25-45% occurring in the premenopausal age and increase to 40% at the age of 70.^{2,3} At the 2021 meeting, the International Society for the Study of Women's Sexual Health and the North American Menopause Society discuss that the problem of urinary disorders was a combination of several syndromes of disorders of the external genitalia, urological disorders, and sexual disorders due to hypoestrogenism at the time of perimenopause. These syndromes are referred to as the «genitourinary syndrome of menopause» (GSM).^{3,4}

Several previous studies have stated that the prevalence of malaise in women is higher to the point that it interferes with their activities and worsens their

quality of life. The longer the malaise from Stress Urinary Incontinence (SUI) to urge incontinence. GSM is often not diagnosed as real, although it often causes disturbances in marital relations and disturbances in the quality of life, even though it is considered a natural aging process or the aging process.⁴⁻⁷

The aging process occurs at the cellular level in the form of changes in collagen in the tissue which are filling the space between the vagina and the urethra or bladder (pubocervical fascia tissue), where there is a very significant change in the expression of collagen types I and III in patients with SUI despite receiving hormonal therapy.^{8,9} This aging process is caused by an anatomical defect in the tissue that causes reduced flexibility of

the vagina (vaginal laxity) as an organ integrated with fascia, ligaments, muscles, and connective tissue in the pubocervical area. The strength of the muscles in the vagina will affect the contraction of the muscles at the outlet of the bladder neck (bladder neck) in controlling the voiding process.^{5,7}

The use of fractionated CO₂ laser technology with ablation can make the neocollagenization process in the skin, atrophic process, and increase blood vessel supply so that the process of regenerating structures in the mucosa, including the vaginal mucosa, is expected to trigger neocollagenization of collagen in the vaginal mucosa so that the malaise of the syndromes in the genitourinary syndrome of menopause can be resolved.^{10,11}

Based on the above background, this study aims to determine whether non-invasive therapy using the laser method with the Questionnaire for Urinary Incontinence Diagnosis (QUID) as a diagnostic standard can improve the quality of life of patients with GSM problems. Specifically, this study aims to determine the characteristics of stress-type urinary incontinence patients in GSM and the sensitivity, specificity, and non-invasive laser therapy in the intervention of problematic stress-type urinary incontinence in GSM.

METHODS

This study applied a quasi-experimental method using the Pre and Post-test design method, which was carried out on patients who came to get treatment at Anugerah Women & Children Hospital Semarang with the main symptom of genitourinary syndrome who meets the inclusion criteria in the form of SUI and urge-incontinence (UI). This research was conducted for one year, from January 1st, 2019, to January 1st, 2020.

All patients were thoroughly examined, and all problem conditions were included in an internationally agreed questionnaire in The Questionnaire for Urinary Incontinence Diagnosis (QUID). In this questionnaire, six questions describe the patient's malaise, starting with "Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments when you cough or sneeze?", "... when

you bend down or lift something?", "... when you walk quickly, jog or exercise?", "... while you are undressing in order to use the toilet?", Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?" and "Do you have to rush to the bathroom because you get a sudden, strong need to urinate?"

Thirty-one patients received intravaginal fractionated CO₂ laser Femilift® therapy, divided into three procedures within a span of 1 month. One month after the course of therapy was completed, the patient was advised to self-examine and fill out the second QUID questionnaire without any oral therapy intervention. Three months after the Femilift® intravaginal fractionated CO₂ laser therapy, the patient was again advised to be examined and asked to fill out the third QUID questionnaire.

Type of Intervention

The use of photothermal energy technology with laser technology will improve neocollagenization, elasticity, and neoangiogenesis in organs and tissues in the vaginal area, which will impact increasing fibroblasts and vascularization of blood vessels in intravaginal tissues. With the heat generated by the laser that was beamed up to 63°C, the collagen in the vaginal epithelium will undergo remodeling, triggering the process of intravaginal epithelial collagenization. Collagen stimulation in the form of tissue remodeling will occur due to this intervention, resulting in a wound healing process triggered by the growth of new tissue or rejuvenation. Combined superficial ablation uses the heat energy of a fractional CO₂ laser delivered from a special probe inserted into the vagina directed by the doctor on the anterior side of the upper vaginal wall to trigger collagen remodeling.

The fractionated CO₂ laser uses the Femilift® brand from the Alma laser system, which through a special probe focuses the laser beam into small spots that are emitted intravaginally for minimal effect on surrounding tissue but penetrate deep enough into the mucosa to induce tissue neocollagenization. After the first

laser shot is released, the doctor will rotate the probe ±2 cm to fire a second shot. It is done gradually until the entire length of the vagina is exposed by the CO₂ fractionated laser. After completion, the doctor will perform a vaginal speculum examination to ensure no complications in the vaginal mucosa.

