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REVIEW ARTICLE

Vaginal Laser Therapy for Stress Urinary Incontinence: A Systematic Review of Prospective Randomized Clinical Trials

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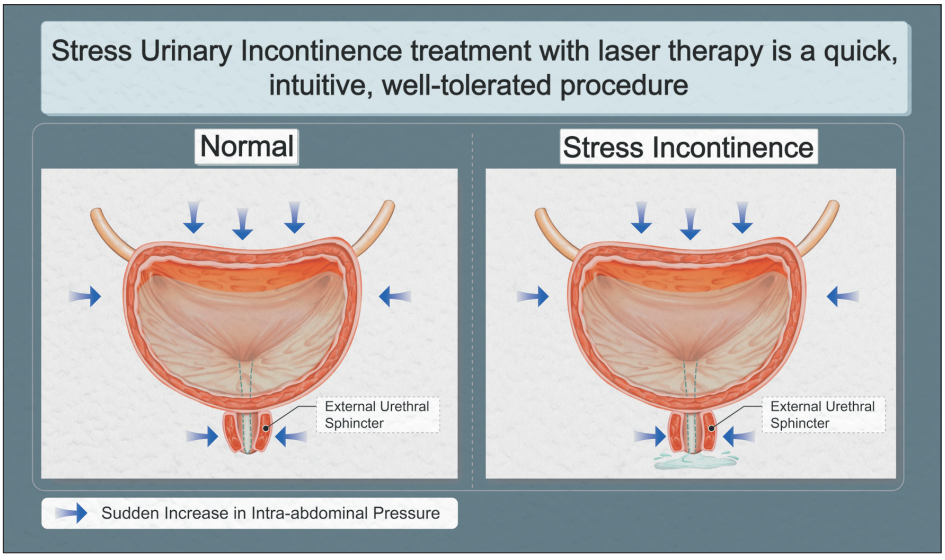
The most common type of urinary incontinence in women is stress urinary incontinence (SUI) which negatively impacts several aspects of life. The newly introduced vaginal laser therapy is being considered for treating SUI. This systematic review aimed to evaluate the efficacy of vaginal laser therapy for stress urinary incontinence in menopausal women. We searched the following databases: MEDLINE (via PubMed), EMBASE, Cochrane Library databases, Web of Science, clinical trial registry platforms, and Google Scholar, using the MeSH terms and keywords [Urinary Incontinence, Stress] and [(lasers) OR laser]. In our systematic review, prospective randomized clinical studies on women diagnosed with SUI as per the International Continence Society's diagnostic criteria were included. The Cochrane Risk-of-Bias assessment tool for randomized clinical trials was used to evaluate the quality of studies. A total of 256 relevant records in literature databases and registers and 25 in additional searches were found. Following a review of the titles, abstracts, and full texts, four studies involving 431 patients were included. Three studies used CO2-lasers, and one used Erbium: YAG-laser. The results of all four studies revealed the short-term improvement of SUI following both the Erbium: YAG-laser and CO2-laser therapy. SUI treatment with CO2-laser and Erbium: YAG-laser therapy is a quick, intuitive, well-tolerated procedure that successfully improves incontinence-related symptoms. The long-term impact of such interventions has not been well established as most trials focused on the short-term effects.

Key Words: Laser, Stress incontinence, Systematic review



Stress incontinence occurs when the muscles and other tissues that support the urethra (pelvic floor muscles) and the muscles that control the release of urine (urinary sphincter) weaken

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INTRODUCTION

Urinary incontinence is a widespread public health issue that affects 200 million people [1]. According to recent data, urinary incontinence affects more females than males [2]. The most common type of urinary incontinence in women is stress urinary incontinence (SUI) which affects up to 35% of adult women and more than 50% of postmenopausal women [3]. Urine leakage during physical activity that increases abdominal pressure, such as coughing, sneezing, laughing, or exercising, is known as SUI [1]. Damage to pelvic floor structures caused by vaginal delivery, as well as changes in the collagen composition of the endopelvic fascia due to aging or menopausal estrogen reduction, can result in insufficient urethral support [4,5]. SUI has a negative impact on many aspects of life, significantly reducing daily functioning related to work, physical activity, or intimate relationships.

