DOI: 10.4081/aiua.2025.14644

REVIEW

Does minimally invasive approach using vaginal laser therapy improve outcomes and remain safe for female with stress urinary incontinence? A systematic review and meta-analysis of randomized controlled trials

Khoirul Kholis [1], Syarif [1], Syakri Syahrir [1], Moh. Anfasa Giffari Makkaraka [1], Ahmad Taufik Fadillah Zainal [1], Adrian Manuel Sutanto [2], Muhammad Asykar Palinrungi [1]

[1] Division of Urology, Department of Surgery, Faculty of Medicine, Hasanuddin University, Makassar, Indonesia;
[2] Faculty of Medicine, Hasanuddin University, Makassar, Indonesia.

Summary *Introduction & Objectives: Stress urinary incontinence (SUI) frequently affects women and can negatively impact their physical health, emotional state, and social life. In recent years, growing interest in less invasive treatment options has prompted the development of vaginal laser therapy (VLT) as a potential alternative for patients who have not responded to conventional treatments before considering more invasive procedures. However, the clinical effectiveness of VLT remains controversial across studies. This review aims to assess the effectiveness and safety of VLT in managing SUI.*
Materials & Methods: A comprehensive search of the literature was carried out in PubMed, ScienceDirect, and Scopus databases using appropriate keywords. The methodological quality of the selected studies was evaluated with the Revised Cochrane Risk of Bias tool (RoB 2). Data were analysed through meta-analysis using Review Manager version 5.4. The protocol of this systematic review was registered in PROSPERO (CRD420251164307).
Results: A total of seven studies involving 584 participants were analysed. The results demonstrated that VLT significantly improved ICIQ-UI SF [MD = -1.54 (-2.15 – (-0.93)), p = < 0.00001], PISQ-12 [MD = 1.22 (0.47-1.96), p = 0.001], and FSFI [MD = 1.62 (0.41-2.82), p = 0.009] compared with the sham laser group. Across most studies, only minor adverse events related to the VLT intervention were reported.
Conclusions: Our study demonstrated that VLT led to a statistically significant improvement in ICIQ-UI SF, PISQ-12, and FSFI scores among patients undergoing the procedure. Additional research is needed to directly compare VLT with other therapeutic options, including urethral bulking agents and non-invasive approaches for SUI.

KEY WORDS: *Vaginal Laser; Urological procedures; Stress Urinary Incontinence; Systematic-review; Meta-analysis.*

Submitted 11 November 2025; Accepted 3 December 2025

INTRODUCTION

Urinary incontinence (UI) is among the most prevalent medical disorders and represents a significant global health issue, impacting nearly 200 million people worldwide. Among its various forms, *stress urinary incontinence* (SUI) is the most frequently encountered, defined by the involuntary loss of urine during actions that elevate intra-abdominal pressure - including coughing, sneezing, or physical exertion - and is estimated to occur in up to 35% of adult women (1, 2). This condition primarily develops due to weakened pelvic floor musculature, urethral sphincter dysfunction, and compromised connective tissue integrity, including the collagen components of the pelvic floor. Structural damage associated with vaginal delivery, along with age-related or menopause-induced alterations in collagen content within the pelvic fascia, may further compromise urethral support (3, 4). SUI has substantial implications for women's quality of life, negatively affecting occupational performance, physical activity, and sexual well-being (5).

Pelvic floor muscle training (PFMT) is one of the most widely implemented conservative management strategies for SUI, designed to improve the strength and functionality of the pelvic floor muscles. Through targeted exercises, these muscles can be reinforced, and voluntary tightening of the pelvic diaphragm prior to increases in intra-abdominal pressure may effectively reduce urinary incontinence (6). Despite its benefits, the success of PFMT often depends on patients' long-term adherence, consistent exercise routines, and ongoing professional supervision, which may limit its overall effectiveness (7). On the other hand, surgical intervention with *mid-urethral sling* (MUS) techniques utilizing synthetic mesh materials has become the standard and primary treatment for women with SUI (8). This technique improves urethral support and enhances sphincteric closure, achieving cure rates ranging from approximately 64% to 89% (7, 9). However, despite favorable outcomes, MUS surgery may lead to complications such as intraoperative bladder injury, hematoma, and persistent pelvic pain (10, 11). Therefore, there remains a continuing need for new non-invasive or minimally invasive therapeutic approaches that can reduce complication rates while maintaining high levels of clinical safety and efficacy.

One of the minimally invasive treatments that has been

explored as a treatment modality for managing SUI is *vaginal laser therapy* (VLT). Two primary laser systems are typically utilized for this purpose: the Erbium:YAG laser (2940 nm) and the CO_2 laser (10,600 nm) (6). The fractional microablative technique is most often performed with a CO_2 laser, whereas several studies have utilized the ablative setting of the Erbium:YAG laser (12). Both modalities generate photothermal effects within the vaginal tissue, where localized temperature elevation disrupts the triple-helix structure of collagen. This thermal denaturation leads to collagen fiber contraction - resulting in thicker, shorter fibrils - and stimulates neocollagenesis. The resulting tissue remodeling enhances vaginal wall thickness, elasticity, and firmness, thereby improving suburethral support and urinary continence (13).
Despite these proposed mechanisms, the current evidence regarding the effectiveness of VLT in treating SUI remains inconclusive (14, 15). Current clinical guidelines do not recommend its use due to insufficient data, which prevent drawing definitive conclusions regarding its safety and effectiveness (16-18). Moreover, although most studies report no serious adverse effects (19, 20), isolated cases of severe complications have been documented, including large hematocolpos (21), as well as other adverse outcomes such as a burning sensation in the vaginal area, fibrosis, and chronic pelvic pain (22). Given these uncertainties, this systematic review and meta-analysis were conducted to further assess the clinical effectiveness and safety outcomes of VLT for managing SUI.

Materials and methods

Protocol

This systematic review protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO) (CRD420251164307).

Eligibility criteria

Studies were included in this systematic review if they fulfilled the following conditions: (1) written and published in English; (2) employing a *randomized controlled trial* (RCT) design; (3) involving participants diagnosed with SUI; (4) implementing any form of vaginal laser therapy as the intervention; (5) comparing outcomes with a sham laser control group; and (6) reporting at least one of the following outcomes: *International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form* (ICIQ-UI SF), *Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire* (PISQ-12), *Female Sexual Function Index* (FSFI), or procedure-related adverse events.

Search strategy

In this study, a comprehensive and systematic search of the literature was conducted on 20 July 2025 across three major electronic databases, including PubMed, ScienceDirect, and Scopus, using the following keywords: ("Vaginal Laser" OR "Vaginal Laser Therapy" OR "Laser Vagina") AND ("Stress Urinary Incontinence" OR "SUI") AND ("Female" OR "Women"). To minimize the risk of overlooking any potentially eligible studies, the search process was conducted without imposing any restrictions related to publication year, language, or database-specific filters. This approach was designed to ensure maximum retrieval sensitivity and comprehensiveness of the literature search.

