Review Article

Efficacy and Safety of Vaginal Laser Therapy for Stress Urinary Incontinence: Systematic Review of Randomized Controlled Trials

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ABSTRACT

Vaginal laser therapy has emerged as a popular, minimally invasive treatment for stress urinary incontinence (SUI), proposed to work through thermal tissue remodeling. However, evidence from randomized controlled trials (RCTs) is conflicting, creating uncertainty for its clinical use. To systematically review and synthesize evidence from RCTs on the efficacy and safety of vaginal laser therapy for the treatment of pure SUI in women. A systematic review was conducted following PRISMA guidelines. A comprehensive search of PubMed/MEDLINE, Web of Science, SCOPUS, and Cochrane Central was performed. Only RCTs comparing vaginal laser (Er:YAG or CO2) to sham procedures, pelvic floor muscle training (PFMT), or other controls in women with SUI were included. Six RCTs with a total of 466 participants were included. The findings were highly inconsistent. Two sham-controlled RCTs reported significant improvement in the laser group for objective cure (59% vs. 36% sham) and quality of life. In contrast, three other sham-controlled RCTs found no significant difference between laser and sham on primary outcomes, with one reporting a subjective cure rate of less than 2% in both groups. One trial found laser to be non-inferior to PFMT at 4 months, but both interventions had low long-term success, with most patients seeking alternative treatments within two years. Heterogeneity was high regarding laser parameters, outcome measures, and patient populations. The procedure was consistently safe, with only minor, transient adverse events reported. Given the high cost and unproven efficacy, vaginal laser should not replace established SUI treatments. It should be considered investigational and used only in the context of further large, well-designed RCTs with long-term follow-up.

Keyword: Stress Urinary Incontinence; Vaginal Laser; Er: YAG Laser; CO2 Laser; Systematic Review; Randomized Controlled Trial; Minimally Invasive Procedures.

Introduction

An extremely common and upsetting condition that severely lowers the quality of life for millions of women worldwide is stress urinary incontinence (SUI), which is the involuntary flow of urine upon effort or exertion. Its prevalence is substantial, affecting an estimated 35% of the female population, with incidence increasing with age and other factors such as childbirth and menopause [1]. The economic and psychosocial burden of SUI is profound, encompassing direct healthcare costs, reduced productivity, and often leading to social isolation, anxiety, and depression [2]. The pathophysiological basis of SUI is primarily attributed to urethral hypermobility and intrinsic sphincter deficiency, resulting from weakened pelvic floor muscles and connective tissues that fail to provide adequate support to the bladder neck and urethra [3].