Data Analysis

Univariate and bivariate analyses with Paired T-test were conducted using STATA version 19.

RESULTS

This study involved 31 patients with the problem condition of genitourinary syndrome of menopause who met the inclusion criteria in the form of SUI and urge incontinence with a patients age mean of 52.19 (±6.19) years. Most of the participants' birth history was by cesarean section (48.40%), while for spontaneous and vacuum deliveries, each was 25.80%. The proportion of participants with parity >3 times was 35.48%, while participants with parity less than equal two times were 64.52%. Menopausal status had a proportion of 74.19%, while those who had not menopause were 25.81%. Table 1 presents the clinical and demographic characteristics of the participants in this study analyzed with univariate analyses.

In figure 1, there was a significant improvement after three times of Femilift® laser CO₂ fractionated intravaginal therapy, where malaise of bedwetting when coughing or sneezing was significantly reduced. However, there was still some leakage that was not as expected one month after the procedure, and the problem was cured-a total of 3 months after therapy.

Three months after therapy, the main problem of patients with GSM experienced a very significant recovery, where 51.6% who experienced SUI could hold urine both during exercise and carrying heavy objects, while 45.1% experienced incontinence. Those who had urge incontinence found that there was no need to rush to the bathroom to urinate, and there was no feeling of discomfort in the lower abdomen just before urinating.

The normality test results show that all of the data among groups were normally

distributed ($p>0.05$). Table 2 shows that the mean \pm SD of SUI value after one month after treatment was 5 ± 2.488 , lower than the SUI value before treatment. After three months of treatment, the value was 5 ± 1.257 , also lower than the SUI value

before treatment. With a p -value <0.05 , there was a difference before treatment and one month after the treatment that was given to the participants. Table 2 shows changes in pre-intervention SUI values one month and three months after

treatment was analyzed with Paired T-test.

Based on Table 3, the the mean \pm SD UI value after 1 month after treatment was 5 ± 2.488 and is lower than the UI value before the treatment was given. Meanwhile, the value 3 months after treatment was 5 ± 1.753 and lower than the UI value before the treatment was given. With a p -value < 0.001 , there is a difference before and one month after the treatment was given to the participants. Table 3 Changes in UI value before and one month after treatment was analyzed with Paired T-test.

Table 1. Respondent characteristic.

Variable	Laser (n=31) n,%
Age (years; mean \pm SD)	52.19 \pm 6.19
Birth Delivery	
C-section	15 (48.40)
Spontaneous	8 (25.80)
Vacuum	8 (25.80)
Parity	
≤ 2	20 (64.52)
> 3	11 (35.48)
Menopause status	
Not menopausal	8 (25.81)
Menopausal	23 (74.19)

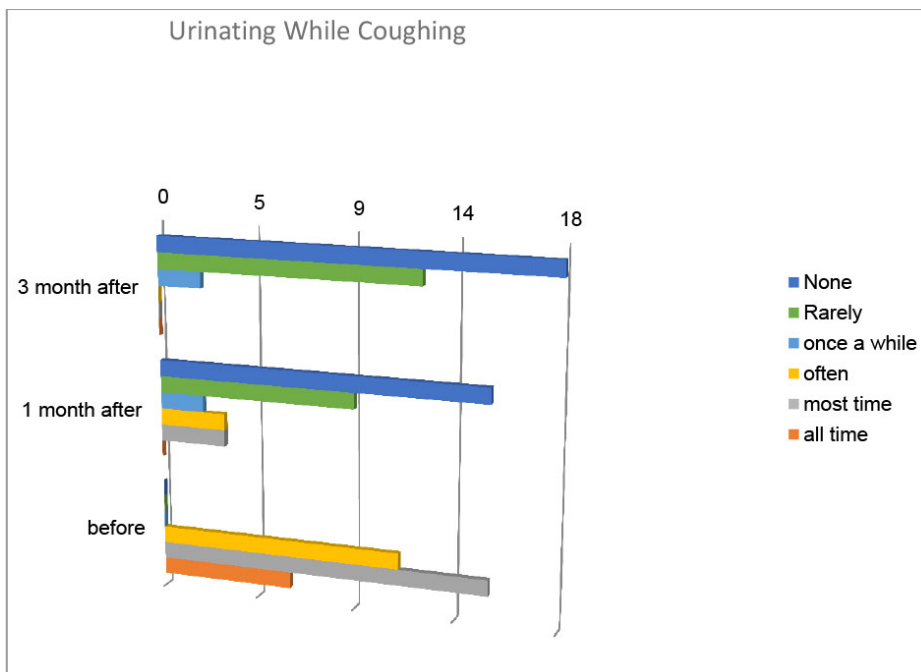


Figure 1. Comparison of the results of the QUID questionnaire before and after fractionated CO₂ laser therapy.

Table 2. Changes in pre-intervention SUI values, one month, and three months after treatment.