Selection process

Study selection was carried out independently by three reviewers using the web-based screening platform Rayyan (rayyan.ai). Two investigators (MA and AM) initially reviewed the titles and abstracts of all identified studies according to predefined inclusion and exclusion criteria, followed by a detailed full-text evaluation to confirm eligibility. The third reviewer (AT) subsequently cross-checked all screening decisions to ensure methodological accuracy and consistency. In cases where discrepancies arose between reviewers, discussions were held until a consensus was achieved. The entire selection process adhered to the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) guidelines, ensuring transparency and methodological rigor.

Data extraction

The data extraction process was carried out independently by two reviewers (MA and AM). Information gathered included key study characteristics such as research design (RCT), participant demographics (e.g., age, number of subjects, and group allocation), the diagnostic criteria used to define SUI, characteristics of the vaginal laser intervention (e.g., laser type, number of sessions, follow-up duration), and study outcomes (ICIQ-UI SF, PISQ-12, FSFI, and procedure-related adverse events). A third investigator (AT) reviewed and validated the extracted data to ensure accuracy and completeness. Any inconsistencies or disagreements among reviewers were discussed and resolved by mutual consensus. All finalized data were systematically recorded and organized in a Microsoft Excel spreadsheet for further analysis.

Risk of bias (quality) assessment

The methodological rigor and potential risk of bias of all included studies were evaluated independently by two reviewers (MA and AT) using the Revised Cochrane Risk of Bias Tool (RoB 2). This tool assesses bias across five distinct domains: (1) randomization process, (2) deviations from intended interventions, (3) missing outcome data, (4) outcome measurement methods, and (5) selective reporting of results. Following domain-specific evaluations, an overall risk-of-bias judgment was assigned to each study. In cases of differing opinions between reviewers, discrepancies were carefully reviewed and reconciled through discussion until a consensus was achieved.

Statistical analysis

All statistical computations and meta-analyses were performed using *Review Manager* (RevMan) version 5.4 developed by the Cochrane Collaboration (UK). Each selected outcome variable was evaluated on a continuous numerical scale to ensure consistency in data interpretation across studies. For continuous parameters, treatment effects were calculated as the difference between baseline and post-treatment values, thereby reflecting the mean change associated with VLT. The findings were expressed as *mean differences* (MDs) accompanied by 95% *confidence intervals* (CIs) to represent the precision of the effect estimates. To evaluate statistical heterogeneity among the included studies, the I^2 statistic was applied. A I^2 value below 50% indicated low heterogeneity, prompting the use of a fixed-effects model, whereas an I^2 value of 50% or higher suggested moderate to substantial heterogeneity, in which case a random-effects model was employed. The summarized outcomes were visually presented in Forest plots, providing a clear overview of the pooled results. Statistical significance was defined as a p-value less than 0.05. Furthermore, funnel plots were generated for each primary outcome to detect potential publication bias or asymmetry across studies. Additional subgroup analyses were undertaken to explore potential variations in treatment effects. These analyses were stratified by laser type (CO_2 *versus* Er:YAG), number of treatment sessions (two or fewer sessions versus more than two), and duration of follow-up (less than 48 weeks versus 48 weeks or longer). This approach allowed for a more detailed evaluation of factors that might influence clinical outcomes.

Results

Literature search and screening results

The comprehensive literature search yielded a total of 1,737 potentially relevant studies across the selected electronic databases. Following the removal of 1,066 duplicate records, 671 studies proceeded to the initial screening stage, where titles and abstracts were carefully reviewed against the predefined eligibility criteria. During this phase, 652 studies were excluded as they did not meet the inclusion parameters. Subsequently, 19 full-text articles were evaluated in detail. Among these, 6 studies could not be retrieved in full text, while another 6 were excluded for reasons such as non-randomized design, absence of relevant outcomes, or use of non-comparable interventions. Hence, 7 studies met all inclusion criteria and were incorporated into the final quantitative analysis (further details are provided in ***Supplementary Table***). The overall process of identification, screening, eligibility assessment, and inclusion is depicted in the PRISMA flow diagram (Figure 1), which summarizes the systematic selection and exclusion of studies throughout the review process.

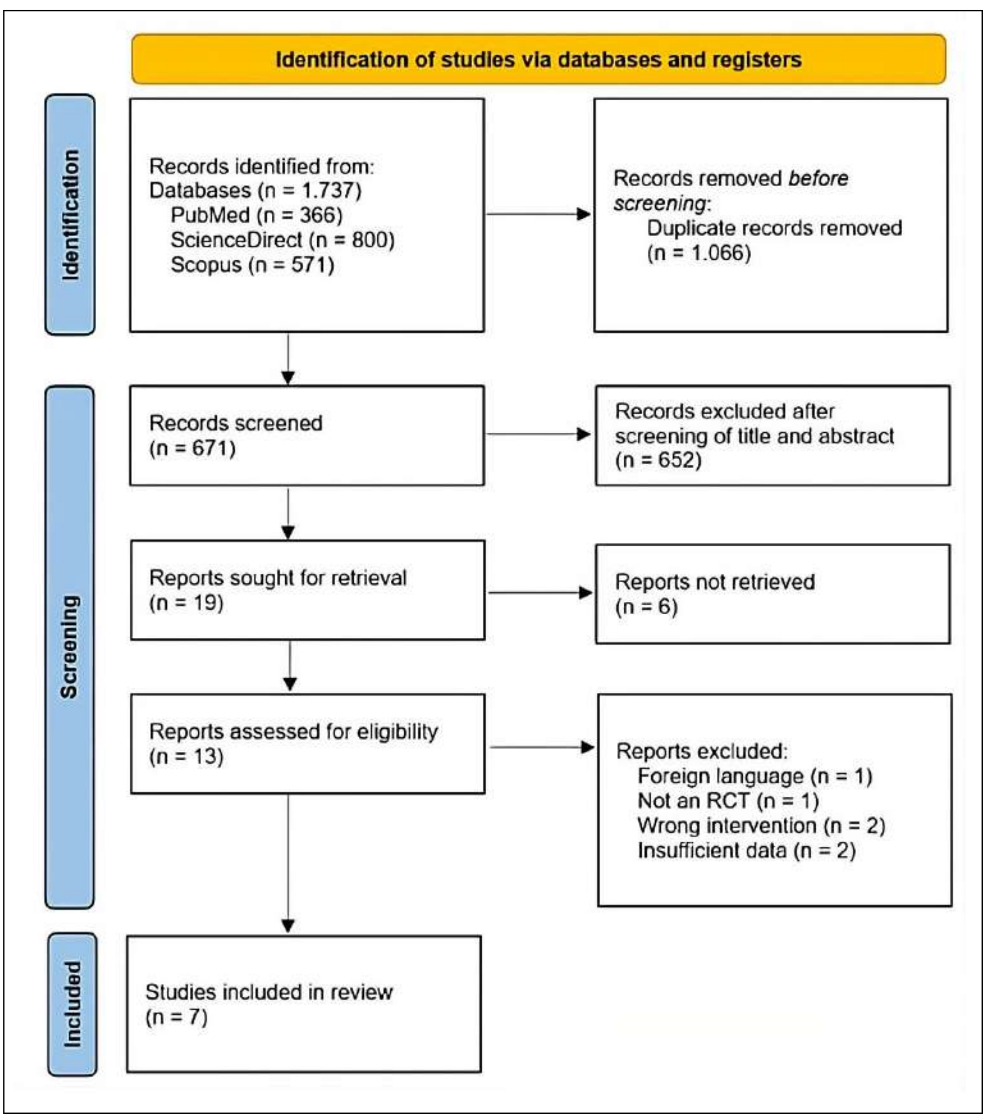


Figure 1.
Flow of literature search and selection based on Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA).

