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Meta-Analysis

Laser therapy for stress urinary incontinence in women: a systematic review and meta-analysis

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ABSTRACT

Stress urinary incontinence (SUI) is a prevalent condition among women, significantly impacting their quality of life. Laser therapy has emerged as a non-invasive treatment option, but its efficacy remains uncertain due to limited evidence. This systematic review and meta-analysis aimed to evaluate the effectiveness of laser therapy in improving SUI symptoms, measured by changes in international consultation on incontinence questionnaire-urinary incontinence short form (ICIQ-UI SF) scores. A comprehensive search was conducted across PubMed, Web of Science, Scopus, Medline, the Cochrane Library, and Google Scholar, yielding 532 records. Six studies, including three randomized controlled trials and three prospective studies, met the inclusion criteria. Data were synthesized using a random-effects model. The meta-analysis included 507 women with SUI. Pooled analysis revealed a statistically significant reduction in ICIQ-UI SF scores following laser therapy, with a mean difference of -2.15 (95% CI: -4.26 to -0.05, p=0.05). Substantial heterogeneity was observed (I^2=85%, p<0.00001). Studies with longer follow-up periods, such as Okui, 2019 (mean difference: -4.66, 95% CI: -6.89 to -2.43), demonstrated greater improvements. Funnel plot analysis suggested no significant publication bias. Laser therapy significantly improves SUI symptoms, as evidenced by reductions in ICIQ-UI SF scores. However, variability in treatment protocols and study designs underscores the need for standardized approaches and further research to confirm long-term efficacy.

Keywords: Urinary incontinence, Stress incontinence, Laser therapy, Meta-analysis, Systematic review

INTRODUCTION

Stress urinary incontinence (SUI) is a prevalent condition characterized by the involuntary leakage of urine during physical activities that increase abdominal pressure, such as coughing, sneezing, or exercising.[1,2] It is the most common type of urinary incontinence in women, significantly affecting quality of life and psychological well-being. SUI is often caused by the weakening of pelvic floor muscles and connective tissues, as well as the loss of urethral support, due to factors such as childbirth, aging, hormonal changes during menopause, obesity, or chronic respiratory conditions.[1,3,4]

The burden of SUI is considerable, with millions of women worldwide experiencing its effects. Its impact is not limited to physical symptoms; SUI is associated with emotional distress, reduced self-esteem, social isolation, and impaired sexual function. Despite its prevalence and impact, many women delay seeking treatment due to stigma or misconceptions about available therapeutic options.[4-6]

Conventional management of SUI includes conservative approaches, such as pelvic floor muscle training and lifestyle modifications, as well as invasive interventions like surgical procedures. pelvic floor muscle training, often referred to as Kegel exercises, has been shown to improve pelvic floor muscle strength and reduce symptoms of SUI. Surgical interventions, including mid-urethral slings and bulking agents, are typically reserved for moderate to severe cases and have demonstrated high

success rates. However, surgery is not without risks, and postoperative complications or prolonged recovery periods may deter some patients from pursuing this option.[6-8]

In recent years, laser therapy has emerged as a minimally invasive alternative for the treatment of SUI. Vaginal laser therapy, specifically fractional CO_2 and erbium lasers, has gained attention for its potential to improve the structural integrity of vaginal and pelvic tissues. These lasers work by inducing collagen remodelling and neovascularization in the targeted tissues, thereby enhancing urethral support and reducing SUI symptoms.[9,10]

Laser therapy offers several advantages, including its non-invasive nature, minimal discomfort, and short recovery time. Sessions are typically performed in an outpatient setting, making the procedure convenient for patients. Furthermore, laser therapy may appeal to women who are not candidates for surgery or those seeking an alternative to pharmacological or surgical treatments. Despite these benefits, the mechanism of action, long-term efficacy, and safety of laser therapy remain topics of active research and debate.[4,8,9]

Existing studies on laser therapy for SUI have reported promising outcomes, with improvements in symptom severity, quality of life, and patient satisfaction. However, these studies vary widely in terms of methodology, sample size, laser protocols, and follow-up durations. Some trials have demonstrated substantial symptom relief, while others report modest or negligible improvements. This variability underscores the need for a comprehensive evaluation of the current evidence to establish the role of laser therapy in the management of SUI.[10-12]

Moreover, there are concerns regarding the standardization of laser parameters, such as wavelength, energy settings, and treatment intervals, which may influence treatment outcomes. The lack of consensus on optimal treatment protocols presents a barrier to widespread adoption and integration into clinical practice. Additionally, while laser therapy is generally considered safe, reports of adverse events, including vaginal burns and scarring, necessitate careful consideration of its risk profile.[11,13]

The growing interest in non-invasive therapies like laser therapy highlights the importance of understanding their clinical utility. A systematic review and meta-analysis of the existing literature can provide valuable insights into the efficacy and safety of laser therapy for SUI, guiding clinicians and informing patient care. The aim of this systematic review and meta-analysis is to evaluate the effectiveness of laser therapy in improving symptoms of SUI in women, as measured by changes in validated incontinence questionnaires and other clinical outcomes.

