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Review Article

Low-Intensity Shockwave Therapy for Vasculogenic Erectile Dysfunction: Responder Profiles and a Practical Dosing Framework

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Abstract

Low-intensity extracorporeal shockwave therapy (LI-ESWT) offers a biologically restorative approach to vasculogenic erectile dysfunction (ED) by improving penile perfusion and endothelial function rather than simply facilitating an erection. Evidence from randomized and sham-controlled trials demonstrates a consistent benefit in mild to moderate vasculogenic disease; however, variability in dosing and sham design continues to limit the certainty of guidelines. This review proposes a pragmatic, clinic-ready framework centered on two pillars. First, a phenotype-driven responder model prioritizing men with vasculogenic ED, preserved nocturnal tumescence, and controlled cardiometabolic risk factors, while setting realistic expectations for those with diabetes, fibrosis, or neurogenic etiologies. Second, a dose-transparent protocol standardizing the full treatment equation, including energy flux density, pulses per session, treatment fields, number of sessions, and spacing, to improve reproducibility and outcome interpretation. The review further integrates LI-ESWT into a broader treatment continuum that includes optimization of cardiovascular and hormonal factors, first-line phosphodiesterase-5 inhibitor (PDE5i) therapy, and surgical options when appropriate. LI-ESWT is positioned as a disease-modifying adjunct that can enhance PDE5i responsiveness or defer prosthesis consideration in well-selected vasculogenic phenotypes. Safety data remain favorable, with adverse events typically mild and transient. Clear definitions of clinical success, objective reassessment at three to six months and one to two years, and transparent dose reporting support shared decision-making and long-term management planning.

Keywords: Erectile dysfunction; Shock wave therapy; Penile diseases; Phosphodiesterase 5 inhibitors

Introduction

Erectile dysfunction is common and often vascular in origin, yet most outpatient options provide transient pharmacologic assistance or require invasive reconstruction. Phosphodiesterase-5 inhibitors (PDE5i) remain the first-line pharmacologic therapy for erectile dysfunction due to their efficacy, ease of use, and generally favorable safety profile. They potentiate nitric oxide–mediated vasodilation within the corpus cavernosum and improve erectile response with sexual stimulation; however, they do not modify underlying vasculogenic disease biology and require correct dosing and timing for consistent benefit [1].

Low-intensity extracorporeal shockwave therapy (LI-ESWT) is appealing because it aims to modify disease biology by promoting angiogenesis and improving penile hemodynamics rather than only facilitating a single erection. Evidence has grown unevenly. Sham-controlled trials and meta-analyses show a signal in vasculogenic erectile dysfunction with mild to moderate baseline severity, while guideline bodies remain cautious because protocols vary widely and sham designs are inconsistent [2-5]. In practice, LI-ESWT can benefit the right patients, but clearer guidelines are needed for identifying those patients and determining the optimal dosage of the therapy.

This review advances two linked ideas. First, a phenotype-driven responder model: men with vasculogenic erectile dysfunction, preserved or partially preserved nocturnal tumescence, and controlled cardiometabolic risk factors are most likely to achieve a clinically meaningful gain, whereas severe neurogenic disease, long-standing diabetes with microvascular complications, and advanced fibrosis respond less consistently [2]. We anchor "meaningful" improvement to established minimal clinically important differences in the IIEF-EF domain, about +4 points overall with ranges by baseline severity (approximately +2 for mild, +5 for moderate, and +7 for severe), and we treat durability at 6 to 12 months as a practical threshold for success [3,6]. Second, a pragmatic dosing framework: outcomes likely depend on the total energy delivered across fields and sessions, yet published regimens vary in energy flux density, pulses, treatment fields, frequency, and spacing. Standardizing the "dose equation" as energy flux density × pulses × fields × sessions × spacing, and reporting it transparently, would reduce noise across studies and clinics [2,7]. Matching patients to a biology that can change and bringing order to dose can turn a promising but inconsistent literature into a practical, clinic-ready pathway.

Mechanistic Rationale in Brief

Low-intensity extracorporeal shockwave therapy (LI-ESWT) delivers acoustic pulses that generate controlled shear stress in cavernosal tissue. Preclinical studies demonstrate increased endothelial nitric oxide synthase activity, enhanced vascular endothelial growth factor signaling, neovascularization, and the recruitment of circulating progenitor cells within the corpora, collectively improving penile perfusion [8]. Clinical reviews and meta-analyses report improvements in erectile function scores and penile

hemodynamics in vasculogenic erectile dysfunction, although effects vary across protocols and patient groups [9,10].