Newly introduced vaginal laser therapy is being considered for the treatment of SUI. A CO2-laser (SmartXide2 V2LR; Monalisa Touch, Florence, Italy) and an Erbium: YAG-laser (Fotona Smooth™ XS; Fotona, Ljubljana, Slovenia) have been used to treat postmenopausal women with SUI [6-8]. Previously, three systematic reviews reached different conclusions. A systematic review of 31 studies recruiting 1,530 adult women on vaginal and/or urethral laser application for SUI found improvement; however, the study quality could be improved, according to the authors [9]. On the other hand, Alsulihem et al. [10] reported a modest efficacy of Erbium: YAG-laser and fractional CO2-laser for improving SUI in a systematic review of 27 studies (while the overall quality of studies was poor, and 23/27 studies were case series with the level of evidence 4). Another systematic review included 13 studies that enrolled 818 SUI patients who underwent laser therapy and reported that laser therapy might be a practical, minimally invasive treatment option for SUI. However, the included studies' methodological limitations make them prone to significant bias, limiting their scientific integrity. The majority of the included studies had low methodological quality because they were individual case-control studies, case series, or low-quality cohorts (Oxford Level of Evidence 3b and 4) [11]. As we can see, previous systematic reviews were hindered by a shortage of solid evidence. Newer studies have also been published that have not been included in the above reviews. As a result, we sought to conduct a systematic review to address these limitations by including randomized clinical trials to evaluate the efficacy of laser therapy on SUI.

MATERIALS AND METHODS

Protocol and ethical consideration

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines [12] were used to report this study. Because the study only included previously published studies, no ethical approval was required.

Search strategy and selection criteria

We searched the following databases: MEDLINE (via PubMed), EMBASE, Cochrane Library databases, Web of Science, clinical trial registry platforms, and Google Scholar, using the MeSH terms and keywords [Urinary Incontinence, Stress] and [(lasers) OR laser]. Our final step was to look through the references of relevant reviews and similar articles to identify new records.

Prospective randomized clinical studies on women diagnosed with SUI according to the International Continence Society's diagnostic criteria were included in our systematic review. There was no age or race limit. We did not include any of the following studies: Cohort studies, case-control studies, case series, literature reviews, comments, letters, pre-clinical or basic research experiments, conference abstracts, studies where full text could not be retrieved, or data were missing, duplicates, articles written in languages other than English.

All the databases were searched by an experienced researcher (A.R.). Two groups of two researchers (Group 1: F.D and V.M, and Group 2: M.Sh and M.Sh.J) independently screened the titles and abstracts and then the full texts of potentially eligible studies against the predefined eligibility criteria after eliminating duplicates. Consensus or an appeal to a senior researcher (A.R) was used to resolve disagreements. A PRISMA flow diagram was used to document the study selection process [12].

Data collection and risk of bias assessment

The following variables were extracted independently by two researchers (F.D and M.Sh): first author; publication year; country of origin; patient sample size; type of trial; type of laser; laser therapy mode; the total number of sessions; follow-up duration; assessment parameters; and complications. The consensus was used

to settle disagreements. A pilot test was carried out prior to the formal extraction.

A.R and F.D. independently assessed the quality of all included studies and discussed discrepancies until a consensus was achieved. The Cochrane Risk-of-Bias assessment tool for randomized clinical trials was used to evaluate the quality of studies. Each type of bias is graded as either "Low", "Unclear", or "High" [13].

Assessment of the certainty of the evidence

The Grading of Recommendations Assessment, Development, and Evaluation approach [14] was used to assess evidence's certainty. Two experienced researchers (V.M and A.R) rated each domain separately for each outcome and resolved discrepancies through consensus.

RESULTS

We found 256 relevant records in literature databases and registers and 25 in additional searches. Following a review of the titles, abstracts, and full texts, four studies involving 431 patients were included [6-8,15]. A PRISMA flow diagram illustrates the selection process (Fig. 1). The risk of bias assessment is presented in Table 1. The final score for high-quality studies is above half (more than 50%).

