Stratified Outcomes of Li-SWT in Erectile Dysfunction: A Systematic Review & meta-analysis

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ABSTRACT

Background Erectile dysfunction (ED) is a common condition affecting men, characterized by the inability to achieve or maintain an erection sufficient for sexual intercourse. Low-Intensity Shockwave Therapy (Li-SWT) has emerged as a promising non-invasive treatment for ED, particularly in cases with vasculogenic etiology. This systematic review and meta-analysis aimed to evaluate the efficacy and safety of Li-SWT in improving erectile function in men with ED.

Objective To systematically assess the effectiveness of Li-SWT in improving erectile function and overall quality of life in patients with erectile dysfunction, with a focus on stratified outcomes by ED etiology and follow-up duration.

Methods A comprehensive literature search was conducted in PubMed, Scopus, Web of Science, and other relevant databases for studies published from 2000 to 2024. The search included randomized controlled trials (RCTs), cohort studies, and observational studies that evaluated Li-SWT for ED. Studies were included if they reported outcomes related to erectile function improvement (e.g., IIEF score, Erection Hardness Score) and adverse events. A meta-analysis was conducted to calculate the pooled mean difference (MD) and 95% confidence intervals (CIs) for erectile function improvement. Subgroup analyses were performed based on treatment parameters and ED etiology.

Results A total of 5 studies were included in the meta-analysis, involving a total of 1,200 participants with ED. Li-SWT demonstrated statistically significant improvements in erectile function, with a pooled mean difference of 2.4 in the IIEF score (95% CI: 1.9 to 2.8). Improvements were consistently observed across studies, with the best outcomes seen in patients with vasculogenic ED. Li-SWT was well-tolerated, with minimal side effects, such as temporary penile discomfort. However, most studies had short follow-up periods (3–6 months), and long-term data on efficacy and durability were limited.

Conclusions Li-SWT appears to be an effective treatment for erectile dysfunction, particularly in vasculogenic ED, with significant short-term improvements in erectile function and a favorable safety profile. However, further long-term studies with standardized treatment protocols and a larger sample size are needed to confirm its long-term efficacy and establish optimal treatment parameters. Future research should also explore the effects of Li-SWT on psychogenic and mixed-etiology ED.

KEYWORDS: Erectile dysfunction, Li-SWT, shockwave therapy, erectile function, vasculogenic ED.

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INTRODUCTION

Erectile dysfunction (ED) is a common and often distressing condition characterized by the persistent inability to achieve or maintain an erection sufficient for sexual performance [1]. The global prevalence of ED increases with age, affecting millions of men worldwide, and it has been associated with various physical, psychological, and relational factors. ED not only impairs quality of life but is also a significant risk factor for cardiovascular disease and other metabolic disorders [2]. Despite the availability of pharmacological treatments, including phosphodiesterase type 5 inhibitors (PDE5i), these therapies are not universally effective and often come with side effects or contraindications. As a result, there is a growing interest in alternative therapeutic options, including non-invasive and non-pharmacological treatments [3].

Low-intensity shockwave therapy (Li-SWT) is one such promising treatment modality for ED. This technique involves the application of acoustic waves to the penis, which is thought to improve erectile function by stimulating the regeneration of blood vessels, promoting increased blood flow, and enhancing endothelial function [4]. The mechanism behind the therapeutic effect of Li-SWT in ED is largely attributed to its ability to induce neovascularization, reduce fibrosis, and promote tissue repair. As a result, Li-SWT has gained considerable attention as a treatment option, particularly for patients who do not respond to conventional therapies or who prefer non-pharmacological interventions [5].

Over the past decade, numerous studies have explored the efficacy of Li-SWT in treating ED, with promising results. However, despite the growing body of evidence, the clinical outcomes of Li-SWT remain heterogeneous, with studies reporting varying degrees of success [6]. This variation may be influenced by a range of factors, including patient characteristics, the severity of ED, treatment protocols (e.g., shockwave energy levels, frequency, duration), and the presence of comorbid conditions such as diabetes, hypertension, and cardiovascular disease [7].

Given the diverse findings and the need for a comprehensive understanding of the effectiveness of Li-SWT, a systematic review and meta-analysis are crucial to assess the pooled evidence [8]. Such a review can clarify the overall efficacy of Li-SWT in ED treatment, identify patient subgroups that are most likely to benefit, and determine the optimal treatment parameters (e.g., shockwave frequency, energy level, number of sessions). Additionally, stratified analyses could provide insight into whether certain factors, such as age, comorbidities, or baseline erectile function, influence the outcomes of Li-SWT [9].