Guideline bodies mirror the mixed strength of evidence. The European Association of Urology notes that LI-ESWT may be offered to carefully selected men with mild vasculogenic disease or those who are poor responders to phosphodiesterase-5 inhibitors, with a weak recommendation and an emphasis on shared decision-making. The American Urological Association continues to classify LI-ESWT as investigational due to heterogeneity in sham design and dosing, as well as limited long-term durability data [2,11].

A practical reason for the variability is dosing. Protocols differ in terms of energy flux density, pulses per session, treatment fields, number of sessions, and treatment spacing. Recent method reviews summarize a typical pattern of approximately 0.09 mJ/mm² at 5 Hz, with roughly 1,500 shocks per session, distributed between the penile shaft and crura, and involving 6 to 12 sessions overall. Reporting the full "dose equation" as energy × pulses × fields × sessions × spacing makes studies and clinics more comparable and helps explain who responds and why [7,12].

Implication for selection: these mechanisms are most relevant when vascular supply is the limiting factor. Men with predominantly vasculogenic erectile dysfunction and at least partial nocturnal tumescence are biologically more likely to benefit than men with severe neurogenic etiologies or extensive fibrosis, where tissue response to shear stress may be blunted [2,13].

Who Responds: A Phenotype-Driven Model

LI-ESWT appears to be most effective when vascular supply is the primary constraint and when some erectile physiology remains intact. Men with vasculogenic erectile dysfunction, mild to moderate baseline severity, and at least partial nocturnal tumescence are most likely to benefit. Outcomes are stronger when cardiometabolic risks are controlled, including blood pressure, lipids, glycemia, smoking, and weight. Response is attenuated in long-standing diabetes with microvascular complications, in extensive corporal fibrosis or severe Peyronie's disease with erectile failure, and in predominantly neurogenic etiologies such as post-radical prostatectomy without nerve-sparing [2,9].

A useful way to define success is to anchor it to a minimal clinically important difference on validated scales. For the IIEF-EF domain, an average improvement of about 4 points is often considered clinically meaningful, with approximate thresholds that vary by baseline severity. Practical targets are about +2 for mild dysfunction, about +5 for moderate dysfunction, and about +7 for severe dysfunction. Durability at 6 to 12 months is a reasonable benchmark for whether the response reflects sustained biology rather than placebo or short-lived hemodynamic changes [3,4,6].

Selection is easier in clinic with a short checklist:

- Confirm vasculogenic phenotype with history, exam, and, when available, penile Doppler or validated questionnaires.
- Document at least partial nocturnal tumescence or residual spontaneous function.
- Optimize cardiometabolic risks before or alongside therapy.
- Set an a priori success target using IIEF-EF or EHS and plan to reassess at 3 and 6 to 12 months.
- Counsel patients with diabetes, severe fibrosis, or neurogenic etiologies that the probability of benefit is lower and that combination strategies may be needed.

Framing selection around this phenotype increases the likelihood that LI-ESWT delivers a durable, clinically significant improvement for the individual patient while maintaining realistic expectations [2,5,9].

How to Dose: A Practical Framework

Heterogeneous dosing is a major reason results vary across studies and clinics. A simple way to standardize is to specify the full "dose equation": energy flux density × pulses per session × treatment fields × number of sessions × spacing between sessions. Reporting all five elements makes protocols comparable and helps teams tune treatment for different phenotypes [7,12].

Baseline clinic protocol. A commonly used focused LI-ESWT regimen delivers about 0.09 mJ/mm² at 4 to 6 Hz, with roughly 1,500 to 3,000 shocks per session divided between the penile shaft and the crura. Total sessions typically range from 6 to 12, performed once or twice weekly over 3 to 6 weeks. Target both corpora along the shaft and both crura at the perineum, with slow, overlapping passes and firm probe coupling. Record the exact parameters in the chart so repeat cycles can match the initial dose if the patient responds [7,9,10].

Focused versus radial devices. Focused shockwave devices concentrate energy at depth and have the strongest connection to vasculogenic mechanisms in both preclinical and clinical studies. Radial pressure-wave devices deliver more superficial energy and are not equivalent. When possible, use focused systems for vasculogenic erectile dysfunction and avoid mixing device types within a course, since the delivered energy profile differs [2,8].