The characteristics of the studies and their participants are shown in Table 2. In the individual studies, the number of subjects examined ranged from 72 to 139. There were two studies in Brazil, one in Slovenia and one in Israel. Three studies used CO2-lasers (SmartXide2 V2LR; Monalisa Touch) [7,8,15], and one used Erbium: YAG-laser (Fotona Smooth^{TM} XS; Fotona) [6]. SUI was evaluated before the laser therapy and after the last laser therapy session by International Consultation assessed SUI on Incontinence Questionnaire–Urinary Incontinence Short Form (ICIQ-UI SF), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, and International Consultation on Incontinence Questionnaire Overactive Bladder, Urinary Distress Inventory-6 (UDI-6), Likert scale (evaluating the subjective improvement of incontinence), stress tests, voiding diary, and pad test. The follow-up period was defined as the time between the last laser therapy and the assessment of outcomes which ranged from 14

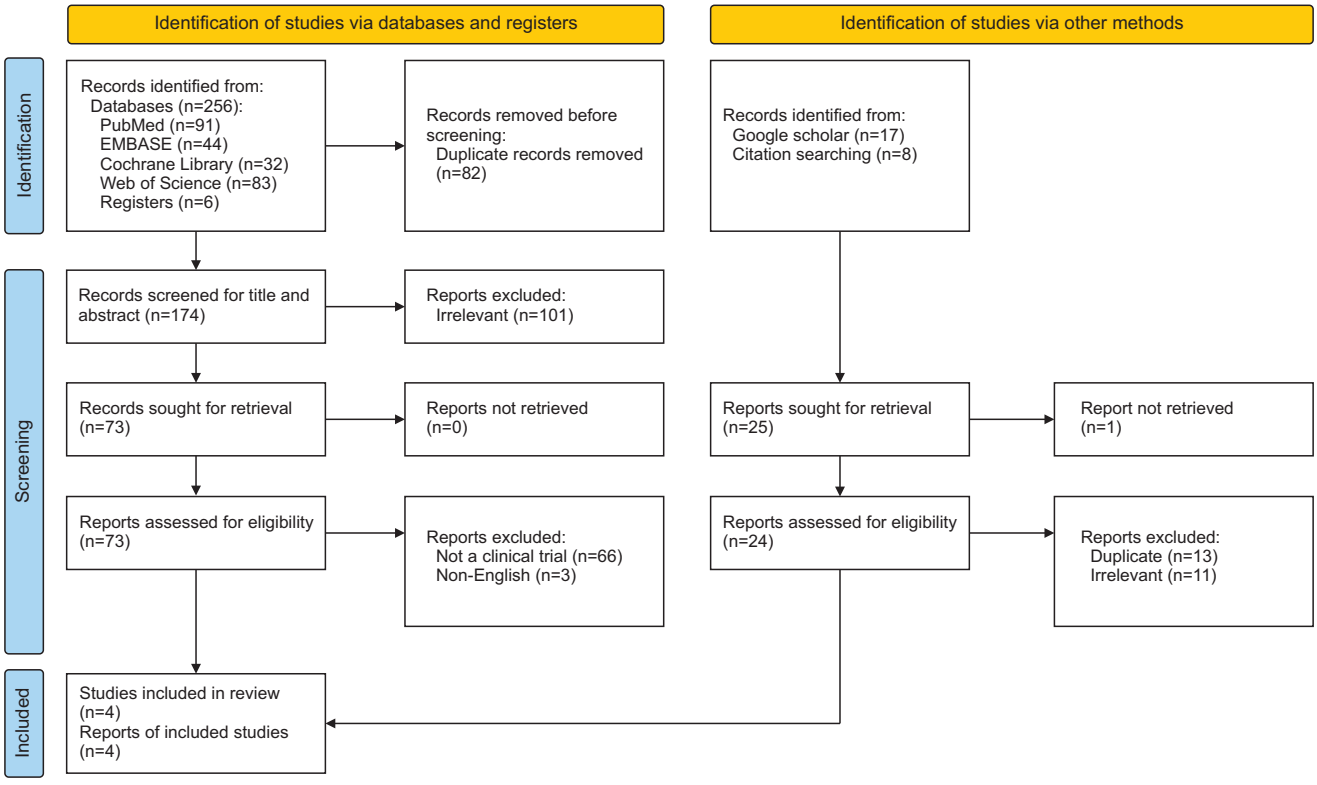

Fig. 1. Flowchart of study.