Characteristics of included studies

All studies included were published between 2018 and 2025. In total, seven RCTs (23-29) met the eligibility criteria, comprising 584 female participants diagnosed with SUI. The sample size of individual studies ranged from 18 to 69 participants, with mean ages varying between 39.9 and 55.4 years, reflecting a predominantly middle-aged population. The diagnostic confirmation of SUI across most studies was based on standardized clinical methods, which included a positive cough stress test, 24-hour pad weight test indicating urine leakage, or urodynamic evaluation. Regarding the laser systems utilized, four of the RCTs used CO_2 lasers (24-26, 28), while the remaining three studies applied the Erbium: YAG-laser (Er:YAG) (23, 27, 29). Treatment outcomes were systematically evaluated both before the initiation of therapy and after completion of the final session, using validated and widely adopted patient-reported outcome measures. These included the *International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form* (ICIQ-UI SF) to assess symptom severity, the *Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire* (PISQ-12) to evaluate sexual function, and the *Female Sexual Function Index* (FSFI) to gauge broader aspects of sexual well-being. Most treatment protocols consisted of two to three laser sessions, commonly spaced one month apart. The follow-up periods varied considerably, ranging from immediate post-treatment assessments to as long as 48 weeks after the final intervention, providing insights into both short-term and longer-term outcomes. In all included studies, the control groups underwent sham laser procedures, which replicated the active treatment process without delivering actual laser energy, thereby ensuring blinding and minimizing placebo-related bias. Detailed information regarding study design, population characteristics, and intervention protocols is presented in Table 1.

Quality assessment

The methodological quality and potential sources of bias within each included RCT were assessed using the Cochrane *Risk of Bias 2* (RoB 2) tool, which examines five distinct domains (30). The assessment revealed that most studies were rated as having "some concerns" regarding potential bias, while one study was classified as high risk. A visual summary of the overall quality appraisal is illustrated in Figure 2.

Results of meta-analysis

ICIQ-UI SF

The meta-analysis of ICIQ-UI SF outcomes included a total of seven studies (23-29). The combined results demonstrated a statistically significant improvement in ICIQ-UI SF scores among patients treated with VLT compared with those in the sham laser groups, with a mean difference of -1.54 (95% CI: -2.15 to -0.93, p <

Table 1.
Baseline characteristics data of included studies.

No	Author (Publication Year)	Study Design	Population	Intervention	Follow-Up Duration	Comparison	Mean Age (years)		No. of Participants		Outcome Assesments			Adverse Event
							Laser	Sham	Laser	Sham	ICIQ-UI SF	PISQ-12	FSFI	
1	*Blaganje et al.* (2018)	SBRCT	Premenopausal women aged 35-65 years with SUI	Er:YAG vaginal laser (1 session)	12 weeks	Sham laser	39.95	41.84	56	56				Increased vaginal discharge (laser 49/56, sham 6/56); transient urgency (laser 2/56), vaginal dryness (laser 1/56)
2	*Seki et al.* (2022)	DBRCT	Women aged 18-80 years with SUI	Fractional CO_2 vaginal laser (3 sessions)	8 weeks	Sham laser	50.2	50.6	38	38		-		Mild vaginal bleeding (laser 29%, sham 24%); dysuria (laser 23%, sham 1%)
3	*Alexander et al.* (2022)	SBRCT	Women aged 18-80 years with SUI	Fractional CO_2 vaginal laser (3 sessions)	12 weeks	Sham laser	51.5	54.6	49	48			-	Vaginal bleeding (laser 3/49, sham 1/48); transient urgency (sham 1/48)
4	*Temtanakitpaisan et al.* (2023)	DBRCT	All women with SUI and MUI (stress predominant)	Fractional CO_2 vaginal laser (4 sessions)	12 weeks	Sham laser	49.7	52.8	28	28		-	-	Mild vaginal pain during laser that resolved spontaneously
5	*Yim et al.* (2025)	SBRCT	All women with SUI	Er:YAG vaginal laser (2 sessions)	48 weeks	Sham laser	54.6	55.4	48	23		-	-	Higher pain scores in laser group; vaginal spotting (laser 59%, sham 13%)
6	*Sigurdardottir et al.* (2025)	SBRCT	Women aged 30-65 years with mild to severe SUI (ICIQ-UI SF score 1-18)	Fractional CO_2 vaginal laser (3 sessions)	48 weeks	Sham laser	45.5	46.3	19	18		-	-	Bladder infection (laser 1/19); vaginal bleeding (laser 1/19), vaginal discomfort (laser 1/19, sham 1/18)
7	*Lee et al.* (2025)	DBRCT	All women with SUI	Er:YAG vaginal laser (2 sessions)	24 weeks	Sham laser	49.3	54	69	66			-	Dysuria (laser 2/69; sham 1/66); UTI (laser 1/69), increased incontinence (laser 1/69), vaginal discomfort (laser 1/69); vaginal discharge (sham 2/66)

SUI: Stress Urinary Incontinence; MUI: Mixed Urinary Incontinence; SBRCT: Single Blind Randomized Controlled Study; DBRCT: Double Blind Randomized Controlled Study; Er:YAG: Erbium-doped Yttrium-Garnet; CO_2: Carbon Dioxide; ICIQ-UI SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form; PISQ-12: Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire-12; FSFI: Female Sexual Function Index.

Figure 2.
Risk of bias assessment using the revised Cochrane risk-of-bias tool for randomized trials (RoB 2.0).

0.00001) with moderate heterogeneity (I^2 = 31%), suggesting consistent findings across studies. When stratified according to laser type, both subgroups showed significant improvements relative to controls. The CO_2 laser subgroup (24-26, 28) produced a mean difference of -1.25 (95% CI: -2.12 to -0.38, p = 0.005), while the Er:YAG laser subgroup (23, 27, 29) demonstrated a mean difference of -1.82 (95% CI: -2.67 to -0.97, p < 0.00001). However, the comparison between these two subgroups revealed no statistically significant difference in treatment effect (p = 0.36) (Figure 3A). Further analysis based on the number of treatment sessions indicated that both categories benefited from VLT. The subgroup receiving two or fewer sessions (23, 27, 29) showed a mean difference of -1.82 (95% CI: -2.67 to -0.97, p < 0.001), whereas the subgroup undergoing more than two sessions (24-26, 28) demonstrated a mean difference of -1.25 (95% CI: -2.12 to -0.38, p = 0.005). Nevertheless, the difference between these two subgroups was not statistically significant (p = 0.36) (Figure 3B). Subgroup evaluation based on follow-up duration also showed significant within-group improvements. For studies with follow-up periods shorter than 48 weeks (23, 25, 26), the mean difference was -1.82 (95% CI: -2.59 to -1.04, p < 0.00001), while in trials with follow-up durations of 48 weeks (24, 27, 28) showed a mean difference of -1.09 (95% CI: -2.08 to -0.10, p = 0.03). The comparison between these two subgroups again showed no significant differences (p = 0.26) (Figure 3C). Visual inspection of the funnel plots for the ICIQ-UI SF outcome (***Supplementary Figures 1A-C***) revealed a symmetrical distribution.

