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Low-Intensity Extracorporeal Shockwave Therapy for Erectile Dysfunction: A Systematic Review of Efficacy, Patient Selection, and Optimal Treatment Parameters

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Abstract: **Background:** Erectile dysfunction (ED) is a prevalent condition affecting men across all age groups, with a significant impact on quality of life, self-esteem, and interpersonal relationships. Low-intensity extracorporeal shockwave therapy (Li-ESWT) has emerged as a promising non-invasive treatment modality demonstrating improvements in erectile function with a favourable safety profile. However, the evidence base remains heterogeneous, and consensus regarding patient selection, optimal treatment protocols, and long-term sustainability of effects is lacking. **Objective:** To provide a critical, clinician-oriented synthesis of the current evidence on the effectiveness, safety, optimal patient profile, and treatment parameters of Li-ESWT in the management of ED. **Methods:** A systematic literature search of PubMed, MEDLINE, Cochrane Library, EMBASE, and grey literature databases was conducted for articles published from 2016 to 2023. Following PRISMA 2020-guided screening of 1,302 titles, 164 abstracts, and 94 full-text articles, 20 studies were included. Quality assessment was performed using the Newcastle-Ottawa Scale, STROBE Checklist, and Cochrane Risk of Bias Tool (RoB 2). A narrative synthesis approach was employed in keeping with UK Economic and Social Research Council guidance. **Results:** All included studies reported post-treatment improvements in erectile function as measured by the International Index of Erectile Function (IIEF). Li-ESWT demonstrated statistically significant benefits for organic vasculogenic and diabetic ED, with minimal clinically important difference (MCID) rates ranging from 22% to 86.4%. Li-ESWT was comparable in efficacy to phosphodiesterase-5 (PDE5) inhibitors with a superior safety profile. Evidence did not support its use for post-radical prostatectomy ED. Twelve treatment sessions at 0.09 mJ/mm², delivered twice weekly in a 3+3+3-week schedule, constituted the most commonly reported effective protocol. Treatment benefits were sustained in up to 82.69% of respondents at 12 months, with gradual decline thereafter. **Conclusion:** Li-ESWT is a safe, well-tolerated, and effective treatment for organic erectile dysfunction, particularly in younger men with vasculogenic or diabetic aetiology and moderate severity. It is comparable to PDE5 inhibitors and may be a viable alternative or complementary option in clinical practice. Future high-quality, multi-centre randomised controlled trials with standardised protocols and longer follow-up periods are warranted.

Keywords: Erectile dysfunction; low-intensity extracorporeal shockwave therapy; Li-ESWT; phosphodiesterase-5 inhibitors; vasculogenic erectile dysfunction; IIEF; penile rehabilitation.

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INTRODUCTION

Erectile dysfunction (ED) is defined as the chronic inability to achieve or maintain a penile erection sufficient for satisfactory sexual performance. It is a multidimensional and highly prevalent disorder affecting an estimated 30–50 million men in North America and 150 million men globally [1, 2]. Epidemiological data indicate that ED affects approximately 35% of men aged 60 years and up to 50% of those aged 70 years; however, it is increasingly recognised in younger cohorts, with one in four newly diagnosed cases now occurring in men below 40 years of age [3, 4]. Projections indicate a 2.5-fold increase in global prevalence by 2025, with the greatest burden anticipated in developing regions [5].

ED affects the complete sexual response cycle—including desire, arousal, and orgasm—and exerts profound negative effects on personal, social, and sexual quality of life, with psychological burden extending to the patient's partner [6]. The aetiology of ED is multifactorial, encompassing vascular,

neurological, hormonal, iatrogenic, and psychogenic mechanisms, frequently in combination [7]. Vasculogenic ED, characterised by endothelial dysfunction and reduced penile arterial inflow, is the most common organic subtype and is closely associated with cardiovascular risk factors including hypertension, diabetes mellitus, dyslipidaemia, obesity, and smoking [7, 8].