Table 1. Quality assessment of included studies

Domain	Signalling questions	Study no.			
		1	2	3	4
1. Risk of bias arising from the randomization process	1.1 Was the allocation sequence random?	Y	Y	Y	Y
	1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y	Y	Y	Y
	1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?	N	N	N	N
	Risk-of-bias judgement	L	L	L	L
2. Risk of bias due to deviations from the intended interventions	2.1. Were participants aware of their assigned intervention during the trial?	N	N	N	N
	2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	N	N	Y	Y
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?	-	-	Y	Y
	2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?	-	-	PY	PY
	2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?	-	-	Y	Y
	2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y	Y	Y	Y
	Risk-of-bias judgement	L	L	S	S
3. Missing outcome data	3.1 Were data for this outcome available for all, or nearly all, participants randomized?	Y	Y	Y	Y
	Risk-of-bias judgement	L	L	L	L
4. Risk of bias in measurement of the outcome	4.1 Was the method of measuring the outcome inappropriate?	N	N	N	N
	4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?	N	N	N	N
	4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?	N	NI	Y	Y
	4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?	N	PY	PY	PY
	4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?	N	PY	PY	PY
	Risk-of-bias judgement	L	S	S	S
5. Risk of bias in selection of the reported result	5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	Y	Y	Y	Y
	5.2. Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?	Y	Y	Y	Y
	5.3 Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible analyses of the data?	Y	Y	Y	Y
	Risk-of-bias judgement	L	L	L	L

Y: yes, N: no, NI: no information, H: high risk-of-bias, L: low risk of bias, S: some concerns, PY: probably yes.

weeks to 12 months.

The first study found that the ICIQ-UI SF improved significantly more after a single session of non-ablative 2,940 nm Erbium:YAG than in the sham control group months after a three-month follow-up period with no adverse events [6].

The second study found statistically significant improvements in the positive cough test, mean pad weight

Table 2. Summary of trials

Study no.	Author (year)	Country	Study design	Population	Intervention	Comparator	Outcome measure	Assessment tool	Follow-up duration	Findings	Adverse events
1	Blaganjea et al. (2018) [6]	Slovenia	Double blind randomized controlled trial	114 premenopausal women with stress urinary incontinence	A single session of non-ablative 2,940 nm Er:YAG session (XS Dynamis, Fotona) The laser group received therapeutic laser irradiation with 10 J/cm^2 fluence, 7 mm spot size, and nonablative thermal smooth 1 pulses.	The sham group received the same procedure but with no therapeutic irradiation.	The severity of stress urinary incontinence	ICIQ-UI SF SFPISQ-12	3 mo	3 months after treatment the ICIQ-UI SF were significantly more improved in the laser group than in the sham control group.	None.
2	Lauterbach et al. (2022) [7]	Israel	Double blind randomized controlled trial	131 Women aged 45–70 y with stress urinary incontinence	A 5-minute single session of CO2 Laser settings with energy level of 12.5 m J and a density of 10%.	The sham group received the same procedure but with no therapeutic irradiation.	The severity of stress urinary incontinence	ICIQ-UI SF SFPISQ-12 UDI6 Cough test 1-h pad weights	6 mo	At 3 months post-treatment, the study found statistically significant improvements in the positive cough test, mean pad weight test, UDI-6, ICIQ-UI, and PISQ-12. However, 6 months post-treatment values were similar to baseline.	Immediate adverse effects reported by the women in intervention group included a stinging sensation that lasted up to 2 min (38%), local sensitivity that lasted up to 2 days (45%) and lower abdominal cramping (8%). No major complications.
3	Aguiar et al. (2020) [8]	Brazil	A randomized clinical Trial	72 premenopausal women aged 50 y and older, with stress urinary incontinence	The fractional CO2 laser or using of Promesterin	Using of vaginal lubricant	Genitourinary syndrome of menopause	ICIQ-UI SF ICIQ-OAB	14 wk	The total ICIQ-UI SF score of the CO2 laser group was significantly lower in the intragroup comparison (baseline vs. week 14). This group also experienced a statistically significant decrease in nocturia. In terms of the total ICIQ-OAB score, the CO2 laser group exceeded the lubricant group in the intergroup comparison.	None.

Table 2. Continued

Study no.	Author (year)	Country	Study design	Population	Intervention	Comparator	Outcome measure	Assessment tool	Follow-up duration	Findings	Adverse events
4	Seki et al. (2022) [15]	Brazil	Double blind randomized controlled trial	114 women with stress urinary incontinence	3-monthly outpatient treatment sessions of CO2 laser or radiofrequency	Sham control group	The severity of stress urinary incontinence	ICIQ-SF Likert scale (evaluating subjective improvement of incontinence) stress tests, Voiding diary pad test I-QoL	12 mo	The laser group showed 72.6% subjective improvement and 45.2% objective cure of incontinence, compared to 30.0% and 14.0 % for control group. Significant reduction in the number of episodes of urinary incontinence was found according to voiding diaries and pad weight. The laser group had significantly less urgency and urinary loss during sexual intercourse. I-QoL and ICIQ-SF both showed an improvement in quality of life.	No major complications.