METHODS

This study was conducted as a systematic review and meta-analysis, adhering to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.[14] The aim was to synthesize evidence on the effectiveness of laser therapy for SUI in women by pooling data from relevant studies. A predefined protocol guided the systematic search, selection criteria, data extraction, and analysis to ensure methodological rigor. The time frame of this study is from September 2024 to January 2025.

Search strategy

A comprehensive literature search was conducted in multiple electronic databases, including PubMed, Web of Science, Scopus, Medline, the Cochrane Library, and Google Scholar, to identify studies evaluating laser therapy for SUI in women. The search was performed using a combination of keywords and medical subject headings (MeSH) terms such as "stress urinary incontinence," "SUI," "laser therapy," "vaginal laser," "ICIQ-UI SF," and "efficacy." Boolean operators ("AND" and "OR") were employed to refine the search strategy. The initial search yielded 532 records. No restrictions were applied regarding language or publication date to maximize inclusivity.

Eligibility criteria

Studies were included if they met the following criteria: (1) women with a clinical diagnosis of SUI, (2) intervention with laser therapy, (3) comparison with baseline values or alternative interventions, (4) reporting of the ICIQ-UI SF scores or other standardized SUI outcome measures, and (5) randomized controlled trials (RCTs) or prospective studies. Exclusion criteria were studies involving mixed incontinence without separate data for SUI, case reports, reviews, and conference abstracts without full-text availability.

Study selection

After removing duplicates, the titles and abstracts of 291 records were screened independently by two reviewers to identify potentially relevant studies. Discrepancies were resolved through discussion or consultation with a third reviewer. Forty studies were retrieved for full-text evaluation, of which 34 were excluded for not meeting eligibility criteria. Common reasons for exclusion included insufficient data, non-SUI populations, and non-standardized outcome measures. Six studies, comprising three RCTs and three prospective studies, were included in the final analysis.

Data extraction

Data extraction was performed independently by two reviewers using a standardized form. Extracted

information included study characteristics (author, year, country, design), participant demographics (sample size, age, inclusion criteria), intervention details (laser type, dosage, follow-up duration), and outcome measures (ICIQ-UI SF scores). Discrepancies were resolved through consensus.

Statistical analysis

All statistical analyses were performed using review manager (RevMan) version 5.4. Microsoft Excel was utilized for data organization and preliminary calculations, while EndNote X9 facilitated reference management. Visualizations, including forest and funnel plots, were generated in RevMan to illustrate pooled estimates and publication bias. A random-effects model was employed to account for potential heterogeneity among the included studies. Pooled mean differences (MD) with 95% confidence intervals (CI) were calculated for continuous outcomes. Heterogeneity was assessed using the chi-squared test and quantified with the I^2 statistic, where $I^2>50\%$ indicated substantial heterogeneity. Sensitivity analyses were conducted by excluding studies with outlier effect sizes or high risk of bias. Funnel plots were generated to assess publication bias, supplemented by Egger's test.

Ethical considerations

Since this meta-analysis involved secondary data analysis from previously published studies, ethical approval was not required. The study adhered to principles of transparency and reproducibility, ensuring proper citation of all included studies.

RESULTS

The systematic search yielded 532 records from six databases: PubMed, Web of Science, Scopus, Medline, the Cochrane Library, and Google Scholar. After removing 241 duplicates, 291 records underwent title and abstract screening. During this screening phase, 249 records were excluded for reasons such as irrelevance to the study topic, lack of focus on SUI/failure to meet the inclusion criteria. A total of 42 articles were retrieved for full-text review, but 2 were not accessible, leaving 40 studies for eligibility assessment. Of these, 34 studies were excluded due to reasons such as lack of quantitative outcomes, incomplete data, or inappropriate intervention comparisons. Ultimately, 6 studies met all inclusion criteria and incorporated into meta-analysis. These six studies provided quantitative data suitable for synthesis, as depicted in PRISMA flow diagram (Figure 1).