Figure 3.
Forest plots of ICIQ-UI SF outcome.
(A) Laser type subgroup; (B) Treatment session subgroup; (C) Follow-up duration subgroup.

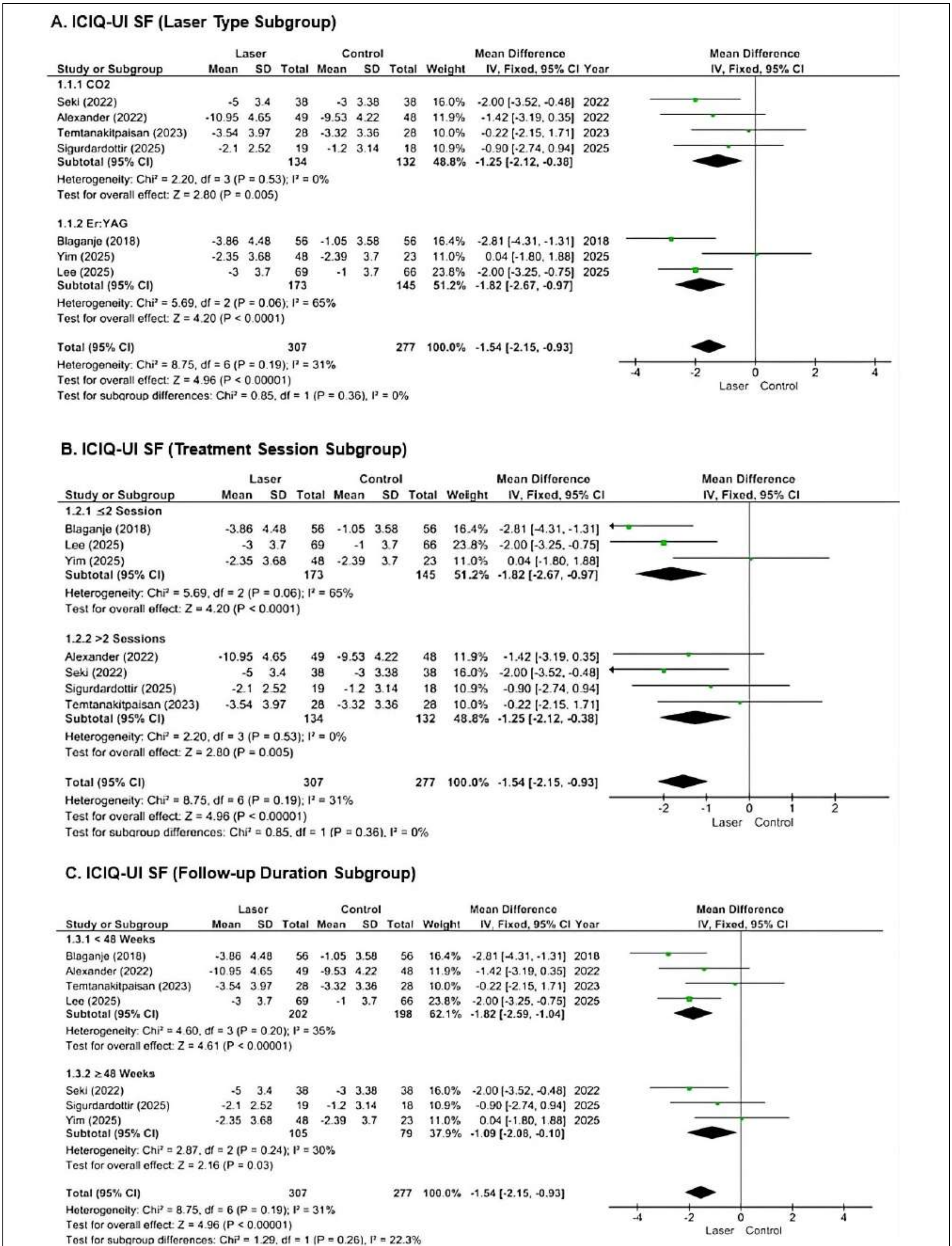


Figure 4.
Forest plot of PISQ-12 outcome.

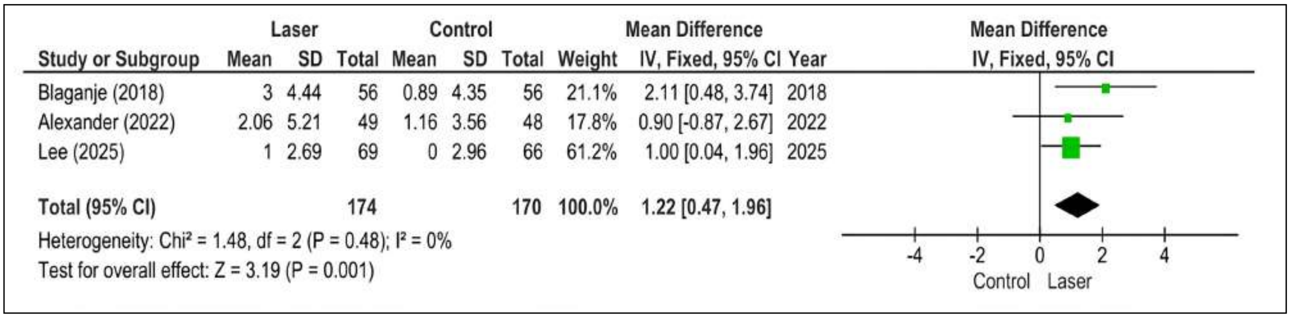
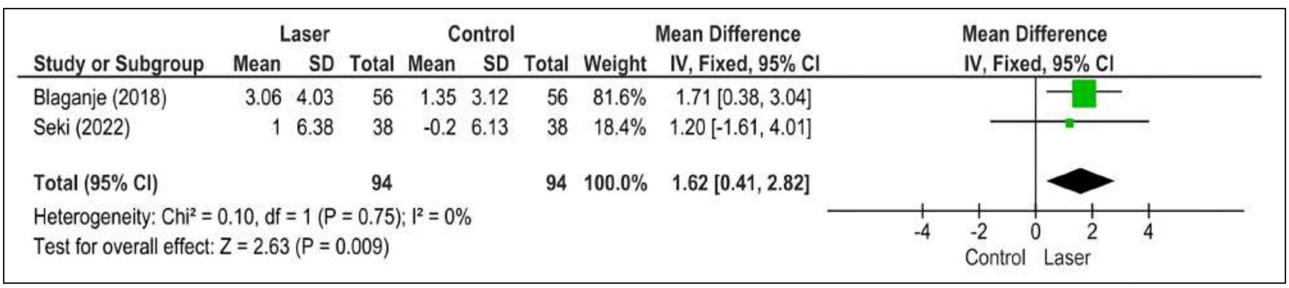


Figure 5.
Forest plot of FSFI outcome.