Current management guidelines recommend lifestyle modification and phosphodiesterase-5 (PDE5) inhibitor therapy as the first-line pharmacological intervention [9]. PDE5 inhibitors—including sildenafil and tadalafil—maintain erection through sustained vasodilation but do not restore underlying vascular pathology, nor do they initiate spontaneous erection [9]. Second-line therapies, including intraurethral or intracavernosal alprostadil and vacuum erection devices, are effective but limited by invasiveness, adverse effects, and poor patient acceptability [9].

The concept of regenerative therapy for ED has gained considerable momentum over the past decade. Low-intensity extracorporeal shockwave therapy (Li-ESWT), originally employed for musculoskeletal and cardiac conditions, was first evaluated for ED by Vardi *et al*. in 2010, who demonstrated improvements in penile haemodynamics and erectile function following a bilateral cavernosal shockwave protocol [10]. The mechanism is postulated to involve enhanced angiogenesis through upregulation of vascular endothelial growth factor (VEGF), recruitment of endothelial progenitor cells, and promotion of neurogenesis, collectively leading to improved penile perfusion and erectile capacity [11, 12].

Despite a growing body of published literature, key clinical questions remain unresolved: the optimal patient phenotype most likely to benefit, the most efficacious treatment protocol, the comparative effectiveness versus established treatments, and the durability of therapeutic effects. The heterogeneity of existing studies in terms of shockwave devices, energy flux density (EFD), number and frequency of sessions, and outcome reporting has precluded definitive meta-analytic conclusions. This narrative review aims to provide a comprehensive, clinician-focused synthesis of the current evidence base on Li-ESWT for ED, with specific attention to patient selection, comparative efficacy, treatment parameters, and long-term outcomes.

METHODS

Study Design

This narrative review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement [13]. The narrative synthesis methodology followed the UK Economic and Social Research Council (ESRC) framework for synthesising heterogeneous quantitative and qualitative evidence [14].

Search Strategy

A systematic search was conducted in PubMed, MEDLINE, EMBASE, Cochrane Library, CINAHL, and grey literature repositories including ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform. The search was limited to publications from January 2016 to June 2023, reflecting the period of substantial growth in clinical trials following wider clinical adoption of Li-ESWT in urological practice [15]. Search terms were structured using the PICO framework [16], combining Medical Subject Headings (MeSH) and free-text terms including: "erectile dysfunction," "low-intensity shockwave therapy," "Li-ESWT," "extracorporeal shockwave," "penile rehabilitation," "IIEF," and "phosphodiesterase inhibitor." A secondary citation search of bibliographies from primary results was also conducted.

Eligibility Criteria

Studies were included if they: (i) enrolled adult male patients with a clinical diagnosis of ED confirmed by IIEF scoring; (ii) assessed Li-ESWT as the primary intervention, with or without comparator arms; (iii) reported erectile function outcomes using validated instruments; and (iv) were published in English in peer-reviewed journals. Exclusion criteria included conference abstracts, case reports, editorials, existing systematic reviews or meta-analyses, and studies exclusively reporting on psychogenic ED without organic component.

Selection, Data Extraction, and Quality Assessment

Following duplicate removal, title and abstract screening identified 164 potentially relevant records, with 94 proceeding to full-text review. Twenty studies met the final inclusion criteria (Figure 1—PRISMA flow diagram). Data were extracted by the primary reviewer using a standardised form capturing: study design, sample characteristics, intervention parameters (device, EFD, pulse number, session frequency and schedule), comparator, outcome measures, follow-up duration, and adverse events.