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The management of SUI follows a stepped-care approach, beginning with conservative interventions. First-line conservative treatment consists of lifestyle modifications and supervised pelvic floor muscle training (PFMT), which aims to improve the strength and function of the urethral supporting structures [4]. While effective, PFMT is limited by issues of long-term patient adherence and variable efficacy [5]. For women who do not achieve sufficient improvement with conservative measures, mid-urethral sling (MUS) surgery has been established as the gold standard surgical treatment for decades, offering high objective and subjective cure rates [6]. However, surgery carries inherent risks, including perioperative complications, groin pain, voiding dysfunction, and rare but serious issues like organ perforation and mesh erosion, which have tempered enthusiasm for its universal application [7]. This therapeutic gap between conservative management and invasive surgery has fueled the search for effective, minimally invasive office-based procedures [4]. In recent years, energy-based devices, particularly fractional micro-ablative lasers, have emerged as a promising and popular minimally invasive treatment for genitourinary syndrome of menopause (GSM) and have been subsequently proposed as a novel therapy for SUI [8]. The proposed mechanism of action for lasers like the Erbium: YAG (Er: YAG) and Carbon Dioxide (CO_2) involves the principle of photothermal stimulation. The laser energy is absorbed by the vaginal mucosa and underlying connective tissue, inducing controlled thermal damage. This triggers a wound-healing response characterized by neocollagenesis, elastogenesis, and the remodeling of the extracellular matrix, ultimately leading to tissue tightening and improved support of the urethra and bladder neck [9]. Proponents suggest this can restore fascial support and improve coaptation of the urethral mucosa, thereby reducing urine leakage under stress. Despite growing commercial adoption and patient interest, the evidence base for the efficacy of vaginal laser therapy for SUI remains controversial and is rapidly evolving. Initial studies, often uncontrolled case series or cohort designs, reported promising outcomes in terms of symptom improvement and patient satisfaction. However, the recent publication of several high-quality randomized controlled trials (RCTs) with sham-control groups has produced conflicting results, with some demonstrating superiority over sham and others showing no significant difference, highlighting the potent influence of the placebo effect in incontinence treatments. This divergence in evidence creates significant uncertainty for clinicians and patients alike regarding the true value of this technology [8]. Therefore, the objective of this systematic review is to critically appraise and synthesize the current evidence from randomized controlled trials exclusively, to evaluate the efficacy and safety of vaginal laser therapy for the treatment of pure stress urinary incontinence in women, and providing a clear and evidence-based conclusion on its role in modern clinical practice.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) standards were strictly followed in the conduct and reporting of this systematic review [10]. To find all pertinent published randomised controlled trials (RCTs) that examined the effectiveness and safety of vaginal laser therapy for the management of stress urinary incontinence (SUI) in women, a thorough and methodical search strategy was created and put into action. The electronic bibliographic databases searched from inception to included PubMed/MEDLINE, Web of Science, SCOPUS, and Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy utilized a combination of relevant medical subject headings (MeSH) terms and free-text keywords related to "stress urinary incontinence," "vaginal laser," "Er: YAG laser," "CO_2 laser," and "randomized controlled trial." No date or language restrictions were initially applied to ensure the broadest possible capture of relevant studies. To ensure a rigorous and unbiased selection process, two independent reviewers screened the search results, selected studies that met the pre-defined eligibility criteria, extracted the data, and performed the risk of bias assessment for all included studies. Any discrepancies between the reviewers at any stage of the process were resolved through discussion or by consultation with a third reviewer. Eligibility Criteria: Using the PICOS framework, pre-established eligibility criteria served as the basis for the study selection process. Randomised controlled trials that recruited adult women with urodynamic SUI or pure stress urine incontinence as their primary diagnosis were included. Any type of vaginal laser therapy (such as CO_2 laser or Er: YAG) utilized as a main treatment was the intervention of interest. Pelvic floor muscle training (PFMT), additional active therapies, sham laser operations, or no treatment were all included in the comparator. Measures of efficacy, such as objective urine leakage evaluation (e.g., 1-hour pad test), subjectively patient-reported outcomes

(e.g., ICIQ-SF, UDI-6 scores), and patient-reported improvement or cure rates, were the main outcomes of interest. Adverse event incidence and quality of life metrics were secondary outcomes. Studies were excluded if they included patients with mixed urinary incontinence or overactive bladder as the primary diagnosis, if the laser therapy was used as an adjuvant treatment post-surgery, or if the study design was non-randomized (e.g., cohort studies, case series, reviews, editorials). Conference abstracts were excluded due to the inability to adequately assess methodological quality and extract sufficient data. Data Extraction: The titles and abstracts of all records retrieved from the database searches were screened for eligibility by two independent reviewers using the web-based systematic review software Rayyan (QCRI) [11]. This tool facilitated a blinded screening process to minimize bias. Studies deemed potentially relevant by either reviewer were advanced to a full-text review. Both reviewers then separately evaluated these articles' full texts in relation to the inclusion and exclusion criteria. Any disputes about inclusion were settled by arbitration by a third reviewer or by consensus. Data were extracted onto a standardised, piloted data extraction form for every study that was included. Study characteristics (first author, publication year, country, study design, sample size), participant demographics (age, SUI severity, and diagnosis method), intervention details (laser type, protocol, number of sessions), comparator details, primary and secondary outcomes with results at all reported time points, and reported adverse events were among the features of the extracted data. Data Synthesis Strategy: Given the anticipated clinical and methodological heterogeneity among the included studies—particularly concerning the type of laser, treatment protocol, choice of comparator, and outcome measures—a narrative synthesis was deemed the most appropriate approach. The results were presented in structured summary tables detailing the study characteristics, patient demographics, and comprehensive results for all outcomes. The findings were synthesized thematically, comparing and contrasting the results across studies based on the type of control group (sham vs. active comparator) and the reported efficacy and safety outcomes. Risk of Bias Assessment: Using the updated Cochrane risk-of-bias technique for randomised trials (RoB 2), two reviewers independently evaluated the risk of bias in the included randomised controlled trials [12]. This instrument assesses bias in five areas: (1) bias resulting from the randomisation procedure; (2) bias resulting from departures from the planned interventions; (3) bias resulting from incomplete outcome data; (4) bias in outcome measurement; and (5) bias in the choice of the reported result. Each domain was deemed to indicate "some concerns," "low risk," or "high risk" of bias. The judgements in all domains were then used to calculate the total risk of bias for each study. The two reviewers had a conversation to settle any differences in the risk of bias evaluations.