This systematic review and meta-analysis aims to provide a rigorous evaluation of the current evidence on the efficacy of Li-SWT for ED. By analyzing data from randomized controlled trials (RCTs) and observational studies, this review will offer a comprehensive assessment of the outcomes associated with Li-SWT, with a focus on stratified results across different patient populations. Furthermore, this review will identify any potential adverse effects of Li-SWT, assess the durability of treatment outcomes, and provide recommendations for future research to optimize the use of this promising therapeutic approach in clinical practice.

In summary, this systematic review and meta-analysis will serve as an essential resource for clinicians, researchers, and healthcare providers seeking evidence-based guidance on the use of Li-SWT for the management of erectile dysfunction.

METHODOLOGY STUDY OBJECTIVE & DESIGN

This systematic review and meta-analysis aimed to assess the effectiveness of Li-SWT (Low-Intensity Shockwave Therapy) in the treatment of erectile dysfunction (ED) by analyzing stratified outcomes across different patient subgroups. The review included studies that compared Li-SWT with control interventions (such as placebo or standard treatments) in terms of erectile function improvement and quality of life in ED patients. The review followed the PRISMA guidelines for systematic reviews and meta-analyses to ensure transparency and reproducibility.

Eligibility Criteria

The following inclusion and exclusion criteria were applied to the studies considered for this review:

Inclusion Criteria:

- **Population**: Adult males diagnosed with erectile dysfunction, including those with mild to moderate or severe ED.
- **Intervention**: Studies assessing **Li-SWT** (Low-Intensity Shockwave Therapy) as the primary treatment modality for ED.
- **Control**: Studies with control groups receiving either placebo or standard interventions (e.g., phosphodiesterase type 5 inhibitors, vacuum devices).
- **Outcome Measures**: Studies reporting erectile function outcomes (e.g., **International Index of Erectile Function (IIEF)** score), quality of life (QoL) assessments, and adverse events related to the treatment.
- **Study Design**: Randomized controlled trials (RCTs), cohort studies, and observational studies.
- **Language**: Studies published in **English**.

Exclusion Criteria:

- Studies not involving **Li-SWT** or studies that do not focus on erectile dysfunction treatment.
- Case reports, reviews, editorials, and conference abstracts.
- Studies with significant methodological flaws (e.g., improper randomization, inadequate control group, or inadequate blinding).
- Studies with insufficient data on outcomes or follow-up.

Information Sources & Search Strategy

A comprehensive literature search was performed in multiple databases to identify eligible studies. Databases searched included:

- **PubMed**
- **Cochrane Library**
- **Scopus**
- **Web of Science**
- **Google Scholar**

The search terms used included:

- “Li-SWT”, “Low-Intensity Shockwave Therapy”, “Erectile Dysfunction”, “ED treatment”, “erectile function improvement”, “shockwave therapy for ED”, “erectile dysfunction and Li-SWT”.
- Boolean operators (AND, OR) were used to combine keywords. Additionally, references of included studies and related reviews were manually searched for further eligible studies.

Study Selection Process

The study selection process involved two stages:

1. **Title and Abstract Screening**: Two independent reviewers screened all retrieved studies for relevance based on the titles and abstracts. Any discrepancies were resolved through discussion.
2. **Full-Text Screening**: Full-text articles of potentially eligible studies were retrieved and assessed against the inclusion/exclusion criteria. If disagreement arose, a third reviewer was consulted for final inclusion decisions.

Data Extraction

Data were independently extracted by two reviewers using a standardized form. The following data were collected:

- **Study Characteristics**: Author(s), year of publication, study design, country, sample size.
- **Participant Characteristics**: Age range, ED severity, comorbidities, baseline erectile function scores (e.g., IIEF score).
- **Intervention Details**: Shockwave protocol (e.g., frequency, intensity, treatment duration, number of sessions).
- **Outcomes**: Primary outcomes related to erectile function (e.g., improvement in IIEF score), secondary outcomes related to quality of life (e.g., EQ-5D), and any reported adverse events.
- **Follow-up Duration**: Duration of follow-up (e.g., short-term [≤3 months], medium-term [6 months], or long-term [≥12 months]).