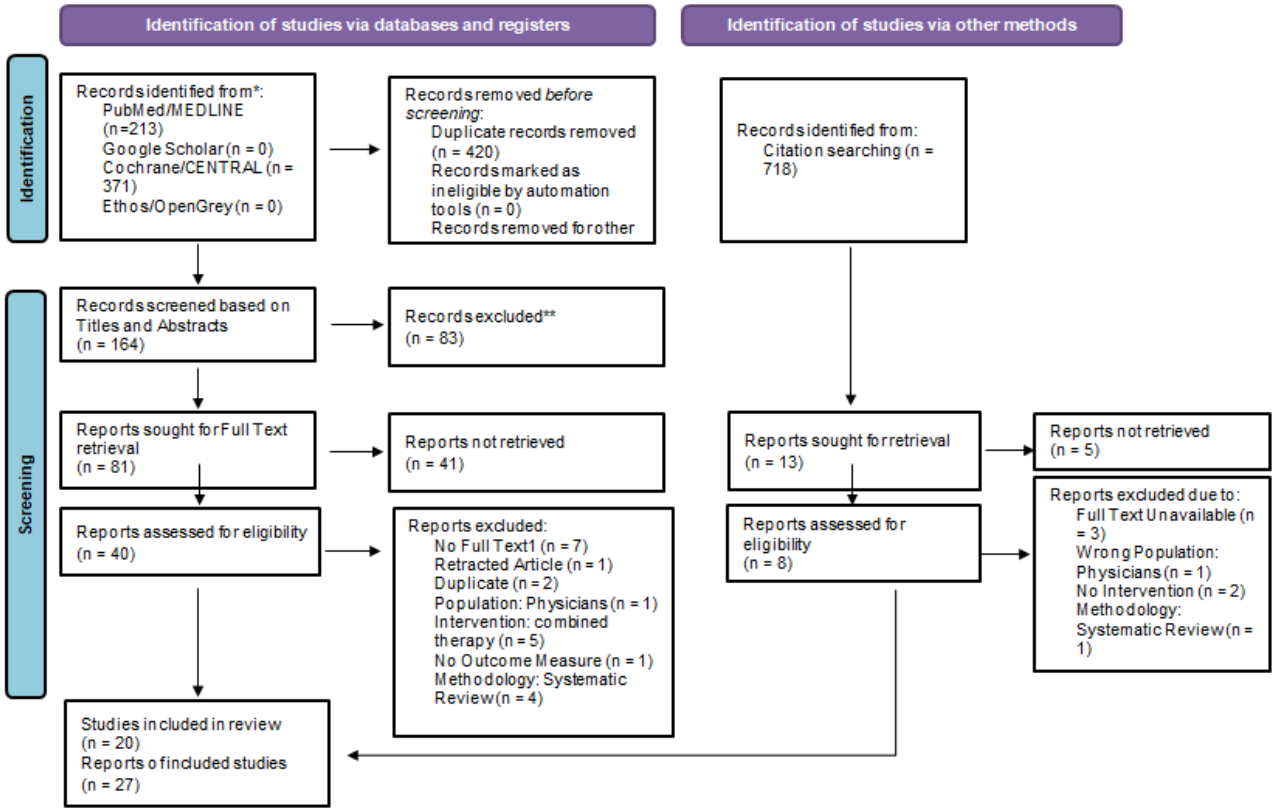

Fig-1: Systematic Search Selection Process using PRISMA

Quality of non-randomised studies was evaluated using the Newcastle-Ottawa Scale (NOS) [17] and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist [18]. Randomised controlled trials (RCTs) were assessed using the revised Cochrane Risk of Bias tool (RoB 2) [19] across five domains: randomisation process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of reported results.

RESULTS

Study Characteristics

The final review included 20 studies comprising 15 randomised controlled trials (RCTs), three prospective open-label interventional studies, one retrospective cohort, and one cross-sectional study. Studies were conducted across Europe, Asia, the Middle East, Africa, and Australia, reflecting increasing global adoption of Li-ESWT in clinical urology. Sample sizes ranged from 24 to 152 participants. The majority of studies (>50%) enrolled patients with vasculogenic organic ED; two studies focused on diabetic ED, two on post-radical prostatectomy ED, and the remaining studies included mixed organic aetiologies.

The International Index of Erectile Function (IIEF) and its abbreviated five-item version (IIEF-5) served as the primary outcome measure across all studies. A minimal clinically important difference (MCID) of five or more points in the erectile function domain of the IIEF was adopted by ten studies as the threshold for clinical significance. Secondary outcomes included erectile function domain subscore, orgasmic function, intercourse satisfaction, overall sexual satisfaction, and psychosocial wellbeing measured by the Self-Esteem and Relationship (SEAR) questionnaire [20].

Quality Assessment

Five of the 15 RCTs were rated as low overall risk of bias, three as having some concerns, and seven as high risk. Common methodological limitations included absence of allocation concealment, open-label design, and unblinded outcome assessment. The five non-RCT studies demonstrated adequate methodological rigour on NOS evaluation, meeting at least six of nine criteria. Although seven studies were rated as high risk of bias—primarily due to lack of blinding and small sample sizes—15 of 15 RCTs showed low risk of bias for selection of the reported result domain, indicating outcome reporting was pre-specified and consistent.