Results

(Figure 1) shows that, 365 records were identified through database searches. After the removal of 177 duplicates, 188 records were screened based on title and abstract, leading to the exclusion of 87 records. The full texts of 101 reports were sought for retrieval; however, 76 were not retrieved, leaving 25 reports to be assessed for eligibility. Following a full-text review, 19 reports were excluded due to wrong outcomes (n=11), wrong population (n=5), or being conference abstracts (n=3), resulting in a final inclusion of 6 studies in the systematic review. As detailed in (Table 1), the studies were conducted across several countries, including Brazil [13], Hong Kong [14], Canada [15], Denmark [16], a multinational consortium [17], and Belgium [18]. The laser platforms utilized were primarily Erbium: YAG (Er: YAG), with one trial employing a fractional CO2 laser [16]. A critical aspect of the study designs was the choice of comparator group. Three trials [14, 15, 16] employed a sham-controlled design, which is considered the gold standard for minimizing performance bias when assessing a device-based therapy. Another trial compared laser directly to an established first-line conservative treatment, pelvic floor muscle training (PFMT) [13], while one study used PFMT as both a comparator and a concomitant therapy for all participants [18]. The sample sizes varied, with the largest trial randomizing 144 participants [15] and the smallest being a pilot study with 40 participants [13]. The patient populations were generally well-defined, with most studies requiring a urodynamic or clinical confirmation of SUI, though the severity of symptoms ranged from mild to moderate [18] to more severe cases. The outcomes and key findings of these trials, summarized in (Table 2), reveal a stark contrast in conclusions regarding the efficacy of vaginal laser therapy. The protocols for laser application differed, with the number of sessions ranging from two [14, 15, 17] to three [13, 16], and up to six in the trial comparing it to PFMT [18]. The follow-up periods also varied, with most studies

reporting outcomes at 6 and 12 months [13, 14, 17], while others had shorter endpoints at 4 [18] or 6 months [15]. The primary outcomes were diverse, including objective measures like the 1-hour pad test [13, 17] and a variety of validated subjective patient-reported outcome measures (PROMs) such as the ICIQ-SF, UDI-6, and KHQ questionnaires. The results are mixed. Two sham-controlled trials [17, 13] reported positive findings, with one demonstrating a significantly higher objective treatment success rate for the active laser group compared to sham (59% vs. 36%) at 6 months [17]. Conversely, the other two sham-controlled trials [14, 15, 16] found no significant difference between laser and sham intervention on their primary outcomes, with one reporting a remarkably low and equivalent subjective cure rate of less than 2% in both groups [15]. The trial comparing laser to PFMT found them to be comparable and non-inferior, though both provided only limited and short-lasting subjective benefit, leading most patients to seek alternative treatments within two years [18]. The heterogeneity in results can be attributed to several factors. Key differences include the laser parameters (type, energy, and number of sessions), the rigor of the sham control (e.g., whether it mimicked sound and sensation), the primary outcome measure chosen (objective vs. subjective), and the characteristics of the enrolled population (SUI severity, and hormonal status). Furthermore, the concomitant use of PFMT in some studies, like the Danish trial where it was mandated for all participants [16], may confound the isolated effect of the laser therapy. Safety profiles were generally reassuring across all studies, with no serious device-related adverse events reported [17, 18] and only minor, transient side effects were mentioned. The most common reported issue was a single bladder infection [16]. This overall positive safety profile was a consistent finding, suggesting that the procedure was well-tolerated even if its efficacy remains under debate. (Figures 2, 3) shows risk of bias assessment for included studies using ROB2 tool.