Variable	Mean \pm SD	CI (95%)	P-value
Pre-intervention	11 \pm 1.148	10.99821 - 11.8405	<0.001
One month after intervention	5 \pm 2.488	4.635847 - 6.460927	
Pre-intervention	11 \pm 1.148	10.99821 - 11.8405	<0.001
Three Months After intervention	5 \pm 1.257	4.313035 - 5.235352	

DISCUSSION

Urge incontinence and some conditions, such as lifestyle changes, Kegel exercises, energy, and manual physiotherapy, require patience and a long time to recover.^{6,7} Previous studies have shown the use of non-surgical therapy using a fractionated intravaginal Femilift® CO₂ laser, showing molecular changes in the collagen in the vaginal mucosa as seen from an electron microscope. The fractionated CO₂ Femilift® Laser is reported to improve the vaginal mucosal epithelium and the symptomatic complaints of the atrophic vagina.^{9,11,12} The thermal heat from the Laser of CO₂ fractionated into vaginal mucosal tissue will increase the activity of fibroblast cells so that there is a combination of extracellular matrix and cellular components to improve the function and flexibility of the vaginal mucosa.^{13,14}

The Femilift® fractionated CO₂ laser is reported to have a high level of efficacy through the thermal heat of the illuminating laser beam and penetrates through the microlesion (<500 microns) to the deep vaginal mucosa.¹⁵ The effect of thermal heat causes micro ablation so that the process of replacing damaged mucosal tissue with new mucosal tissue restores the flexibility of the vaginal mucosa and restores the strength of the supporting muscles of the bladder both in patients with stress urinary incontinence and because of urge urinary incontinence.⁸⁻¹¹ By using a questionnaire whose validity has been internationally recognized in the form of the Questionnaire for Urinary Incontinence Diagnosis (QUID), the researcher wanted to compare the success

Table 3. Changes in UI values before and one month after treatment.

Variable	Mean ± SD	CI (95%)	P-value
Pre-intervention	12±2.045	11.12079 - 12.62115	<0.001
One month after intervention	5±2.488	4.853225 - 7.082259	
Pre-intervention	12±2.045	11.12079 - 12.62115	<0.001
Three months after intervention	5±1.753	4.518273 - 5.804307	

of non-invasive therapy.⁷ In this study, we found a statistically significant decrease in the average SUI value before treatment compared with one month and three months after treatment (Table 2 and 3; $p < 0.05$).

Fractionated CO₂ laser ablation therapy can improve collagen structure and trigger the replacement of new collagen in the vaginal mucosa that occurs when the laser is emitted so that the temperature of the mucosa will increase to 63°C. It will trigger the microbe process in the vaginal epithelium with a depth of 50-125 m. Therefore, neocollagenization, improvement of elasticity and neoangiogenesis occurred, which caused an increase in fibroblasts and an increase in blood vessel vascularization, making the vaginal mucosal layer flexible and thickened.¹³ SUI and urge incontinence happen due to an unhealthy lifestyle, high stress, changes in female hormones, and increasing age which should be treated with Kegel exercises from an early age making it an unpopular choice today.^{16,17}

Femilift® CO₂ fractionated laser is a minimally invasive therapy using a laser beam that is patterned in such a way that it can penetrate through microlesions so that it can trigger neocollagenization, improvement of elasticity, and neoangiogenesis, which cause an increase in fibroblasts and an increase in blood vessel vascularization so that the vaginal mucosal layer will become flexible and thickened. This fractionated CO₂ laser therapy can be done on an outpatient basis because it is done without the need for anesthesia and has relatively fast results, and can immediately return to normal activities (no downtime), making it a very effective, efficient therapy and improving the quality of life of the patients.¹⁸

The limitation of this study was the sample size of only 31 patients with the non-heterogenous sample.

CONCLUSION

Fractionated CO₂ laser therapy is very safe and effective in patients with Stress Urinary Incontinence (SUI) and Urge incontinence, which is the genitourinary syndrome of menopause. This fractionated CO₂ laser therapy can be done on an outpatient basis because it is done without the need for anesthesia and has relatively fast results, and can immediately return to normal activities and improve the quality of life.

ETHICAL APPROVAL

This study has received Ethical Research approval from the Medical and Health Research Ethics Committee (MHREC) Faculty of Medicine, Public Health and Nursing Gajahmada University – DR Sardjito General Hospital with number KE/FK/1125/ EC/2021.

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CONFLICT OF INTEREST

The authors report no potential conflicts of interest.

AUTHOR CONTRIBUTION

IAS, PHS, and AKM contributed to drafting the concept and designing the study, conducting a literature search, drafting data acquisition and reviewing the manuscripts. IAS and PHS contributed intellectual content, data analysis, and statistical analysis. IAS was a guarantor of the study.

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