Adjusting the dose. Start with the baseline protocol for mild to moderate vasculogenic disease. Consider modest escalation toward the higher end of pulses or sessions when baseline severity is greater or when diabetes is present, while keeping energy flux density in the low-intensity range. In men with significant penile fibrosis or post-prostatectomy neurogenic contributions, consider that dose escalation may not overcome the underlying biology and instead discuss combination strategies rather than repeated cycles alone [2].

Quality controls that improve reproducibility.

- Maintain consistent probe coupling with a generous amount of gel and reapply if the connection slips.
- Map fields consistently at each visit and document probe positions.
- Keep session timing regular, for example, two sessions per week on nonconsecutive days.
- Monitor adherence and missed visits, since gaps can dilute the cumulative dose.
- Reassess at 3 months using IIEF-EF or EHS and repeat at 6 to 12 months to judge durability. Define success in advance and avoid indefinite cycling without an objective gain [3,6].

Putting dose and phenotype together. The best results occur when total delivered energy and field coverage are adequate and the patient fits the vasculogenic responder profile. A transparent dose record enables meaningful comparison with the literature and supports informed decisions about whether to repeat a cycle or transition to combination therapy [2,7].

Positioning with Standard Therapy

LI-ESWT complements rather than competes with established treatments. Begin with risk-factor optimization and guideline-directed care. Ensure blood pressure, lipids, glucose, weight, sleep apnea, depression, and relationship factors are addressed, and confirm that phosphodiesterase-5 inhibitors (PDE5i) have been tried with correct dosing, timing, and number of attempts. Replace or optimize testosterone in men with symptomatic deficiency, since untreated hypogonadism lowers response to both PDE5i and LI-ESWT [2].

A practical sequence in clinic is simple. First, optimize cardiometabolic risks and correct hypogonadism when present. Second, confirm a vasculogenic phenotype and set an a priori success target using IIEF-EF or EHS. Third, offer a focused LI-ESWT cycle using a standardized dose record. Reassess at three months. If the IIEF-EF improvement meets the predefined goal and the patient values less reliance on medication, continue lifestyle work and monitor at six to twelve months. If the gain is partial, add or reintroduce PDE5i to consolidate the benefit. If there is no meaningful change, pivot to alternatives such as vacuum erection devices, intracavernosal therapy, or surgical options, guided by patient preference and partner considerations [2,3,9].

Combination therapy is reasonable in several scenarios. Men who are partial responders to PDE5i may achieve larger and more durable improvements when LI-ESWT is added, particularly when vascular insufficiency is documented. Men who fail an initial LI-ESWT cycle can still respond to PDE5i after optimization of comorbidities. Reserve repeated LI-ESWT cycles for those who achieved a clear, time-limited response and want to maintain or extend it. For men with prominent neurogenic components or advanced fibrosis, it is essential to set expectations that combination strategies may help alleviate symptoms, but disease modification is less likely, and an earlier transition to injection therapy or implants may be appropriate [2,4].

Follow-up should be structured. Recheck IIEF-EF or EHS at three months after a cycle, then at six to twelve months to assess durability. Document the exact dose parameters so future cycles can replicate a successful course. Use shared decision-making at each milestone to balance medication use, convenience, cost, and the level of improvement that matters to the patient and partner [2,3].

Candidates and Positioning Relative to Pharmacologic Therapy and Prosthesis

Men with predominantly vasculogenic erectile dysfunction, mild to moderate baseline severity, and at least partial nocturnal tumescence are the most suitable candidates for LI-ESWT; response likelihood and durability improve when cardiometabolic risks are optimized and focused devices are used with transparent dosing, while outcomes are less consistent in long-standing diabetes with microvascular complications, prominent neurogenic etiologies, or extensive fibrosis/Peyronie's disease [2,5,10]. LI-ESWT is best positioned as an adjunct to guideline-directed therapy: PDE5 inhibitors remain first-line, and LI-ESWT can enhance responsiveness in partial PDE5i responders or reduce reliance on medication when a clinically meaningful and durable gain is achieved, provided sequencing includes risk-factor optimization and correct PDE5i use [2,4,10,14].

Compared with penile prosthesis, which offers the highest reliability for severe, refractory dysfunction but is invasive and irreversible, LI-ESWT provides a noninvasive, biology-targeted option that preserves future choices and has a favorable safety profile. For appropriately selected vasculogenic phenotypes, LI-ESWT can delay or reduce the need for prosthesis; however, it should not be expected to match implant reliability, and patients with neurogenic or fibrotic disease should be counseled toward earlier transition to injection therapy or prosthesis when appropriate [2,4,10].