Discussion

The findings of this systematic review, which rigorously focused on randomized controlled trials (RCTs), present a complex and contradictory landscape regarding the efficacy of vaginal laser therapy for stress urinary incontinence (SUI). The pooled results from six RCTs [13-18] demonstrated a stark lack of consensus, with studies reporting both significant positive outcomes and null results compared to sham procedures. This divergence underscores a critical juncture in the evaluation of this minimally invasive technology and necessitates a thorough discussion contextualized within the broader existing literature, including the studies excluded from our quantitative analysis for methodological reasons. The positive findings from the multicenter trial by O'Reilly et al. [17], which reported a significantly higher objective treatment success rate (59% vs. 36%) and improved quality of life and sexual function compared to sham, provide the strongest evidence to date supporting the efficacy of Er: YAG laser. This aligns with the mechanistic rationale proposed by several non-RCT studies. For instance, Gao et al. [19], in a single-arm study, demonstrated through histology, vaginal tactile imaging, and MRI that fractional CO2 laser treatment led to a thicker epithelium, increased vaginal wall resistance, decreased bladder neck mobility, and overall remodeling of vaginal tissues. Similarly, Long et al. [20] used 3-D transperineal ultrasound to document significant vaginal shrinkage (decreased width and cross-sectional area) following Er: YAG treatment, which they correlated with improved sexual function and symptomatic relief in 74% of their 220-woman cohort. These studies suggest a plausible biological basis for laser efficacy through tissue tightening and reinforcement of pelvic floor support structures. Furthermore, the non-inferiority of laser to pelvic floor muscle training (PFMT) found by da Fonseca et al. [13] and Page et al. [18] positions it as a potential alternative conservative modality for patients who are non-compliant with or non-responsive to traditional physiotherapy. However, this optimistic view was profoundly challenged by the results of other high-quality, double-blind, sham-controlled RCTs. The studies by Lee et al. [15] and Sigurdardottir et al. [16] found no significant difference between active laser and sham intervention on any primary outcome measure. Lee et al. [15] reported an almost identical and negligible subjective cure rate of 1.36% in the laser group versus 0% in the sham group at 6 months. Similarly, Yim et al. [14] reported significant intragroup improvement but no intergroup difference between laser and sham. The presence of a strong placebo effect in SUI treatments is well-documented and powerful [21]. The act of a sophisticated medical procedure, involving the insertion of a laser probe, often accompanied by sounds and sensations, can generate substantial patient expectation of improvement, which is adequately mimicked by a well-designed sham intervention. Therefore, the positive outcomes reported in some uncontrolled studies, such as Gaspar et al. [22] who reported significant improvements in pad tests and