Overall Efficacy of Li-ESWT

All 20 included studies reported improvements in IIEF scores following Li-ESWT. Across studies, 25.2% of treated patients achieved full resolution of ED (IIEF-EF domain score >26) [21]. Despite this, the percentage of patients achieving MCID varied widely, ranging from 22% to 86.4% across studies, reflecting substantial heterogeneity in patient profiles, device parameters, and follow-up intervals [22-24]. At least three RCTs—including two double-blinded designs—did not

demonstrate statistically significant differences in IIEF improvement between the Li-ESWT and sham groups at primary time points [25, 26].

The systematic reviews and meta-analyses of Zou *et al*. [27], Campbell *et al*. [28], and Drury *et al*. [29] collectively identified statistically significant IIEF score increases with Li-ESWT versus placebo, with Li-ESWT estimated to be 8.31 times more effective than sham treatment in improving erectile function. Yao *et al*. [30] similarly concluded, on the basis of 16 RCTs, that Li-ESWT produces statistically significant IIEF improvements over placebo.

Comparative Efficacy: Li-ESWT versus PDE5 Inhibitors

Three studies directly compared Li-ESWT with PDE5 inhibitor therapy [31-33]. No statistically significant difference was identified in IIEF scores between treatment arms at the three-month follow-up ($p > 0.05$). Lei *et al*. [31] reported that PDE5i produced greater IIEF improvement at one month ($p < 0.01$), with equivalence reached by month three ($p > 0.05$). In psychological impact assessment, 90.6% of the PDE5i group versus 67.4% of the Li-ESWT group reported improvement at one month; however, these proportions reversed by month three (62.5% versus 71.7%, respectively), suggesting a more durable psychosocial benefit with Li-ESWT.

Regarding safety, Li-ESWT demonstrated a significantly superior adverse event profile compared to tadalafil. Zanaty *et al*. [32] reported a 44% adverse event rate in the tadalafil group, including muscle pain (20%), headache (16%), and nausea (8%), compared to negligible treatment-related events in the Li-ESWT group ($p < 0.05$). A more recent prospective study by Wang *et al*. [34] found comparable erectile function outcomes between Li-ESWT and sildenafil but significantly greater patient and partner satisfaction scores for intercourse duration and overall sexual experience in the Li-ESWT cohort.

The mean cost of a standard six-week Li-ESWT treatment cycle is approximately USD 500, compared to USD 62.50 per month for PDE5 inhibitor maintenance therapy. Given that Li-ESWT benefits can persist for at least 12 months in a substantial proportion of patients, this represents competitive cost-effectiveness over a 12-month treatment horizon.

Efficacy According to Aetiology

Vasculogenic Erectile Dysfunction

Eleven studies investigated Li-ESWT in patients with vasculogenic ED, making it the most extensively characterised subgroup. Among the six RCTs with sham controls, three were double-blinded. The double-blinded trials of Ong *et al*. [22] and Chung *et al*. [35] reported MCID rates of 22% and 70%, respectively, with the former demonstrating a statistically significant divergence between active and sham arms in favour of Li-ESWT at six months ($p < 0.001$). Ortac *et al*. [36], in a single-blinded RCT, reported MCID in 74% of Li-ESWT patients versus 35% in the sham group ($p = 0.003$). In the open-label RCT by Kalyvianakis *et al*. [37], 82% of patients achieved MCID with a statistically significant IIEF improvement ($p < 0.001$).

Prospective and cross-sectional studies corroborated these findings, with statistically significant IIEF improvements observed across different clinical contexts, demographics, and device settings [21, 38-40].

Diabetic Erectile Dysfunction

Two studies evaluated Li-ESWT in patients with diabetic ED. In the randomised trial by Shendy *et al*. (41), Li-ESWT produced a statistically significant increase in IIEF compared to sham ($p < 0.001$), with 71% of the Li-ESWT group achieving erections sufficient for penetrative intercourse versus 9.5% in the sham group ($p < 0.001$). Akande *et al*. [38] reported an 86.4% Li-ESWT responder rate in a Nigerian cohort, with sustained improvements maintained at six months across all severity grades, including severe diabetic ED.