ICIQ-UI SF: International Consultation on Incontinence Questionnaire–Urinary Incontinence Short Form, SFPISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, UDI6: Urogenital Distress Inventory, ICIQ-OAB: ICIQ-Overactive Bladder, I-QoL: Improvement in quality of life.

test, UDI-6, ICIQ-UI, and The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ) after a 5-minute single session of CO2-laser settings with an energy level of 12.5 m J and a density of 10% at 3 months post-treatment. However, 6 months after treatment, the values were comparable to the baseline. The women in the intervention group reported immediate adverse effects such as a stinging sensation that lasted up to 2 minutes (38%), local sensitivity that lasted up to 2 days (45%), and lower abdominal cramping (8%). However, no serious complications have been reported [7].

With a 14-week follow-up, the third study found that the total ICIQ-UI SF score and nocturia were significantly lower after fractional CO2-laser treatment compared to lubricant use. No serious complications have been reported [8].

The last study in this review showed 72.6% subjective improvement and 45.2% objective cure of incontinence following 3-monthly outpatient treatment sessions of CO2-Laser. According to voiding diaries and pad weight, there was a significant reduction in the number of episodes of urinary incontinence. During sexual intercourse, the laser group experienced significantly less urgency and urinary loss. Both Improvement in quality of life (I-QoL) and ICIQ-SF indicated an improvement in quality of life. No adverse events were reported with the following up period of 12 months [15].

The results of all four studies revealed the short-term improvement of SUI following both the Erbium: YAG-laser and CO2-laser therapy. However, values at 6–12 months post-treatment were similar to those at baseline. There was a significant reduction in the total ICIQ-UI SF score following Erbium: YAG-laser [6] and CO2-laser therapy [7,8,15]. Concerning the characteristic symptoms of OAB, evaluated using the ICIQ-OAB, a significant reduction in nocturia after CO2-laser therapy was also found in one study [8], with no statistical differences in another study [6]. Statistically significant improvements were demonstrated in the study compared to the control group at 3 months post-treatment in positive cough test (44.4% vs. 79.4%, P = 0.002), mean pad weight test (2.3 g ± 1.3 g vs. 5.6 g ± 1.1 g, $P < 0.001$), mean UDI-6 (24.7 ± 12.1 vs. 45.1 ± 13.6 SD, $P = 0.004$), mean ICIQ-UI (16.5 ± 4.3 vs. 10.3 ± 3.8, $P = 0.003$) and mean PISQ-12 (21.3 ± 6.8 vs. 36.6 ± 7.5, P = 0.003) [7]. Subjective improvement and objective cure of SUI were identified respectively in 72.6% and 45.2% after CO2-laser therapy, significantly higher than the 30.0% and 14.0% in the control group. A significant reduction in the number of urinary incontinence episodes was found according to voiding diaries ($P = 0.029$) and pad weight (P = 0.021). The I-QoL and ICIQ-SF also verified improvement in quality of life after CO2-laser therapy [15].

DISCUSSION

Women suffering from SUI have four treatment options: behavioral therapies, vaginal inserts, electrical stimulation, and surgery. The goal is to strengthen and function the muscles that support the bladder, urethra, and other organs in the pelvic region in order to rehabilitate the pelvic floor [16]. There are currently no medications on the market that are specifically designed to treat SUI [17]. Behavioral treatments such as pelvic muscle exercises (Kegels), are simple, self-directed, and have no side effects. However, because of their low efficacy, they are frequently used in conjunction with other treatment options [18]. To treat bladder and pelvic support issues, vaginal inserts and pessaries are commonly used. The uterus, bladder, urethra, and rectum are supported by these devices, which are placed in the vagina.Vaginal pessaries are simple to use and effective in cases of mild SUI. However, its impact on higher grades of SUI has been questioned. Pelvic floor electrical stimulation such as lasers and radiofrequency waves use low-grade electrical current to stimulate weak or inactive pelvic muscles to contract. There are several evidence regarding its efficacy [19]. Electrical stimulation has been shown to be effective for stress incontinence, with cure and improvement rates ranging from 30 to 50% and 6 to 90%, respectively. However, clinical application of this treatment is uncommon due to a lack of physiological and technical data [20]. Surgery is another option for the treatment of SUI, however, the relative effectiveness, cost-effectiveness and cost-beneficial of surgery is still being debated in the medical community [21]. The decision to use each treatment mentioned above should be made based on individual circumstances.