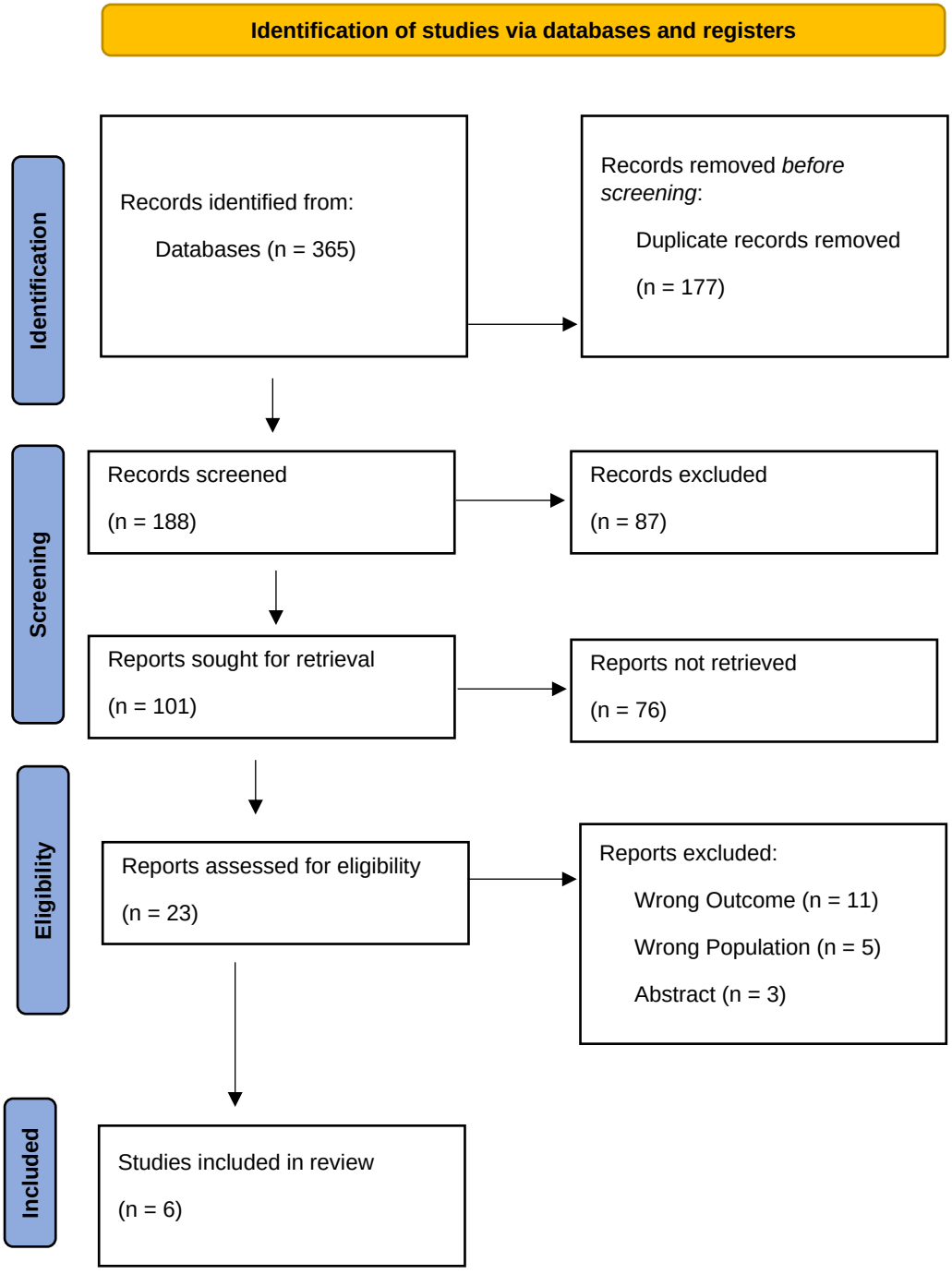

Figure 1: PRISMA 2020 Flow Diagram for Study Selection.

Table 1: Study Characteristics and Demographic Data.

Study ID (Author, Year, [Ref])	Country	Study Design	Laser Type	Control Group	Sample Size (N) Randomized (Completed)	Participant Age, Mean (SD or Range)	SUI Diagnosis	Key Inclusion Criteria
Da Fonseca et al., 2023 [13]	Brazil	Pilot RCT	Er: YAG	Pelvic Floor Physiotherapy	40 (32)	LG: 57.9 ± 6.1; PTG: 62.7 ± 9.1	Clinical and urodynamic	Postmenopausal women with SUI
Yim et al., 2025 [14]	Hong Kong	Single-blinded, multicenter RCT	Er: YAG	Sham treatment	75 (NM)	NM	Urodynamic	Women with urodynamic SUI
Lee et al., 2025 [15]	Canada	Double-blind, sham-controlled RCT	Er: YAG	Sham treatment	144 (144 for primary analysis)	NM	Symptomatic	Adult females with symptomatic SUI
Sigurdardottir et al., 2025 [16]	Denmark	Single-site, patient-blinded, placebo-controlled RCT	CO2	Sham treatment	37 (NM)	NM	Clinical (mild-severe symptoms)	Women with mild to severe SUI symptoms
O'Reilly et al., 2024 [17]	Multicenter	Multicenter, blinded, sham-controlled RCT	Er: YAG	Sham treatment	110 (108 analyzed)	NM	Urodynamic	Women with urodynamic SUI
Page et al., 2025 [18]	Belgium	Single-centre RCT	Er: YAG	Pelvic Floor Muscle Training (PFMT)	60 (58 at 4m)	NM	Clinical (mild-moderate)	Women with mild to moderate SUI

NM: Not Mentioned in the provided abstract; LG: Laser Group; PTG: Physiotherapy Group

Table 2: Intervention, Outcomes, and Key Efficacy Results.