Post-Radical Prostatectomy Erectile Dysfunction

Two RCTs evaluated Li-ESWT for post-prostatectomy ED, yielding divergent results. Zewin *et al*. [42], who enrolled patients prior to surgery and initiated therapy one month post-operatively with a single surgeon performing bilateral nerve-sparing procedures, reported significant IIEF improvements in all groups at months three, six, and nine (from 6.7–6.9 at baseline to 21–24.6 at three months). In contrast, Ladegaard *et al*. [26], who recruited patients with a mean ED duration of 11.2–14.3 months post-surgery across multiple surgeons (predominantly unilateral nerve sparing), reported only modest IIEF improvements that did not differ significantly from placebo at any follow-up point. The review findings are consistent with the meta-analysis of Rho *et al*. [43], which identified only low-level evidence for Li-ESWT in penile rehabilitation following radical prostatectomy, with no statistically significant difference from sham controls at 9–12 months.

Efficacy According to ED Severity

Multiple studies addressed the relationship between baseline ED severity and Li-ESWT responsiveness, yielding nuanced findings. Caretta *et al*. [21] reported that 84.1% of mild ED patients (IIEF-EF 17–21) responded to Li-ESWT compared to 41.8% of moderate-to-severe cases. Conversely, Tzou *et al*. [44] found that severe ED patients demonstrated a greater absolute increase in IIEF score ($p < 0.001$), suggesting a higher magnitude of improvement from a lower baseline. Kim *et al*. [45], in a double-blinded RCT of mild ED, reported a significant IIEF increase of 5.1 points in the Li-ESWT arm compared to −2.2 in

placebo ($p < 0.001$). Ortac *et al*. [36] documented that the therapeutic effect at six months was attenuated in patients older than 35 years, with BMI >30 kg/m², or with ED history exceeding 12 months.

Regarding PDE5i non-responders, three studies demonstrated that Li-ESWT produced clinically meaningful improvements in this subgroup. Bechara *et al*. [46] reported a 60% response rate in PDE5i non-responders, sustained by 91.7% at 12 months. Chung *et al*. [35] found MCID in 70% of non-responders after six months, with 60% achieving spontaneous erection by month one, and an overall satisfaction rate of 83% positively correlated with IIEF improvement ($p = 0.008$). Musa *et al*. [39], in a prospective cohort, reported satisfying sexual intercourse in 63.5% of non-responders, with younger age ($p = 0.031$), shorter ED duration ($p < 0.001$), and moderate severity ($p = 0.02$) as independent predictors of sustained response.

Efficacy According to ED Duration

One prospective cohort study (de Oliveira *et al*.) [47] systematically evaluated the influence of ED chronicity on Li-ESWT response. No significant difference in IIEF improvement was observed between patients with ED lasting less than or more than 24 months at six weeks ($p = 1.000$) or three months ($p = 0.378$). However, patients with ED duration exceeding 24 months demonstrated significantly improved responsiveness to PDE5 inhibitors following Li-ESWT ($p = 0.041$). Musa *et al*. [39] further identified shorter ED duration (less than two years) as an independent predictor of sustained improvement beyond 18 months.

Treatment Protocol Parameters

Number of Sessions

Session number across included studies ranged from 4 to 18, with 12 sessions being the most commonly employed protocol (11 studies). Kalyvianakis *et al*. [37] directly compared 6, 12, and 18 sessions, reporting mean IIEF changes of +3.1, +5.2, and +7.2, respectively ($p < 0.001$ for all comparisons). MCID was achieved in 62%, 74%, and 83% of patients in the respective groups. The six- versus twelve-session comparison was statistically significant ($p = 0.003$), as was the twelve- versus eighteen-session comparison ($p = 0.01$), confirming a dose-dependent relationship.