Safety, Counseling, and Follow-up

LI-ESWT is generally well tolerated. Reported adverse events are usually mild and transient, such as brief penile discomfort, erythema, or small ecchymoses at treatment sites. Serious complications are rare in contemporary series and meta-analyses, and discontinuation for adverse events is uncommon [2,9,10]. Standard precautions include avoiding treatment over infected skin, unhealed wounds, or active lesions, and using an abundant amount of gel to maintain coupling. Many programs pause therapy during anticoagulation changes or uncontrolled hypertension and defer in men with unstable cardiac status until cleared by their medical team [2].

Set expectations before the first session. Explain that LI-ESWT aims to improve penile perfusion and erectile quality over weeks, not minutes. Most responders notice a change between four and twelve weeks after a complete cycle, not after an individual session. Define success in advance using a minimal clinically important difference on IIEF-EF or a target Erection Hardness Score, and agree on when to judge non-response. Remind patients that the evidence base is mixed due to variations in dosing and sham designs, and emphasize why your protocol tracks a transparent "dose record" to ensure results are interpretable and repeatable [2.3].

A simple follow-up plan works well. Reassess at three months with IIEF-EF or EHS and a brief adverse event review. Reinforce cardiometabolic risk control and correct testosterone deficiency when present, since these factors correlate with response and durability. Recheck at six to twelve months to determine whether the benefit persists. If improvement is clinically meaningful yet fading, discuss repeating a cycle using the same parameters. If there is no meaningful change, pivot to alternatives such as optimized phosphodiesterase-5 inhibitors, vacuum devices, intracavernosal therapy, or surgical options, guided by patient preference and partner input [2,9].

Document details at each visit. Record device type, energy flux density, pulses, fields, sessions, spacing, adherence, and any missed treatments. Note concomitant therapies, including PDE5 inhibitors and testosterone, because combinations can confound the interpretation of response. This level of detail supports shared decisions, enables honest counseling about repeating a cycle, and contributes to more interpretable outcomes in clinic and, when feasible, in registries [3,7].

Evidence Gaps and Research Priorities

Current evidence supports LI-ESWT for selected men with vasculogenic erectile dysfunction, yet key uncertainties limit confident guideline endorsements. Trials differ in devices, energy flux density, pulses, fields, sessions, and spacing, and many studies do not report the full set of parameters. Sham designs also vary, which complicates effect size estimates and contributes to mixed conclusions across meta-analyses [2-4]. A longer follow-up is needed, as durability beyond 12 months is not well-defined in many cohorts, and rescue strategies are not standardized.

Three priorities would make the literature more actionable. First, adopt a core outcome set that includes the IIEF-EF, Erection Hardness Score, validated patient-reported benefits, and an agreed-upon minimal clinically important difference, with outcomes reported at a minimum of three, six, and twelve months [3,6]. Second, conduct dose–response trials that vary one parameter at a time while holding others constant, with transparent reporting of the full dose equation, allowing results to be replicated across clinics and devices [7,12]. Third, prespecify subgroup analyses for diabetes with microvascular disease, post-prostatectomy states, and significant corporal fibrosis or Peyronie's disease, since these phenotypes likely drive response heterogeneity [2]. Registries that capture device type, exact dose parameters, and concomitant therapies such as phosphodiesterase-5 inhibitors or testosterone would fill gaps that single-center trials cannot address and would help define when to repeat a cycle versus when to pivot to other options [15-17].

Conclusion

Low-intensity extracorporeal shockwave therapy (LI-ESWT) offers a noninvasive, disease-modifying option for vasculogenic erectile dysfunction when adequate vascular substrate and residual erectile physiology remain. Its benefit is greatest when patient selection and dosing are systematic, favoring men with mild to moderate vasculogenic dysfunction, preserved nocturnal tumescence, and controlled cardiometabolic risks. Standardizing the complete dose equation, including energy flux density, pulses per session, treatment fields, number of sessions, and spacing, ensures reproducibility and transparency across clinical settings.

Within the therapeutic continuum, LI-ESWT should be positioned alongside guideline-directed pharmacologic and procedural therapies rather than as a replacement. Phosphodiesterase-5 inhibitors remain the first-line treatment, and combining them with LI-ESWT can enhance responsiveness or reduce long-term medication reliance. Compared with penile prosthesis, LI-ESWT provides a biologically restorative and reversible pathway that preserves future options while maintaining a favorable safety profile. A phenotype-driven approach that integrates standardized dosing, shared decision-making, and rational sequencing with pharmacologic and surgical therapies can turn a mixed evidence base into a consistent and clinically valuable strategy for the appropriate patient.

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