Study ID (Author, Year, [Ref])	Laser Protocol (Sessions)	Follow-up Timepoints	Primary Outcome(s)	Key Efficacy Results	Safety/ Adverse Events
Da Fonseca et al., 2023 [13]	3 sessions, 1-month interval	1, 3, 6, 12 months	1-hour pad test, QoL questionnaires (KHQ, IQOL)	Cure rate (pad test) at 12m: LG 56.25% vs PTG 50% ($p>0.05$). Both groups showed significant improvement in QoL.	Both treatments reported safe
Yim et al., 2025 [14]	2 sessions, 4 weeks apart	6, 12 months	Reduction in PFDI UDI stress subscale score	Significant reduction in UDI stress scores in laser group at 6m & 12m ($p<0.001$). No significant difference between laser and sham groups.	NM
Lee et al., 2025 [15]	2 sessions, 6 weeks apart	6 weeks, 6 months	Subjective cure (ICI-Q-SF Q3) at 6 months	No difference in subjective cure rate at 6m (Laser: 1.36% vs Sham: 0%). No significant differences in most subjective/objective measures.	NM
Sigurdardottir et al., 2025 [16]	3 sessions, 4 weeks apart	Post-treatment	ICIQ-UI SF score, Standardized stress test	No difference in ICIQ-UI SF scores (Laser: 12.2 vs Sham: 12.7, $p=0.70$). No difference in stress test performance.	One adverse event (bladder infection)
O'Reilly et al., 2024 [17]	2 sessions, 1 month apart	6, 12 months	1-hour pad weight test at 6 months	Treatment success (pad test): Active 59% vs Sham 36% (OR 3.63, $p=0.02$). Significant improvement in KHQ and sexual function vs sham.	No device-related adverse events reported

Page et al., 2025 [18]	3-6 applications	4, 24 months	Change in UDI-6 score at 4 months	Laser was non-inferior to PFMT at 4 months. Subjective cure low in both groups (Laser 11% vs PFMT 8%). Most patients sought alternative treatment by 24m.	No serious adverse events

NM: Not Mentioned in the provided abstract; m: months; QoL: Quality of Life; KHQ: King's Health Questionnaire; IQOL: Incontinence Quality of Life; PFDI: Pelvic Floor Distress Inventory; UDI: Urinary Distress Inventory; ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form; ICIQ-UI SF: International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form

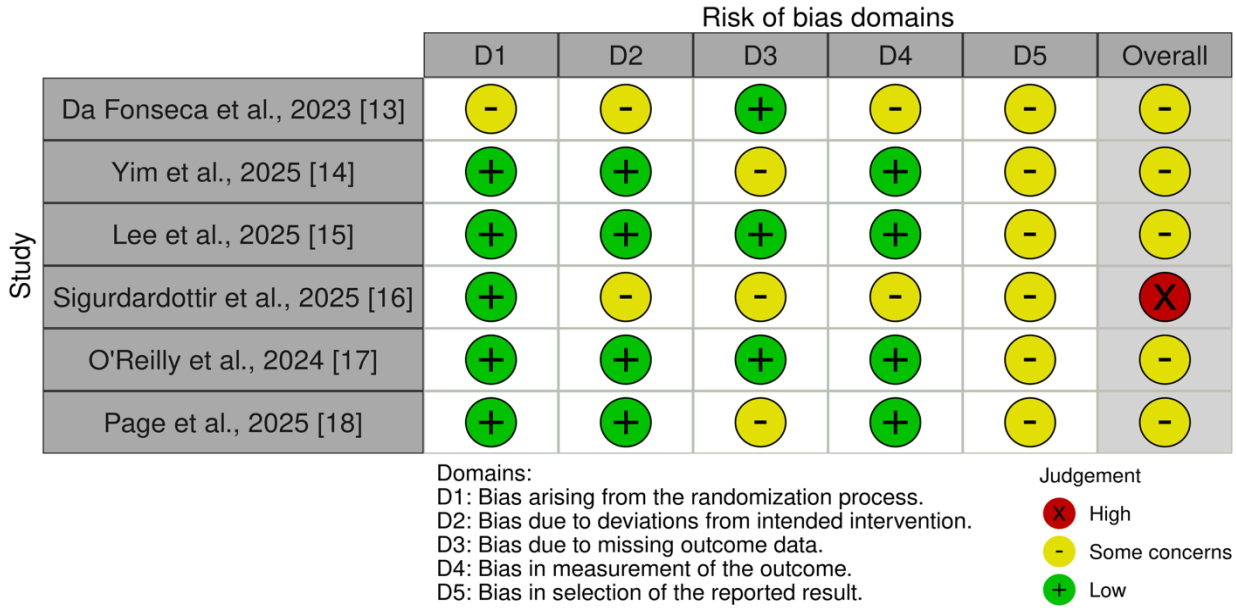

Figure 2: Risk of bias using ROB2 tool.