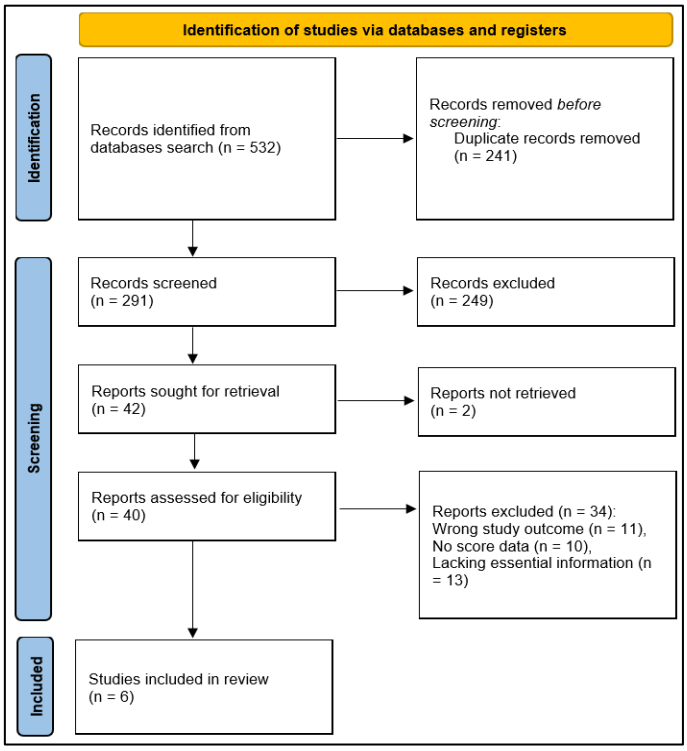

Figure 1: PRISMA flow diagram for the summary of the study search and screening processes.

Characteristics of the included studies

Table 1 summarizes the characteristics of the included studies. The six studies included in the meta-analysis were conducted across diverse geographical locations, encompassing Brazil, Australia, Israel, Taiwan, and Japan. Four of these studies were RCTs while two were prospective observational studies.[15-20] The randomized designs strengthen the quality of evidence, whereas the inclusion of prospective studies broadens the scope of data by incorporating real-world outcomes.

Table 1: Characters of the include studies, (n=6).

Study	Country	Design	Participants number included in analysis	Age (in years)	Follow up
Aguiar et al[15]	Brazil	RCT	72	57.28±5.15	14 weeks
Alexander et al[16]	Australia	RCT	97	Mean: 53	3 months
Lauterbach et al[17]	Israel	RCT	131	45-70	6 months
Lin et al[18]	Taiwan	Prospective study	62	48.43±12.75	2 months
Okui[19]	Japan	Prospective study	100	48.7±13.9	12 months
Seki et al,[20]	Brazil	RCT	77	50.2±8.7	6 months

The sample sizes varied from 62 participants in Lin et al to 131 participants in Lauterbach et al, with a total of 539 women included across all studies.[17,18] The age of participants ranged widely, with studies such as Lauterbach et al including women aged 45-70 years, while Lin et al reported a mean age of 48.43 years (±12.75).[17,18] Aguiar et al and Seki et al also reported mean ages exceeding 50 years, reflecting a predominantly middle-aged population.[15,20] This diversity in age distribution ensures the applicability of the findings to women of different age groups suffering from SUI.

Follow-up durations differed substantially across studies, ranging from 2 months in Lin et al to 12 months in Okui.[18,19] Most studies used a follow-up period of 3 to 6 months, which provides insights into the medium-term effectiveness of laser therapy.[16,17,20] The variability in follow-up periods allowed assessment of both immediate and sustained treatment effects, though longer follow-up durations would be more informative for evaluating the long-term efficacy of this intervention.

Quantitative data synthesis

The primary outcome of the meta-analysis was the change in ICIQ-UI SF scores, which were reported in all six studies (Figure 2). The pooled analysis demonstrated that laser therapy significantly improved ICIQ-UI scores compared to baseline, with a mean difference of -2.15 (95% CI: -4.26 to -0.05, p=0.05). However, there was substantial heterogeneity across the studies (I^2=85%, p<0.00001), indicating variability in the effect sizes.