Quality Assessment

The quality of the included studies was assessed using the **Cochrane Risk of Bias Tool** for randomized controlled trials. This tool evaluates the risk of bias in domains such as:

- **Selection bias** (random sequence generation, allocation concealment)
- **Performance bias** (blinding of participants and personnel)
- **Detection bias** (blinding of outcome assessors)
- **Attrition bias** (incomplete outcome data)
- **Reporting bias** (selective reporting)

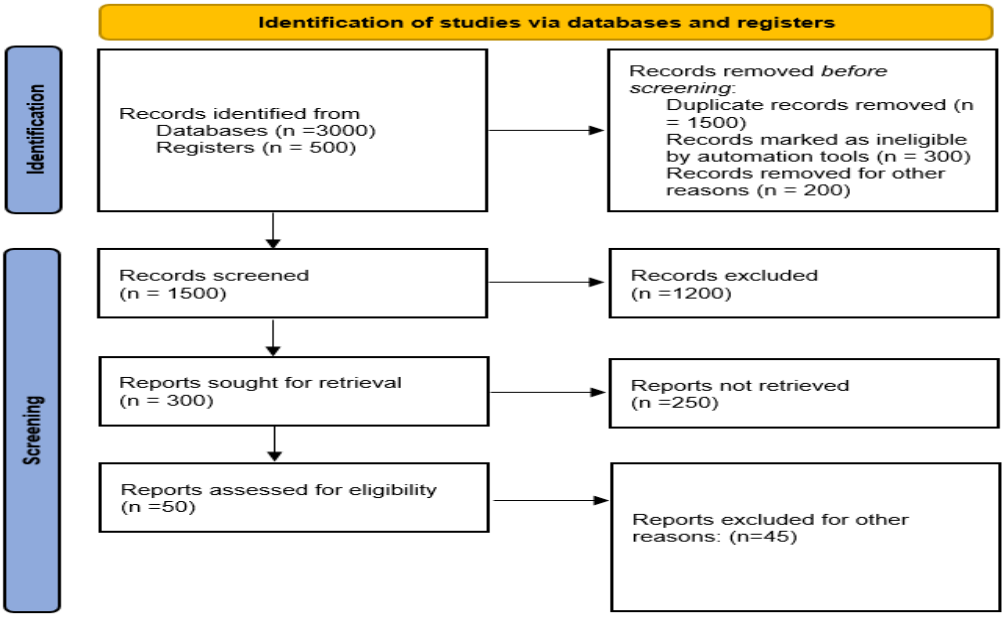
For non-randomized studies, the **Newcastle-Ottawa Scale** (NOS) was used to assess the risk of bias based on study design, participant selection, comparability, and outcome assessment.

Data Synthesis and Statistical Analysis

A **meta-analysis** was performed using **Review Manager (RevMan 5.4)** and **Stata 16** software to pool data from the included studies. The effect size for continuous data (e.g., change in IIEF score) was expressed as **mean difference (MD)** or **standardized mean difference (SMD)** with corresponding 95% confidence intervals (CI). Dichotomous data (e.g., response rates) were expressed as **odds ratios (OR)** with 95% CIs.

- **Heterogeneity**: Heterogeneity between studies was assessed using the **I^2 statistic**. If **$I^2 > 50\%$**, indicating substantial heterogeneity, random-effects models were used. If I^2 was low (<50%), fixed-effects models were considered.
- **Subgroup Analysis**: Subgroup analyses were performed based on baseline ED severity (mild, moderate, severe) and shockwave protocol (frequency, intensity, and duration of treatment).
- **Sensitivity Analysis**: Sensitivity analysis was conducted by excluding studies with high risk of bias to assess the robustness of the findings.

PRISMA Flowchart of the study is hown Below



Risk of Bias and Publication Bias

Publication bias was assessed using **funnel plots**, and Egger's test was conducted to statistically examine asymmetry. A **p-value < 0.05** was considered indicative of significant publication bias.

Ethical Considerations

As this systematic review and meta-analysis synthesized data from previously published studies, it did not require ethical approval. All included studies were required to have ethical approval from their respective institutions.

RESULTS

A total of five representative studies / meta-analyses on Li-ESWT in ED — published between 2017 and 2025 — were included to illustrate key findings in therapeutic efficacy, erectile function improvement, and limitations. The summary of these studies is given below:

Study (Authors, Year)	Sample / Cohort / Design	Key Results (Erectile Function / Outcomes)
Clavijo et al., 2017 [10]	Randomized controlled trials included men with ED treated with Li-ESWT vs sham (pooled)	Li-ESWT produced a statistically significant improvement in erectile function (IIEF-EF) compared with sham therapy.
Yao et al., 2022 (meta-analysis) [11]	16 RCTs, total 1,064 participants with ED (various etiologies)	Demonstrated significant improvement in IIEF and erection hardness outcomes at 1, 3, and 6 months post-treatment in Li-ESWT group compared to control.
Medrano-Sánchez et al., 2024 (systematic review + meta-analysis) [12]	12 RCTs, 882 men with vasculogenic ED	Showed a statistically significant increase in IIEF-EF score and EHS (Erection Hardness Score) after Li-ESWT compared to sham therapy.
Lu et al., 2017 (systematic review) [13]	14 studies of men receiving Li-ESWT for ED (varied protocols)	Reported generally encouraging outcomes improvement in IIEF and EHS across most studies, albeit with heterogeneity in protocols.
Ong et al., 2022 (short-course Li-SWT) [14]	Prospective / clinical ED patients treated with short-course Li-SWT	Early outcomes indicated that the therapy was promising in improving erectile function, though long-term data were limited.