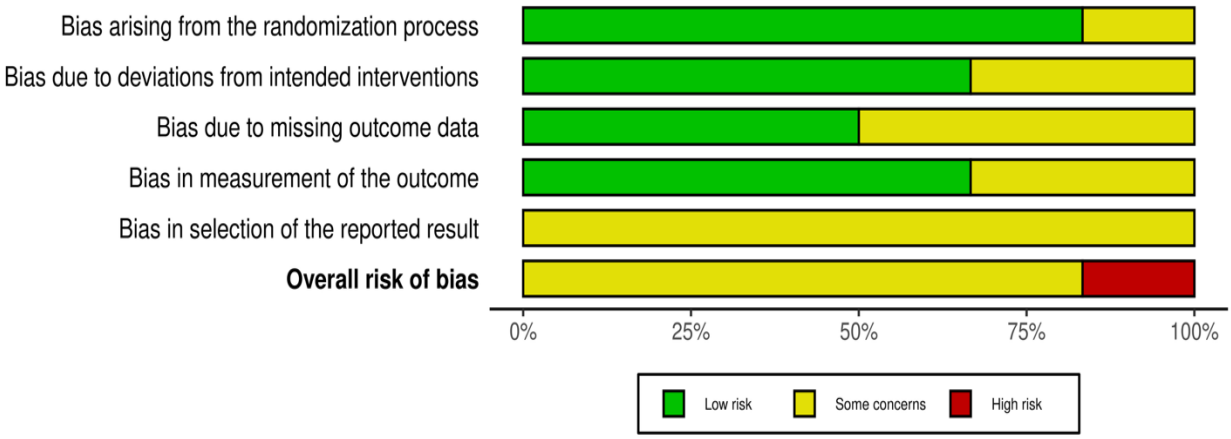

Figure 3: Risk of bias using ROB2 tool.

ICIQ-SF scores in a single-arm study, must be interpreted with extreme caution, as they likely capture a significant placebo component alongside any potential true treatment effect. The results from Okui et al. [23], a large retrospective case-matching analysis suggesting similar improvement between laser and sling surgery, are intriguing but are susceptible to profound selection bias and cannot outweigh the evidence from rigorous RCTs. The inconsistency in findings across RCTs can be attributed to several methodological and clinical variables. First, the technical parameters of laser therapy are not standardized. Critical variables such as the laser type (Er: YAG vs. Fractional CO2), power settings, energy delivery, number of sessions (ranging from 2 to 6 in the included RCTs), and interval between sessions differ widely between studies, making direct comparisons difficult. Second, patient selection plays a crucial role. The included trials focused on pure SUI or urodynamic SUI, whereas studies on mixed populations, such as the one by Badawy et al. [24] on mixed urinary incontinence, may show different results due to the confounding influence of urgency symptoms. Third, the choice of outcome measures is critical. While some studies used objective measures like the 1-hour pad test [13, 17], others relied solely on subjective patient-reported outcomes (PROMs) [15, 18], which are more susceptible to placebo influence. Furthermore, the duration of follow-up is a key differentiator. The limited and short-lasting effect noted by Page et al. [18], where most patients sought alternative treatments by 24 months, raises serious concerns about the long-term durability of the treatment effect, a finding supported by Gaspar et al. [22] who noted a fading effect at 18 months requiring maintenance sessions. Limitations of The Study: This systematic review has several limitations. Firstly, the quantitative synthesis was constrained by the significant heterogeneity observed across the included studies, particularly in the type of laser intervention, protocol (number of sessions, energy settings), choice of comparator (sham vs. active PT), primary outcome measures, and follow-up duration. This heterogeneity precluded a meaningful meta-analysis, limiting the conclusions to a narrative synthesis. Secondly, the risk of bias assessment, while conducted with a standardized tool (ROB2), was based primarily on the information available in the study abstracts for several studies, as full texts were not provided for the initial screening. This may have led to an incomplete assessment, particularly for domains such as allocation concealment and selective reporting, which are often detailed in the methods sections of full publications. Consequently, the overall risk of bias for most studies was judged as "some concerns." Finally, the exclusion of non-English studies and the possibility of publication bias, where negative trials are less likely to be published, may have influenced the overall findings of this review.

Conclusion

In conclusion, evidence for vaginal laser therapy for stress urinary incontinence (SUI) is inconsistent. While some trials show benefit, other rigorous studies find it no better than a sham procedure, highlighting a strong placebo effect. The treatment appears safe, but given its high cost and unproven efficacy, it should remain investigational. It must not replace established treatments and should only be used in large, well-designed clinical trials with long-term follow-up. Patients should be fully informed of the current equivocal evidence.

Conflict of Interest

None

Funding

None

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