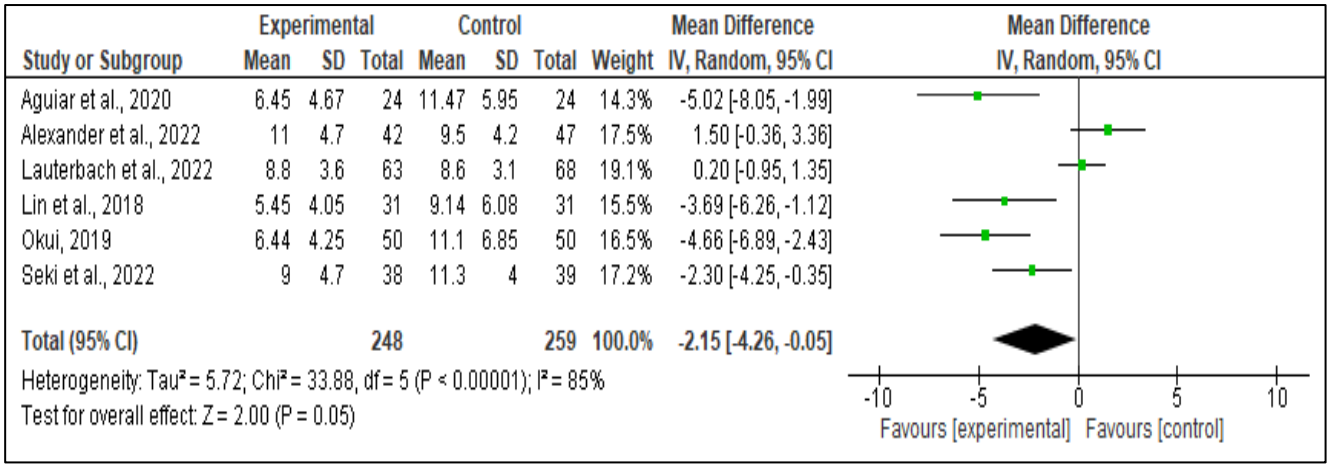

Figure 2: Forest plot of the ICIQ-UI scores changes among the studied populations.

Aguiar et al, Lin et al and Okui et al reported the most substantial improvements in ICIQ-UI scores, with mean differences of -5.02 (95% CI: -8.05 to -1.99), -3.69 (95% CI: -6.26 to -1.12), and -4.66 (95% CI: -6.89 to -2.43), respectively.[15,18,19] These results indicate that laser therapy was highly effective in these populations, particularly for individuals with moderate to severe SUI symptoms. Conversely, Lauterbach et al and Alexander et al reported minimal changes in scores, with mean differences of 0.20 (95% CI: -0.95 to 1.35) and 1.50 (95% CI: -0.36 to 3.36), respectively, highlighting potential variability in the response to therapy.[16,17] Seki et al observed moderate improvements with a mean difference of -2.30 (95% CI: -4.25 to -0.35).[20] These differences could be attributed to variations in study populations, laser parameters, and follow-up durations.

Assessment of publication bias

The potential for publication bias was assessed using a funnel plot (Figure 3), which showed a symmetrical distribution of effect sizes. This finding suggests that the meta-analysis is unlikely to be significantly influenced by

publication bias. The balanced representation of studies included in the analysis strengthens the reliability and generalizability of the pooled results.

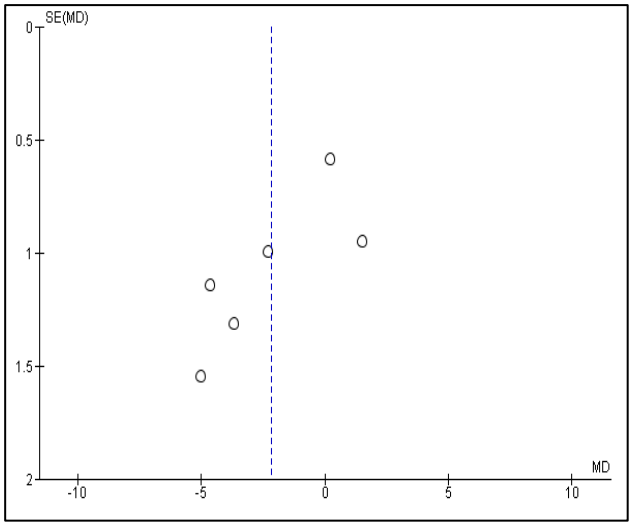

Figure 3: Funnel plot for the assessment of the publication bias.

DISCUSSION

SUI is a prevalent condition among women, characterized by the involuntary leakage of urine during physical activities such as coughing, sneezing, or exercising.[2] It significantly impacts the quality of life, with treatments ranging from conservative approaches, such as pelvic floor muscle training, to surgical interventions. Recently, non-invasive modalities like laser therapy have gained attention for their potential to offer effective symptom relief without the risks associated with surgery.[4,5] While individual studies have reported promising outcomes, the lack of consensus on the effectiveness of laser therapy warrants a systematic review and meta-analysis to synthesize the available evidence and provide robust conclusions.