Vaginal laser therapy, a new treatment option for SUI, has recently been proposed. According to this systematic review, the efficacy and safety of laser therapy for SUI were evaluated, along with the evidence's quality and reliability. SUI severity has consistently been shown to be reduced in the current literature [6-8,15]. SUI patients now have an alternative treatment option other

than surgery in the form of laser therapy. They can be treated with laser procedures that use water-absorbent wavelengths, such as the CO2-lasers (SmartXide2 V2LR; Monalisa Touch) [7,8,15]. CO2-laser has emerged as a new modality for rapid, well-tolerated, and minimally invasive treatment of modality for rejuvenating photoaged skin through ablation of abnormal tissues, followed by collagen regeneration and remodeling, and through heat-induced collagen contraction [15,22]. Perino et al. [23] discovered that the CO2-laser could effectively treat overactive bladder symptoms due to improvements in urethral and bladder mucosa atrophy in a nonrandomized study with a small number of subjects. Thermal effects of laser therapy may promote remodeling and production of new collagen fibers, stimulate elastin formation, and modulate metalloproteinase activation at the molecular level, all of which are important for maintaining the supporting structures of the pelvic floor [23].

Additionally, the Erbium: YAG-laser (Fotona Smooth™ XS) [6] stimulates non-ablative photothermal effects by transferring heat to the vaginal walls through thermal diffusion. In atrophic skin, heat triggers a wound response that leads to tissue remodeling and the neoformation of collagen and elastic fibers. Restoring the vaginal muscle tone is accomplished by tightening the vulvovaginal complex support structures [24,25]. Vaginal Erbium: YAG-laser treatment provides a minimally invasive option for patients with mild to moderate SUI who do not want to undergo an invasive procedure or have contraindications to surgery. Using the Erbium: YAG-laser is a simple procedure that doesn't necessitate extensive surgical training. No bleeding, anesthesia, or hospitalization is required [26]. It is recommended that patients abstain from sexual activity for three days following vaginal Erbium: YAG-laser treatment [27].

There have been varying reports on the number of sessions needed to alleviate the symptoms of SUI. The symptoms of SUI were reduced in certain studies after just one treatment session [6,23]. Two-session treatment was found to be more beneficial in another trial [24]. Another key issue of discussion is the laser's maintenance effect in enhancing SUI. A Double-blind, randomized controlled trial by Blaganje et al. [6] had a relatively short follow-up time (3 months). Another study found that the therapeutic effects of three-session laser treatment with monthly intervals persist for about 12 months. The effect fades but can be maintained and prolonged by "maintenance sessions" performed once every six months [28]. In addition, studies for various gynecological indications have shown that CO2-laser treatment has temporary and short-term effects, regardless of the indication for treatment [8,29]. Collagen tightening induced by three passes of CO2-laser persisted six months after the procedure [16]. The ideal maintenance laser treatment regimen cannot be determined because the cause of the shorter effect cannot be determined at this time.

Laser SUI treatment was found to be safe in this and previous studies [6,27], with no reported serious side effects. Several uncontrolled trials of vaginal Erbium: YAG-laser treatment with longer-term follow-up (12–36 months) recently showed no long-term adverse effects [19,30]. Some minor immediate adverse effects included a stinging sensation that lasted up to 2 minutes, local sensitivity that lasted up to 2 days, and lower abdominal cramping have been reported by the women following CO2-laser therapy [7].

The strength of this review is that the studies included in had a higher level of evidence than what had previously been reported. Because most trials focused on the short-term effects, the long-term impact of such interventions is not well established. Limiting systematic reviews to English only is also the limitation of our study, which can lead to biased effect estimates and reduce generalizability. This should be taken into account in future research.

CONCLUSION

SUI treatment with CO2-laser and Erbium: YAG-laser therapy is a quick, intuitive, well-tolerated procedure that successfully improves incontinence-related symptoms. After further refinement, it has the potential to minimize the frequency of surgical intervention for SUI patients.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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