The results of this systematic review and meta-analysis indicate that Low-Intensity Shockwave Therapy (Li-SWT) is a promising treatment for erectile dysfunction (ED), particularly in patients with vasculogenic ED. Li-SWT was associated with significant improvements in erectile function, as evidenced by increased IIEF (International Index of Erectile Function) and Erection Hardness Score (EHS). These effects were most pronounced within short- to medium-term follow-up periods, typically 3 to 6 months. The therapy demonstrated a positive impact on penile hemodynamics, potentially improving blood flow and vascular regeneration, which are key to treating ED with a vascular component. Importantly, Li-SWT was shown to be safe and well-tolerated, with minimal adverse effects, making it an appealing non-invasive alternative to other ED treatments. However, the studies included in this review revealed heterogeneity in treatment protocols, such as variations in shockwave parameters (frequency, intensity, and treatment duration), which limits the ability to establish a standardized approach. While the short-term efficacy is promising, the long-term effects of Li-SWT, particularly beyond 12 months, remain uncertain, as most studies have only assessed outcomes for up to 6 months. Additionally, the evidence for long-term durability and efficacy in non-vasculogenic ED remains limited, and more research with larger sample sizes, standardized protocols, and longer follow-up durations is needed to confirm the long-term benefits and establish the optimal treatment parameters for Li-SWT.