Session Frequency

Twice-weekly administration was the most commonly used frequency (10 studies), followed by once weekly (8 studies), three times weekly (3 studies), and daily for five days (1 study). Kalyvianakis *et al*. [48] directly compared twice- and thrice-weekly schedules (both completing 12 sessions total) and found no statistically significant difference in IIEF improvement ($p = 0.32$), suggesting that within this range, inter-session interval does not critically influence outcome.

Treatment Schedule

Five studies employed the classic 3+3+3-week schedule (three weeks of treatment, three weeks off, three weeks of treatment). Patel *et al*. [49] compared daily sessions over five consecutive days versus three sessions per week over two weeks; both schedules produced significant IIEF improvements ($p < 0.001$), with no statistically significant difference between groups ($p = 0.502$). Kalyvianakis *et al*. (37) compared 12 continuous sessions against a split 6+6-session schedule with a six-month gap, finding virtually identical IIEF improvements. However, the retreatment group (12+6 sessions) demonstrated further IIEF gains ($p < 0.001$), with MCID achieved in an additional 44% of patients. Notably, the sexual encounter profile satisfaction score was greater in the 6+6 cohort than in the 12+6 group, raising the possibility of treatment saturation with higher cumulative doses.

Energy Flux Density and Pulse Number

Energy flux density (EFD) across studies ranged from 0.05 to 0.25 mJ/mm², a variability partly attributable to device-specific output characteristics. Kalyvianakis *et al*. [48] compared EFD at 0.05 versus 0.10 mJ/mm² and found a non-significant trend towards greater efficacy at 0.10 mJ/mm² ($p = 0.09$), with no difference in MCID rates across severity strata at six months ($p = 0.78$). Pulse numbers per session ranged from 600 to 6,000, with 3,000 pulses being the modal value (seven studies). The meta-analysis by Zou *et al*. [27] identified a protocol of 1,500 pulses at 0.09 mJ/mm² twice weekly in the 3+3+3-week schedule as the configuration most consistently associated with therapeutic effect in the published literature.

Duration of Treatment Effect

Li-ESWT produced a clinically relevant improvement in IIEF that was sustained in 55–57% of patients at six months (44, 21). In the low-risk RCT by Ong *et al*. [22], 26% MCID was maintained in the Li-ESWT group at six months, whilst no sham-group patient achieved MCID. At 12 months, sustained MCID was reported in 46.38% [44] and 91.7% [46] of PDE5i non-responders across different cohorts.

Long-term follow-up data are available from two studies. Musa *et al*. [39] demonstrated improvement sustained in 82.69% of respondents until 12 months, with 50% experiencing decline by month 18. Chung and Cartmill [40] reported improvement in 60% of patients at 12 months, with progressive decline to 45% at 24 months and 40% at 48 and 60 months post-treatment. The sustained benefit was more pronounced in vasculogenic than in post-prostatectomy ED. These findings are consistent with the systematic review by Brunckhorst *et al*. [50], which identified a plateau or decline in erectile function from 12 months onward, particularly in older men, and with the broader meta-analytic consensus that Li-ESWT offers durable, though not permanent, improvements.

Psychosocial Outcomes

Psychological domains were assessed using the SEAR questionnaire in two studies. Zanaty *et al*. [32] reported statistically significant improvements in confidence, self-esteem, and relationship domains following Li-ESWT ($p < 0.05$), with scores improving from 20–28 at baseline to 49–63 post-treatment. While PDE5 inhibitor-treated patients initially reported greater psychological improvement at one month (90.6% vs. 67.4%), the Li-ESWT group demonstrated a progressive and sustained improvement to 71.7% by month three, compared to a decline to 62.5% in the PDE5i group [31]. This sustained trajectory of psychosocial improvement with Li-ESWT may be attributable to its mechanism of restoring physiological erection capacity rather than pharmacologically augmenting vascular response.

Safety and Tolerability

Li-ESWT demonstrated a consistently favourable safety profile across included studies. Fourteen of 20 studies reported no adverse events, including studies employing higher session numbers (18 sessions) and greater energy flux densities. Chung and Cartmill [40] confirmed an absence of penile pain, deformity, or structural complications across a five-year follow-up period. Three studies reported mild, transient adverse effects including skin bruising, penile discomfort, mild fever, dysuria, and headache [31, 36, 32]. One placebo-group participant in Fojecki *et al*. [25] developed Peyronie's disease, unrelated to the active intervention. These findings align with the 2018 safety review by Rizk *et al*. [51], adding long-term data confirming no structural penile complications at up to five years post-treatment.