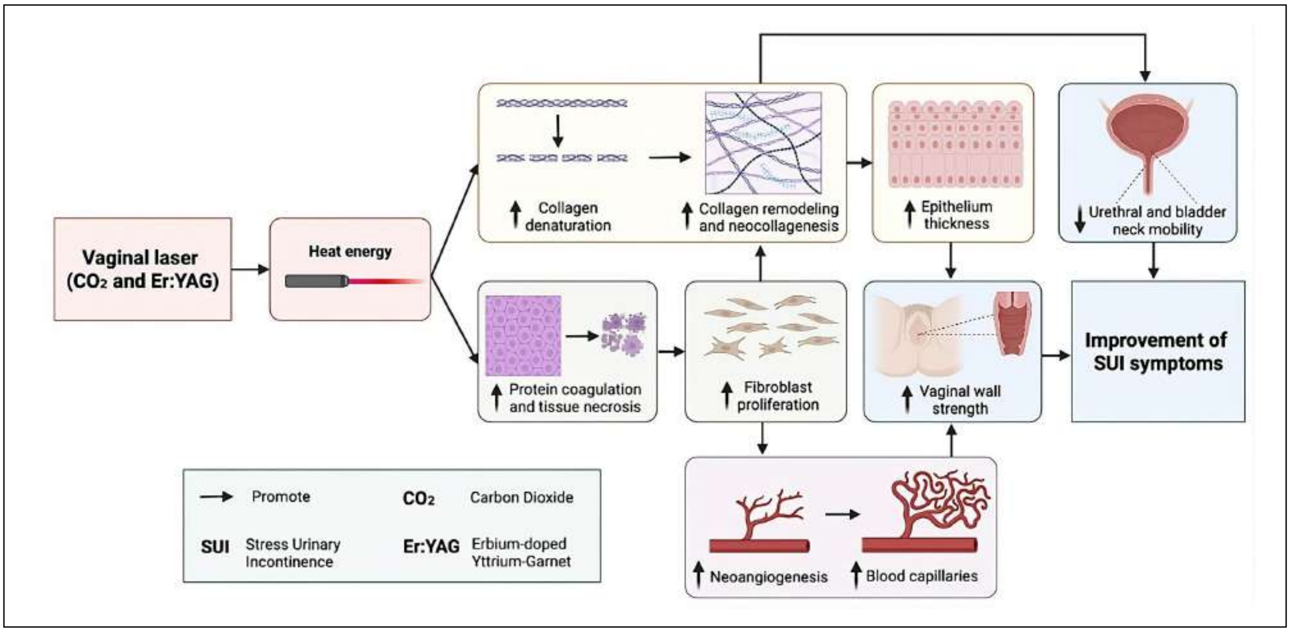
PISQ-12
The meta-analysis assessing PISQ-12 outcomes incorporated data from three studies (23, 25, 29). The pooled findings demonstrated that participants who received VLT exhibited a statistically significant improvement in PISQ-12 scores compared with those in the sham treatment groups, with a mean difference of 1.22 (95% CI: 0.47 to 1.96, p = 0.001, I² = 0%) (Figure 4). The funnel plot corresponding to this analysis displayed a symmetrical pattern (***Supplementary Figure 2***).

FSFI
For FSFI outcomes, data from two eligible studies were analysed (23, 24). The results demonstrated that women who underwent VLT exhibited a statistically significant improvement in total FSFI scores compared with those receiving placebo or sham interventions, with a mean difference of 1.62 (95% CI: 0.41 to 2.82, p = 0.009, I² = 0%) (Figure 5). However, the funnel plot analysis revealed a asymmetrical pattern, which may indicate potential publication bias (***Supplementary Figure 3***).

Adverse events reported
Regarding treatment-related adverse events, the majority of the included studies indicated that VLT was generally well tolerated, with most side effects being mild and transient. In the trial conducted by *Blaganje et al.* (23), a total of 49 out of 56 participants reported increased vaginal discharge, while two individuals experienced transient urgency and one participant noted vaginal dryness following treatment. Other studies (24, 25, 28, 29) reported a few cases of mild vaginal bleeding, vaginal discomfort and dysuria. Furthermore, two studies (26, 27) observed mild pain or burning sensations in the vaginal area during the laser sessions, though these symptoms subsided spontaneously soon after therapy. Only one study by Sigurdardottir et al. reported a serious adverse event (24, 25, 28, 29), involving a bladder infection that required hospital admission but did not result in dropout or long-term complications for the patient.

Discussion
The findings from this meta-analysis indicate that VLT provides significant therapeutic improvements in the management of SUI. as evidenced by a marked reduction in ICIQ-UI SF scores when compared with the sham treatment group. These results align with those of an earlier meta-analysis by *Hafid et al.* that reported an even greater decrease in ICIQ-UI SF scores (MD = -4.805, 95% CI: -5.985 to -3.626, p < 0.001) across ten included studies comprising both randomized and non-randomized designs (31). VLT represents a minimally invasive and well-tolerated option for managing SUI, with strong patient compliance and potential utility across different UI subtypes (32). It is usually conducted in outpatient clinics through three to five sessions at monthly intervals, each lasting 15-30 minutes. Reported outcomes indicate over 70% subjective and objective improvement six months following therapy completion (8, 33). Laser devices transmit energy from an electrical source through a medium such as glass, crystal, or gas, resulting in localized thermal stimulation of vaginal tissue.1 When the suburethral connective tissue reaches temperatures of 60-70°C, collagen denaturation occurs, initiating remodeling and neocollagenesis.8 Furthermore, the ablative properties of the CO_2 laser promote localized protein coagulation and controlled necrosis of vaginal tissue, which in

Figure 6.
Mechanism of the Effect of VLT in Improving SUI Symptoms.



turn activate the fibroblast proliferation, stimulate collagen synthesis (neocollagenesis), and enhance new blood vessel formation (neoangiogenesis) (34).

Histopathological analyses of post-treatment vaginal biopsies using both laser types have revealed increased epithelial thickness, greater capillary density and diameter, enlarged stromal papillae, and evidence of collagen remodeling (35, 36). Collectively, these tissue-level alterations strengthen the anterior vaginal wall and minimize urethral and bladder neck mobility, thereby leading to improved urinary continence (Figure 6) (8, 37).

The subgroup analysis according to laser modality indicated that patients treated with the Er:YAG laser exhibited a slightly greater improvement in ICIQ-UI SF scores compared to those who received CO_2 laser therapy (MD = -1.82 *vs.* -1.25, respectively). However, this difference did not reach statistical significance (p = 0.36).

The fractional microablative CO_2 laser produces controlled micro-injuries that initiate a regenerative cascade characterized by edema formation, granulation tissue development, and subsequent neocollagenesis. In contrast, the non-ablative Er:YAG laser functions through mild hyperthermic stimulation that promotes vasodilation, neoangiogenesis, and collagen remodeling (6). Given that both modalities rely on thermally mediated tissue effects, it is assumed that they induce similar physiological responses. However, the Er:YAG laser differs in its biophysical interaction with tissue, as its wavelength is strongly absorbed by water molecules, allowing for precise heating of deeper collagen layers while minimizing surface ablation and thermal injury. This mechanism reduces the risk of urethral, bladder, or rectal injury and is associated with less postoperative erythema, edema, and discomfort, as well as a shorter tissue recovery period compared with the CO_2 laser (13, 38).