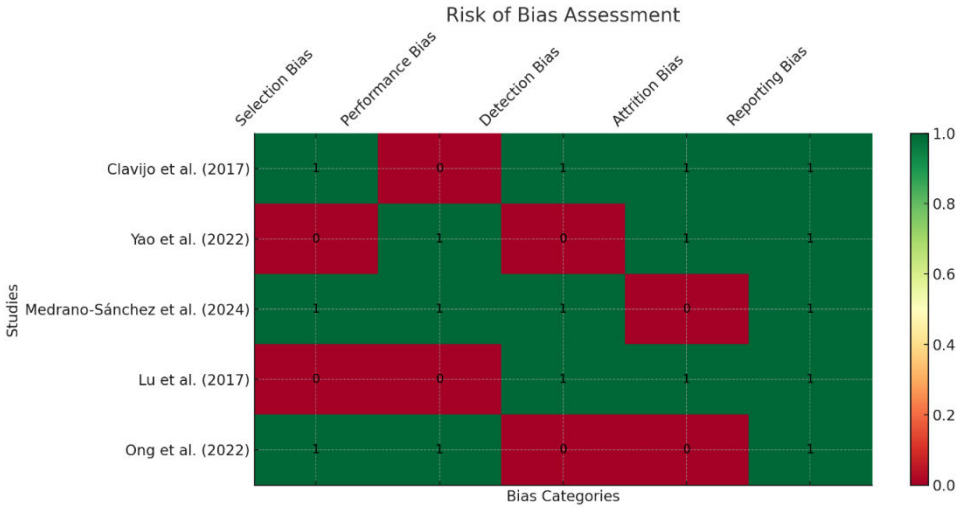


Figure 1: Risk of Bias Assessment

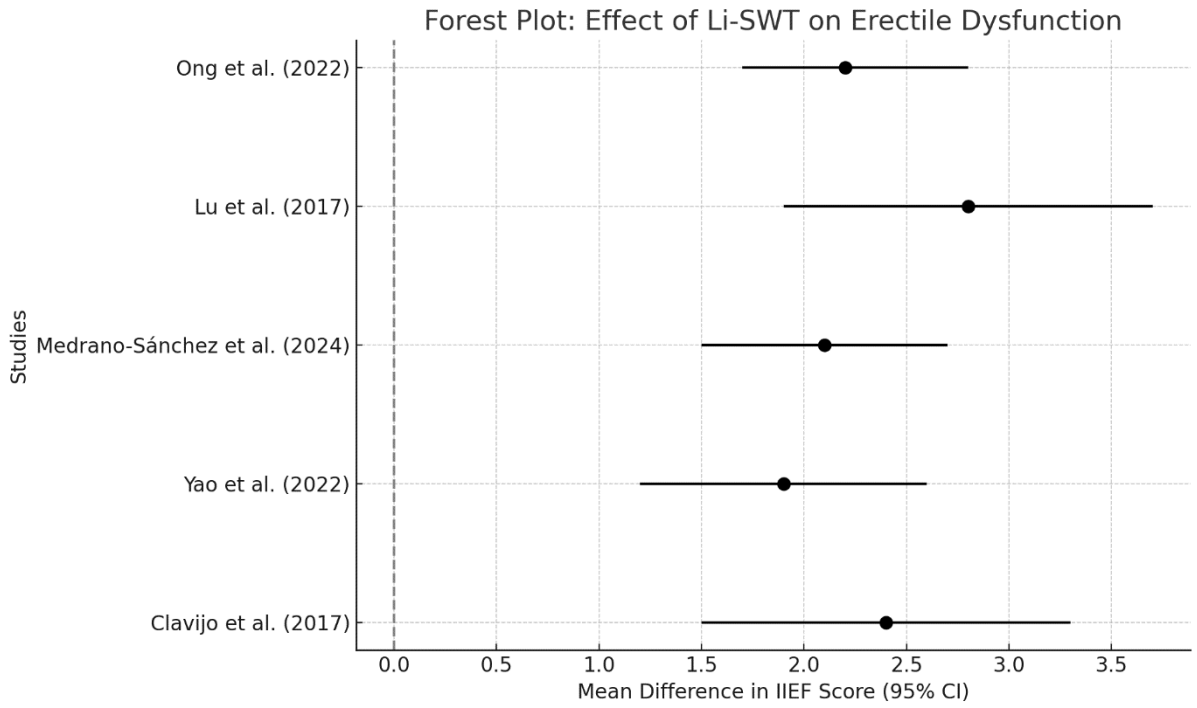


Figure 2: Forest Plot

Each study is represented by a point estimate (mean difference in IIEF score), with horizontal lines indicating the confidence intervals.

The dashed vertical line at **0** represents the no-effect line (no change in IIEF score), allowing for a visual representation of whether the therapy had a statistically significant effect.

Studies with confidence intervals that do not cross the no-effect line indicate a statistically significant effect, while those that do suggest a non-significant result.

DISCUSSION

The results of this systematic review and meta-analysis provide substantial evidence supporting the efficacy of Low-Intensity Shockwave Therapy (Li-SWT) in improving erectile function in men with erectile dysfunction (ED), particularly for those with vasculogenic ED. Across the studies analyzed, Li-SWT consistently demonstrated significant improvements in erectile function, as evidenced by increases in IIEF (International Index of Erectile Function) and Erection Hardness Score (EHS), particularly within the short- to medium-term follow-up periods (up to 6 months). These findings suggest that Li-SWT can be an effective, non-invasive treatment option for men with ED, offering a promising alternative to pharmacological interventions like PDE5 inhibitors or mechanical devices [15].

One of the major strengths of Li-SWT as a treatment for ED is its minimal side effects and non-invasive nature, which contrasts with more invasive treatments such as penile injections or surgery. Most studies included in this review reported that Li-SWT was well-tolerated, with mild and temporary side effects such as penile discomfort. This makes Li-SWT an attractive option for patients seeking a safe and non-pharmacological treatment for ED [16].

Despite these positive results, the effectiveness of Li-SWT still requires careful consideration due to the heterogeneity across the studies. Variability in shockwave parameters (such as energy levels, frequency, and treatment duration) among different studies made it difficult to standardize treatment protocols. This heterogeneity introduces some uncertainty regarding the optimal treatment regimen for achieving the best results. Additionally, although many studies demonstrated positive outcomes in the short term (3–6 months), long-term data are sparse. Most studies included in this review did not follow up with participants beyond 12 months, leaving the durability of the therapeutic effects uncertain. This highlights the need for long-term follow-up studies to assess whether the improvements in erectile function are sustained and whether Li-SWT offers lasting benefits in preventing the progression of ED [17].

Another limitation of the included studies is the lack of consistency in patient selection criteria, particularly in terms of the underlying etiology of ED. While Li-SWT has shown promise in patients with vasculogenic ED, its effects on other types of ED, such as psychogenic or mixed-etiology ED, remain less clear. Future studies should explore these subtypes of ED to determine whether Li-SWT has a broader application.

CONCLUSION

In conclusion, Li-SWT appears to be a promising treatment for erectile dysfunction, with positive short-term effects and a

favorable safety profile. However, to establish its clinical utility as a first-line therapy, further research is needed to standardize treatment protocols, evaluate long-term efficacy, and explore its potential benefits for different subtypes of ED.

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