This meta-analysis included six studies that collectively investigated the efficacy of laser therapy in women with SUI. The pooled analysis demonstrated a statistically significant improvement in ICIQ-UI SF scores following laser therapy, with a mean difference of -2.15 (95% CI: -4.26 to -0.05, p=0.05). However, substantial heterogeneity was observed (I^2=85%, p<0.00001), indicating variability in effect sizes across studies. Improvements were particularly notable in Aguiar et al, Lin et al and Okui where mean differences were -5.02 (95% CI: -8.05 to -1.99), -3.69 (95% CI: -6.26 to -1.12), and -4.66 (95% CI: -6.89 to -2.43), respectively.[15,18,19,] Conversely, Alexander et al and Lauterbach et al reported smaller or negligible effects, with mean differences of 1.50 (95% CI: -0.36 to 3.36) and 0.20 (95% CI: -0.95 to 1.35), respectively.[16,17] Despite the variability, the overall results suggest laser therapy offers a modest benefit for SUI.

The significant improvement in ICIQ-UI SF scores across the studies supports the efficacy of laser therapy as a treatment option for SUI. The observed reductions in symptom severity are consistent with findings from Aguiar et al, Lin et al and Okui where laser therapy demonstrated notable benefits.[15,18,19] These results align with the hypothesized mechanism of laser therapy, which involves collagen remodelling and tissue tightening, thereby enhancing the function of the urethral sphincter and pelvic floor structures.

However, the heterogeneity observed in this analysis warrants further discussion. Variation in effect sizes could be attributed to differences in study designs, populations, and intervention protocols. For example, the studies by Alexander et al and Lauterbach et al which reported minimal improvements, included populations with less severe symptoms at baseline/shorter follow-up durations, potentially limiting the observable benefits of laser therapy.[16,17] In contrast, studies with longer follow-up periods, such as Okui demonstrated more pronounced effects, suggesting that sustained benefits may require extended treatment and evaluation periods.[19-23]

One of the strengths of this meta-analysis is its inclusion of diverse study designs and populations, enhancing the generalizability of findings. By incorporating both randomized controlled trials and prospective studies, the analysis captures a broad spectrum of real-world and experimental evidence. Furthermore, the use of a standardized outcome measure (ICIQ-UI SF) across studies ensures consistency in assessing treatment efficacy.

However, several limitations must be acknowledged. The high heterogeneity observed (I^2=85%) highlights the variability in study populations, treatment protocols, and follow-up durations. While subgroup analyses could help elucidate these differences, the limited number of studies included in this meta-analysis precludes such analyses. Additionally, the presence of publication bias cannot be entirely ruled out, despite the symmetrical funnel plot, as smaller studies with negative results may remain unpublished.

The findings of this meta-analysis have significant implications for clinical practice. Laser therapy represents a promising non-invasive treatment option for women with SUI, particularly for those who are not candidates for surgery or prefer less invasive approaches. The modest improvements observed suggest that laser therapy can provide symptom relief, especially for women with moderate to severe symptoms. However, clinicians should consider individual patient characteristics, such as baseline symptom severity and comorbidities, when recommending this treatment. Moreover, given the variability in outcomes, standardization of laser therapy protocols is crucial to optimize efficacy and ensure reproducibility across settings.

Future research should focus on addressing the limitations identified in this meta-analysis. Large-scale, well-designed randomized controlled trials with standardized treatment protocols and longer follow-up periods are needed to confirm the long-term efficacy and safety of laser therapy for SUI. Subgroup analyses based on baseline symptom severity, patient demographics, and treatment parameters would provide valuable insights into which populations derive the most benefit from laser therapy. Additionally, comparative studies evaluating laser therapy alongside other non-invasive treatments, such as pelvic floor muscle training and pharmacological interventions, would help delineate its relative efficacy and cost-effectiveness.

CONCLUSION

In conclusion, this meta-analysis supports the efficacy of laser therapy in improving SUI symptoms, as evidenced by significant reductions in ICIQ-UI SF scores. While the findings underscore the potential of laser therapy as a non-invasive treatment option, the observed heterogeneity highlights the need for standardized protocols and further research to refine its clinical application. Laser therapy offers a promising alternative for managing SUI, but it is most effective when tailored to individual patient needs and used in conjunction with other evidence-based interventions.

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