The subgroup analysis of ICIQ-UI SF outcomes showed no statistically significant differences between patients based on the number of treatment sessions (≤ 2 *vs.* > 2 sessions, p = 0.36) or follow-up duration (< 48 weeks *vs.* ≥ 48 weeks, p = 0.26). In comparison, a prior meta-analysis conducted by Wang et al. demonstrated that the greatest degree of symptom improvement was typically observed at the six-month (24-week) follow-up (32). However, the available evidence regarding the long-term outcomes of VLT remains limited. Only a small number of studies have extended their follow-up periods beyond one year, with one investigation monitoring participants for up to 36 months and another evaluating results at 24 months post-treatment. In a cohort of 114 patients, Gambacciani et al. reported a gradual reduction in clinical improvement at the 18- and 24-month follow-up assessments, suggesting a possible decline in therapeutic efficacy over time (39). In contrast, Isaza et al. reported that the clinical benefits of CO_2 laser therapy persisted for up to three years (36 months) without requiring additional interventions, supported by histological evidence of vaginal tissue restoration from atrophy, which is an important factor in maintaining urinary continence (34). Another investigation found that the clinical improvements achieved following a three-session laser protocol, administered at one-month intervals, could be maintained for up to 12 months after treatment. Although a gradual reduction in therapeutic effect was noted over time, the benefits could be prolonged through maintenance sessions administered every six months (40). A previous study suggested that the collagen contraction and remodeling induced by a series of three CO_2 laser treatments may persist for approximately six months after treatment (41). However, the optimal frequency and duration of maintenance treatments remain uncertain, as the factors contributing to the gradual decline in efficacy have yet to be clarified (42). Therefore, future high-quality RCTs with long-term follow-up and rigorous statistical evaluation are needed to better define the sustained therapeutic effects and optimal maintenance intervals of VLT in managing SUI.

The evaluation of sexual function and quality of life was conducted using PISQ-12. This instrument has a total score of up to 48 points, where greater values correspond to improved sexual function (43). Previous studies investigating the impact of urinary incontinence and pelvic organ prolapse consistently report that women affected by *pelvic floor dysfunction* (PFD) experience a notable decline in sexual function (44, 45) Consequently, the PISQ-12 has become a standardized and widely used tool for assessing postoperative sexual outcomes in this population, with numerous studies showing approximately a 70% improvement in scores following surgical intervention.

Findings from our meta-analysis indicated that VLT was associated with a notable enhancement in PISQ-12 scores compared with the sham control group. These findings align with the observations of *Jasim et al.*, who observed a statistically significant increase in PISQ-12 scores across all follow-up periods relative to baseline. The mean PISQ-12 score improved progressively, rising from 31.5 before treatment to 37.7 after one month, 39.3 after three months, and 40.6 after six months following VLT ($p < 0.001$) (46). A previous meta-analysis similarly demonstrated an average improvement of 5.39 points (95% CI:1.20-9.58; $p < 0.01$) in PISQ-12 scores following laser therapy for SUI (32). However, a study by *Lauterbach et al.* reported a decline in PISQ-12 scores from before treatment to three months after VLT intervention (Mean = 40.8 to 21.3). This reduction may be attributed to chronic irritation of the vaginal and cervical tissues caused by laser exposure, potentially leading to discharge and negatively affecting both daily and sexual functioning (47).

Another validated and widely used instrument for assessing sexual health in women is the FSFI. This tool includes 19 items distributed across six primary domains of female sexual activity and satisfaction. The cumulative score ranges between 2 and 36, with results ≤ 26.55 considered indicative of potential *female sexual dysfunction* (FSD), while individual domain scores below 3.6 suggest impairment in the corresponding areas (48). Our meta-analysis demonstrated a significant improvement in FSFI scores among patients receiving laser therapy compared to those in the sham group. This outcome aligns with the study by *Ma et al.*, who observed significant post-treatment increases in FSFI scores across all post-treatment follow-up periods relative to baseline values. Specifically, the laser-only group exhibited total FSFI score improvements of 18.2%, 27.8%, and 27.5% at one, six, and twelve months, respectively 49 Similarly, *Long et al.* reported a marked improvement in overall FSFI scores following Er:YAG laser treatment in women with SUI, with the mean score rising from 22.2 to 25.6 at six months ($p < 0.001$). However, despite the observed improvement in sexual function, the post-treatment FSFI scores remained below the established threshold of 26.55, implying that a comprehensive, multidisciplinary approach may still be necessary to effectively manage female sexual dysfunction (22).

Repeated laser treatments promote collagen fiber contraction, leading to tissue shrinkage and retraction, which reflect underlying anatomical remodeling. This process is subsequently followed by neocollagenesis, resulting in tissue enriched with newly formed collagen fibers that exhibit improved tightness and elasticity (38, 50-52). The associated reduction in vaginal diameter may increase the sensation of vaginal firmness, which has been correlated with improved sexual function (22). Since sexual satisfaction depends on the reciprocal interaction between partners, improved vaginal mucosal health and increased tissue tone may promote more positive responses from partners, thereby reinforcing mutual sexual satisfaction (53). Furthermore, the alleviation of SUI symptoms may help prevent distressing situations such as coital incontinence, dyspareunia, and penetration difficulties, thereby enhancing sexual comfort and confidence. Collectively, these improvements can lead to greater sexual desire, arousal, and overall quality of life among sexually active women affected by SUI (22).

This meta-analysis indicated that three of the seven included studies reported episodes of vaginal bleeding, all of which involved the use of CO_2 laser. This adverse event is likely related to the ablative mechanism of action, whereby micro-injury of the vaginal mucosa occurs secondary to tissue heating.6 Among all included studies, only one reported a serious adverse effect in the laser-treated group, which is a bladder infection accompanied by pain that necessitated short-term hospitalization, though the case did not result in dropout or any lasting complications. Consistent with prior evidence, ablative CO_2 vaginal laser therapy has occasionally been linked to mucosal irritation, scarring, or infection (34). In contrast, the remaining studies in our meta-analysis reported only mild and transient adverse effects, with increased vaginal discharge being the most frequently observed. In line with our findings, earlier systematic reviews and meta-analyses also reported no major adverse reactions, reinforcing that VLT is a generally safe and well-tolerated intervention for women experiencing SUI (32, 42).

To the best of our knowledge, the present study constitutes the most recent and comprehensive meta-analysis investigating the therapeutic efficacy of VLT in improving symptoms of SUI and enhancing sexual function among women, while also examining its safety profile. All studies incorporated into this review were RCTs, thereby offering a stronger level of evidence compared to observational designs. Nonetheless, several limitations should be acknowledged. The available data still indicate a moderate degree of potential bias, particularly in the trial conducted by *Alexander et al.* (25), where the lack of blinding among investigators may have introduced performance and detection bias. Furthermore, the limited number of trials assessing PISQ-12 and FSFI outcomes restricts the reliability of conclusions regarding sexual function. Additionally, using objective measures such as urodynamic testing would help reinforce subjective findings derived from ICIQ-UI scores. Despite these limitations, the findings of this meta-analysis carry meaningful clinical implications, suggesting that VLT represents a potentially effective and minimally invasive treatment option for women with SUI – particularly for those who are not ideal candidates for surgical intervention or who prefer conservative management approaches.