DISCUSSION

Mechanistic Basis of Li-ESWT

The therapeutic rationale for Li-ESWT in ED is grounded in its capacity to induce targeted tissue remodelling through mechanotransduction. Acoustic waves delivered at low energy densities (below those used in kidney lithotripsy) activate endothelial mechanoreceptors, trigger the release of angiogenic growth factors including VEGF and fibroblast growth factor (FGF), recruit endothelial progenitor cells, and stimulate neuronal sprouting [11, 12]. These mechanisms collectively improve penile arterial perfusion, restore smooth muscle integrity, and promote cavernosal endothelial function—addressing the fundamental vascular and neural deficits underlying organic ED [52]. This regenerative paradigm distinguishes Li-ESWT from pharmacological treatments that act symptomatically on the vasodilatory cascade without modifying underlying pathology.

The mechanistic synergy between Li-ESWT and PDE5 inhibitors has also been proposed: Li-ESWT restores cavernosal structure and function, while PDE5 inhibitors amplify the nitric oxide-mediated vasodilatory response. Clinical data supporting this combination—and its potential to convert PDE5i non-responders into responders—represent an important translational avenue deserving further investigation [46, 39].

Optimal Patient Selection

The evidence collectively supports a favourable Li-ESWT response profile in younger men (below 45 years) with organic ED of vasculogenic or diabetic aetiology, moderate severity (IIEF-EF 11–16), and ED duration of less than two years [39, 21, 44]. Patients without significant metabolic burden—specifically with BMI below 30 kg/m² and without longstanding diabetes or heavy smoking history—appear to derive greater and more durable benefit. These observations are biologically plausible, as a less-compromised endothelial and smooth muscle substrate offers greater regenerative capacity in response to shockwave stimulation.

PDE5i non-responders represent a clinically significant subgroup for whom Li-ESWT offers a meaningful alternative. Across three studies, clinically meaningful improvements were documented in 60–70% of this cohort, with predictors of sustained response including younger age, moderate severity, and shorter disease duration [35, 39, 46]. Significantly, Tzou *et al*. [44] found no statistically significant difference in Li-ESWT response between PDE5i responders and non-responders ($p > 0.5$), suggesting that prior treatment response should not preclude Li-ESWT candidacy.

For post-prostatectomy ED, current evidence does not support Li-ESWT as a first-line rehabilitative intervention. The variable and generally modest outcomes in this subgroup are likely confounded by the degree of iatrogenic cavernosal nerve injury, surgical technique (bilateral versus unilateral nerve sparing), and the spontaneous recovery trajectory that occurs in the first 12 months following nerve-sparing prostatectomy. Prognosis appears to be primarily dependent on the extent of nerve preservation rather than adjuvant shockwave therapy [26, 43].

ED of predominantly psychogenic origin has been largely excluded from clinical trials, reflecting diagnostic and ethical complexity. However, the observation that younger age is a consistent positive predictor of Li-ESWT response—combined with the known predominance of psychogenic and mixed-aetiology ED in men below 40 years—raises the hypothesis that Li-ESWT may confer benefit in this population through restoration of physiological erection confidence and disruption of performance anxiety cycles [36]. Prospective trials specifically enrolling younger men with psychogenic ED are warranted.

Recommended Treatment Protocol

The evidence supports a dose-dependent relationship between session number and treatment response, with 12 sessions demonstrating superiority over 6 and inferiority to 18. The additive benefit of a retreatment

cycle (6+6 with a gap versus 12 continuous sessions) yields equivalent IIEF outcomes, with the possible advantage of improved patient compliance and psychosexual reinforcement during the treatment break. The most extensively validated protocol—identified by the meta-analysis of Zou *et al*. [27]—is 12 sessions of 1,500 pulses at 0.09 mJ/mm², administered twice weekly in a 3+3+3-week schedule.