Conclusions

The present meta-analysis demonstrated that VLT led to significant improvements in ICIQ-UI SF, PISQ-12, and FSFI scores, confirming its efficacy in alleviating urinary incontinence symptoms and enhancing sexual well-being among women with SUI. Both CO_2 and Er:YAG laser modalities were shown to provide comparable clinical benefits, supporting their use as viable options for symptom management and improvement of overall quality of life in affected patients. None of the included trials reported any severe or major adverse events, suggesting that VLT is a safe and well-tolerated therapeutic approach. Future research directly comparing VLT with other minimally invasive interventions, such as urethral bulking agents, as well as non-invasive approaches, including PFMT or pharmacologic therapy, is necessary to further determine its clinical advantage and cost-efficiency.

Declarations

Ethical approval and consent for participate: *This study did not need any of ethical approval.*

Availability of data and material: *All data and materials from this research are available to the researcher and we will provide it upon request if the researcher needs it.*

Competing interests: *The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.*

Funding: *All funding for this research comes from researchers without receiving research costs or research grants from third parties.*

Authors' contributions:

	KK	S	SS	MAG	ATF	AMS	MAP
Concepts	√			√			
Design	√	√	√	√	√	√	√
Definition of intellectual content	√			√			
Literature search	√			√	√	√	
Data acquisition	√			√		√	
Data analysis	√			√		√	
Statistical analysis	√			√	√	√	
Manuscript preparation	√	√	√	√	√	√	√
Manuscript editing	√	√	√				√
Manuscript review	√	√	√				√
Guarantor	√						

Acknowledgments: *We as authors would like to thank all parties involved in this study, including the Department of Urology, Faculty of Medicine, Hasanuddin University and also Hasanuddin University Hospital.*

Conference presentation: *This article has not been presented at any conference.*

References

1. Lane GI, Barboglio-Romo P, Crescenze I, et al. Vaginal lasers for treating stress urinary incontinence in women. Cochrane Database Syst Rev 2020; 2020:CD013643.

2. Cobley J, Wyndaele M, Hashim H. Pathophysiology of urinary incontinence. Surg - Oxf Int Ed 2023; 41:265-271.

3. Gafni-Kane A, Zhou Y, Botros SM. Predictive modeling and threshold scores for care seeking among women with urinary incontinence: The short forms of the Pelvic Floor Distress Inventory and Urogenital Distress Inventory. Neurourol Urodyn 2016; 35: 949-954.

4. Gandhi J, Chen A, Dagur G, et al. Genitourinary syndrome of menopause: an overview of clinical manifestations, pathophysiology, etiology, evaluation, and management. Am J Obstet Gynecol 2016; 215:704-711.

5. Kołodyńska G, Zalewski M, Rozek-Piechura K. Urinary incontinence in postmenopausal women - causes, symptoms, treatment. Przeglad Menopauzalny Menopause Rev 2019; 18:46-50.

6. Sikora M, Gamper M, Zivanovic I, et al. Current Treatment of Stress Urinary Incontinence by Bulking Agents and Laser Therapy—An Update. J Clin Med 2024; 13:1377.

7. Shin H, Lee Y, Lim S, et al. A new approach to treatment of stress urinary incontinence using non-ablative transurethral laser. Sci Rep 2025; 15:5706.

8. Ruffolo AF, Braga A, Torella M, et al. Vaginal Laser Therapy for Female Stress Urinary Incontinence: New Solutions for a Well-Known Issue-A Concise Review. Med Kaunas Lith 2022; 58:512.

9. Imamura M, Hudson J, Wallace SA, et al. Surgical interventions for women with stress urinary incontinence: systematic review and network meta-analysis of randomised controlled trials. BMJ 2019; 365: l1842.

10. Kuhlmann PK, Dallas K, Masterson J, et al. Risk Factors for Intraoperative Bladder Perforation at the Time of Midurethral Sling Placement. Urology 2021; 148:100-105.

11. Zwierzchowska A, Tomasik P, Horosz E, et al. Sonography as a Diagnostic Tool in Midurethral Sling Complications: A Narrative Review. J Clin Med 2024; 13:2336.

12. Reisenauer C, Hartlieb S, Schoenfisch B, et al. Vaginal therapy of mild and moderate stress urinary incontinence using Er:YAG laser: a real treatment option. Arch Gynecol Obstet 2019; 300:1645-1650.

13. Tadir Y, Gaspar A, Lev-Sagie A, et al. Light and energy based therapeutics for genitourinary syndrome of menopause: Consensus and controversies. Lasers Surg Med 2017; 49:137-159.

14. Kaufman MR, Ackerman AL, Amin KA, et al. The AUA/SUFU/AUGS Guideline on Genitourinary Syndrome of Menopause. J Urol 2025; 214:242-250.

15. Shobeiri SA, Kerkhof MH, Minassian VA, et al. IUGA committee opinion: laser-based vaginal devices for treatment of stress urinary incontinence, genitourinary syndrome of menopause, and vaginal laxity. Int Urogynecology J 2019; 30:371-376.

16. Kobashi KC, Vasavada S, Bloschichak A, et al. Updates to Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline (2023). J Urol 2023; 209:1091-1098.

17. Nambiar AK, Bosch R, Cruz F, et al. EAU Guidelines on Assessment and Nonsurgical Management of Urinary Incontinence. Eur Urol 2018; 73:596-609.

18. Preti M, Vieira-Baptista P, Digesu GA, et al. The clinical role of

LASER for vulvar and vaginal treatments in gynecology and female urology: An ICS/ISSVD best practice consensus document. Neurourol Urodyn 2019; 38:1009-1023.

19. Gambacciani M, Cervigni M, Gaspar A, et al. Safety of vaginal erbium laser: A review of 113,000 patients treated in the past 8 years. Climacteric J Int Menopause Soc 2020; 23: S28-S32.

20. O'Reilly BA, Viereck V, Phillips C, et al. Vaginal erbium laser treatment for stress urinary incontinence: A multicenter randomized sham-controlled clinical trial. Int J Gynaecol Obstet Off Organ Int Fed Gynaecol Obstet 2024; 164:1184-1194.

21. Cañadas Molina A, Sanz Baro R. The first major complication due to laser treatment for stress urinary incontinence: a short report. Climacteric J Int Menopause Soc 2021; 24:206-209.

22. Long C-Y, Lee JP-N, Loo Z-X, et al. The Clinical Effects of Pixel CO_2 Laser on Bladder Neck and Stress Urinary Incontinence. J Clin Med 2022; 11:4971.

23. Blaganje M, Šćepanović D, Žgur L, et al. Non-ablative Er:YAG laser therapy effect on stress urinary incontinence related to quality of life and sexual function: A randomized controlled trial. Eur J Obstet Gynecol Reprod Biol 2018; 224:153-158.

24. Seki AS, Bianchi-Ferraro AMHM, Fonseca ESM, et al. CO_2 Laser and radiofrequency compared to a sham control group in treatment of stress urinary incontinence (LARF study arm 3). A randomized controlled trial. Int Urogynecology J 2022; 33:3535-3542.

25. Alexander JW, Karjalainen P, Ow LL, et al. CO_2 surgical laser for treatment of stress urinary incontinence in women: a randomized controlled trial. Am J Obstet Gynecol 2022; 227:473.e1-473.e12.

26. Temtanakitpaisan T, Chongsomchai C, Buppasiri P. Fractional CO_2 laser treatment for women with stress predominant urinary incontinence: a randomized controlled trial. Int Urogynecology J 2023; 34:2827-2832.

27. Yim LW, Wan OYK, Wong D, et al. Vaginal Laser Treatment on Stress Urinary Incontinence: A Randomized Controlled Trial. Int Urogynecology J. Epub ahead of print 23 May 2025. DOI:10.1007/s00192-025-06160-8.

28. Sigurdardóttir HB, Kirschner B, Obel J, et al. Vaginal CO_2 laser treatment for urinary stress incontinence: A randomized controlled trial. Maturitas 2025; 199:108658.

29. Lee P, Perruzza D, Edell H, et al. Double-blind randomized controlled trial of Er: YAG vaginal laser to treat female stress urinary incontinence. Am J Obstet Gynecol 2025; 232:541.e1-541.e12.

30. Sterne JAC, Savović J, Page MJ, et al. RoB 2: a revised tool for assessing risk of bias in randomised trials. BMJ 2019; 366: l4898.

31. Hafidh B, Baradwan S, Latifah HM, et al. CO_2 laser therapy for management of stress urinary incontinence in women: a systematic review and meta-analysis. Ther Adv Urol 2023; 15:17562872231210216.

32. Wang Y, Wang C, Song F, et al. Safety and efficacy of vaginal laser therapy for stress urinary incontinence: a meta-analysis. Ann Palliat Med 2021; 10:2736-2746.

33. Kuszka A, Gamper M, Walser C, et al. Erbium:YAG laser treatment of female stress urinary incontinence: midterm data. Int Urogynecology J 2020; 31:1859-1866.

34. González Isaza P, Jaguszewska K, Cardona JL, et al. Long-term effect of thermoablative fractional CO_2 laser treatment as a novel approach to urinary incontinence management in women with genitourinary syndrome of menopause. Int Urogynecology J 2018; 29:211-215.

35. Lapii GA, Yakovleva AY, Neimark AI. Structural Reorganization of the Vaginal Mucosa in Stress Urinary Incontinence under Conditions of Er:YAG Laser Treatment. Bull Exp Biol Med 2017; 162:510-514.

36. Salvatore S, Leone Roberti Maggiore U, Athanasiou S, et al. Histological study on the effects of microablative fractional CO_2 laser on atrophic vaginal tissue: an ex vivo study. Menopause N Y N 2015; 22: 845-849.

37. Lin K-L, Chou S-H, Long C-Y. Effect of Er:YAG Laser for Women with Stress Urinary Incontinence. BioMed Res Int 2019; 2019:7915813.

38. Franić D, Fistonić I. Laser Therapy in the Treatment of Female Urinary Incontinence and Genitourinary Syndrome of Menopause: An Update. BioMed Res Int 2019; 2019:1576359.

39. Gambacciani M, Levancini M, Russo E, et al. Long-term effects of vaginal erbium laser in the treatment of genitourinary syndrome of menopause. Climacteric J Int Menopause Soc 2018; 21:148-152.

40. Gaspar A, Maestri S, Silva J, et al. Intraurethral Erbium:YAG laser for the management of urinary symptoms of genitourinary syndrome of menopause: A pilot study. Lasers Surg Med 2018; 50: 802-807.

41. Balk E, Adam G, Kimmel H. Nonsurgical Treatments for Urinary Incontinence in Women: A Systematic Review Update [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); (Comparative Effectiveness Review, No. 212.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK534625/.

42. Ranjbar A, Mehrnoush V, Darsareh F, et al. Vaginal Laser Therapy for Stress Urinary Incontinence: A Systematic Review of Prospective Randomized Clinical Trials. J Menopausal Med 2022; 28:103-111.

43. Kamińska A, Skorupska K, Kubik-Komar A, et al. Reliability of the Polish Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) and Assessment of Sexual Function before and after Pelvic Organ Prolapse Reconstructive Surgery—A Prospective Study. J Clin Med 2021; 10:4167.

44. Li-Yun-Fong RJ, Larouche M, Hyakutake M, et al. Is Pelvic Floor Dysfunction an Independent Threat to Sexual Function? A Cross-Sectional Study in Women With Pelvic Floor Dysfunction. J Sex Med 2017; 14:226-237.

45. Zhuo Z, Wang C, Yu H, et al. The Relationship Between Pelvic Floor Function and Sexual Function in Perimenopausal Women. Sex Med 2021; 9:100441.

46. Jasim S, Khalil Al-Rawi R. Efficacy and safety of vaginal CO_2 Laser treatment in female stress urinary incontinence. Med J Babylon 2018; 15:251.

47. Lauterbach R, Aharoni S, Justman N, et al. The efficacy and safety of a single maintenance laser treatment for stress urinary incontinence: a double-blinded randomized controlled trial. Int Urogynecology J 2022; 33:3499-3504.

48. Kim SR, Moon YJ, Kim SK, et al. Changes in Sexual Function and Comparison of Questionnaires Following Surgery for Pelvic Organ Prolapse. Yonsei Med J 2014; 55:170-177.

49. Ma Y, Liao Y, Lai Y, et al. 16 - Evaluating Changes in Sexual Function and Urinary Symptoms After Fractional CO_2 Vaginal Laser and Physical Therapy in Women with Stress Urinary Incontinence. Continence 2025; 15:101940.

50. Arunkalaivanan A, Kaur H, Onuma O. Laser therapy as a treatment modality for genitourinary syndrome of menopause: a critical appraisal of evidence. Int Urogynecology J 2017; 28:681-685.

51. Lanzafame RJ, de la Torre S, Leibaschoff GH. The Rationale for Photobiomodulation Therapy of Vaginal Tissue for Treatment of Genitourinary Syndrome of Menopause: An Analysis of Its Mechanism of Action, and Current Clinical Outcomes. Photobiomodulation Photomed Laser Surg 2019; 37:395-407.

52. Tien Y-W, Hsiao S-M, Lee C-N, et al. Effects of laser procedure for female urodynamic stress incontinence on pad weight, urodynamics, and sexual function. Int Urogynecology J 2017; 28:469-476.

53. Clayton AH, Valladares Juarez EM. Female Sexual Dysfunction. Psychiatr Clin North Am 2017; 40:267-284.

Correspondence

Khoirul Kholis (Corresponding Author)
khoirulkholis@yahoo.com

Division of Urology, Department of Surgery, Faculty of Medicine, Hasanuddin University, Makassar, Indonesia
Perintis Kemerdekaan St. KM. 10, Tamalanrea, Makassar, Indonesia (Postal Code: 90245)

Syarif
syarif.bakri1981@gmail.com

Syakri Syahrir
drsyakrisyahrir@gmail.com

Moh. Anfasa Giffari Makkaraka
fasagifari@gmail.com

Ahmad Taufik Fadillah Zainal
ahmadtaufik2014004@gmail.com

Muhammad Asykar Palinrungi
apalinrungi@yahoo.com

Division of Urology, Department of Surgery, Faculty of Medicine, Hasanuddin University, Makassar, Indonesia

Adrian Manuel Sutanto
adrianmsutanto@gmail.com
Faculty of Medicine, Hasanuddin University, Makassar, Indonesia