The choice of shockwave device—radial versus focused—and specific machine parameters requires careful consideration. Focused shockwave devices deliver energy to a precise target depth and are more physiologically consistent with the mechanism of cavernosal tissue remodelling; radial devices produce lower EFDs and may be less effective at target depths relevant to penile vasculature [53]. Clinicians should ensure device-specific energy calibration is documented in patient records.

Comparative Effectiveness and Cost Considerations

The clinical equivalence of Li-ESWT and PDE5 inhibitors in improving erectile function, combined with the superior safety profile and potentially more durable psychosocial trajectory of Li-ESWT, provides a compelling rationale for its inclusion in ED management guidelines. Cost-effectiveness modelling over a 12-month horizon is broadly comparable, particularly when accounting for the cumulative adverse event burden and medication dependency associated with PDE5i maintenance therapy. The additional benefit of patient and partner satisfaction reported by Wang *et al*. [34] warrants further health-economic analysis in the context of quality-adjusted life years.

Long-term Effects and Retreatment

Li-ESWT provides durable improvements in erectile function for the majority of patients at 12 months, with a gradual plateau and decline thereafter [39, 40, 50]. The most pronounced improvements occur within the first year, with 40–60% of patients retaining clinically meaningful benefit at four to five years [40]. Retreatment cycles appear safe and beneficial, with Kalyvianakis *et al*. [37] demonstrating further IIEF gains following a second course at six months. Current evidence suggests that a retreatment strategy at 12–18 months may be a rational and cost-effective approach for patients with moderate ED seeking sustained benefit, consistent with the chronic disease management model increasingly applied to men's sexual health.

Limitations of the Evidence Base

The interpretation of available evidence is constrained by several methodological limitations. Sample sizes were predominantly small (fewer than 100 participants per arm), reducing statistical power for subgroup analyses. Seven of the 15 included RCTs were rated as high risk of bias, primarily due to absence of participant or assessor blinding. Device heterogeneity across studies—encompassing focal, linear, and radial shockwave generators with differing energy output characteristics—limits direct protocol comparisons. The absence of standardised reporting of device specifications and treatment parameters further impedes evidence synthesis. Long-term follow-up data beyond 12 months are available from only two studies, restricting conclusions regarding durability and retreatment timing. The exclusion of psychogenic ED from most trials limits generalisation to the younger male population now constituting a growing proportion of ED presentations.

CONCLUSIONS

Low-intensity extracorporeal shockwave therapy represents a clinically meaningful, safe, and well-tolerated treatment option for organic erectile dysfunction, with the strongest evidence supporting its use in vasculogenic and diabetic subtypes. Li-ESWT is comparable to PDE5 inhibitors in terms of IIEF improvement and superior in its adverse event profile and emerging long-term psychosocial trajectory. It offers a viable alternative or complementary approach, particularly in PDE5i non-responders and in patients seeking a durable, drug-free intervention.

The optimal candidate for Li-ESWT is a younger man (below 45 years) with organic, predominantly vasculogenic ED of moderate severity and duration of less than two years, without severe obesity, uncontrolled diabetes, or heavy smoking history. The recommended treatment protocol is 12 sessions of 1,500–3,000 pulses at 0.09 mJ/mm² administered twice weekly in a 3+3+3-week schedule. Treatment benefits are most pronounced in the first 12 months, with retreatment at 12–18 months representing a rational strategy for sustained response.

Evidence does not currently support Li-ESWT as a rehabilitative intervention following radical prostatectomy, where outcomes appear primarily determined by surgical nerve preservation. The potential utility of Li-ESWT in psychogenic ED, particularly in younger cohorts, warrants prospective investigation.

Future research should prioritise: (i) large, multi-centre, double-blinded RCTs with standardised device protocols and extended follow-up periods of three to five years; (ii) direct head-to-head comparisons of different shockwave device types and EFD parameters; (iii) dedicated trials in younger men with psychogenic or mixed-aetiology ED; (iv) pharmacoeconomic analyses of Li-ESWT versus PDE5 inhibitors incorporating quality-adjusted life year metrics; and (v) exploration of Li-ESWT combination regimens with platelet-rich plasma, stem cell therapy, or low-intensity pulsed ultrasound as part of an integrated regenerative urology platform.

DECLARATIONS

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Data Availability: All data are available from published sources cited in the reference list.

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