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ORIGINAL PAPER

Low-intensity extracorporeal shock wave therapy in vasculogenic erectile dysfunction refractory to PDE5 inhibitors: A prospective study with 12- and 18-month outcomes

Giuseppe Saitta [1], Giuseppe Di Paola [1], Simone Di Salvatore [2], Benedetto Calabrese [2], Andrea Simone Ceresoli [1], Franco Mantovani [1], Attilio Luigi Meazza [1], Mauro Seveso [1]

[1] ICCS Milano, Istituto Clinico Città Studi, Milano, Italy;
[2] IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy.

Summary

Background: *Low-intensity Extracorporeal Shock Wave Therapy (Li-ESWT) has emerged as a promising treatment for vasculogenic erectile dysfunction (ED), particularly in men who do not respond to phosphodiesterase type-5 inhibitors (PDE5-Is).*

Objective: *To evaluate the feasibility, safety, and clinical effectiveness of Li-ESWT in men with vasculogenic ED through a prospective 12- and 18-month follow-up.*

Methods: *A prospective observational study was conducted on 188 patients with vasculogenic ED and inadequate response to PDE5-Is. Patients underwent 6 weekly sessions of Li-ESWT. Erectile function was assessed using the International Index of Erectile Function (IIEF) and Erection Hardness Score (EHS). Responders were defined as those achieving ≥ 3-point improvement on IIEF-EF and/or EHS ≥ 3.*

Results: *Mean age was 66.6 years; mean ED duration was 24 months. IIEF-EF improved from 11 at baseline to 21 at 12 months and 18 at 18 months. At 12 months, 71% of patients showed improvement in EHS. Younger age (< 45 years), shorter ED duration (< 12 months), and moderate baseline severity predicted better response ($p < 0.05$). Sustained improvement was observed in 65% of patients at 12 months and 54% at 18 months. No adverse events were reported.*

Conclusions: *Li-ESWT is a safe and effective treatment for vasculogenic ED unresponsive to PDE5-Is, with maximum benefit observed within 12 months. Efficacy tends to decline at 18 months. Larger controlled studies are needed to define long-term outcomes.*

KEY WORDS: *Low-intensity extracorporeal shock wave therapy; Erectile dysfunction; Erection hardness score; International index of erectile function; PDE5 inhibitor non-responders.*

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INTRODUCTION

Erectile dysfunction (ED) is a clinical condition characterized by the inability to achieve or maintain an erection sufficient for satisfactory sexual activity (1). ED can be classified as organic, psychogenic, or mixed according to its etiology (2). Its prevalence increases progressively with advancing age, a trend that has become more pronounced in the context of an aging global population, and is further influenced by common comorbidities such as diabetes mellitus, obesity, cardiovascular disease, and hypertension (3), as well as postoperative complications - for instance, those occurring after radical prostatectomy (4). Psychogenic factors, including depression, anxiety, occupational stress, and marital discord, may also contribute to the onset of ED (5). Taken together, these organic and psychological determinants have led to a marked rise in ED prevalence, while its impact on psychological well-being and intimate relationships underscores the need for effective therapeutic interventions.

First-line treatments for ED typically include *phosphodiesterase type-5 inhibitors* (PDE5i) and intracavernosal injections (6). While these therapies are effective for many men with mild to moderate ED, a substantial subset of patients exhibits poor response or intolerance to these medications (7). Furthermore, PDE5 inhibitors can cause side effects such as headaches, facial flushing, and hearing disturbances (8), whereas intracavernosal injections may lead to pain, priapism, or fibrosis of the corpora cavernosa (9). For men with refractory ED, penile prosthesis implantation represents a definitive option, yet it is invasive and carries risks including penile pain and nerve injury (10). Beyond pharmacological and surgical options, *vacuum erection devices* (VED) represent a non-invasive alternative that can be used either as monotherapy or in penile rehabilitation. Evidence from post-prostatectomy trials shows that VED improves erectile function and may help limit penile shortening (11). VED is generally safe, with adverse effects usually limited to petechiae, transient discomfort, ecchymosis, or penile numbness (12). However, its long-term effectiveness is hampered by poor compliance, largely because of the device's inconvenience and patients' perceptions of limited efficacy (13). Overall, it offers a well-tolerated option for men who do not respond to or cannot use pharmacologic therapies.

Given these limitations, there is growing interest in less invasive treatment modalities that aim to restore natural erectile function rather than merely alleviating symptoms. *Low-intensity extracorporeal shock wave therapy* (Li-ESWT)

has emerged as a promising approach in this context. Originally introduced to improve vascular function in other clinical settings, Li-ESWT has been applied to ED based on its ability to promote angiogenesis, enhance endothelial function, and stimulate tissue regeneration within the corpora cavernosa (14). Early clinical studies suggest that Li-ESWT may improve erectile function sustainably, offering a therapeutic option that is non-invasive, well-tolerated, and potentially disease-modifying, particularly in patients who are unresponsive to conventional pharmacological therapies (15).

Materials and methods

Study design and population

This prospective observational study enrolled 188 consecutive men diagnosed with vasculogenic ED who had shown inadequate response to PDE5-I therapy. Baseline was in June 2021. Patients took these drugs, either in tablet form or in soft gels.Eligible participants were required to be older than 18 years, and to exhibit an *Erection Hardness Score* (EHS) of 2 or less, despite ongoing PDE5-I treatment. Additionally, all participants underwent penile ultrasonography to confirm the diagnosis of vasculogenic ED and to exclude other potential etiologies.

Patients were excluded if they presented with neurogenic or hormonal causes of ED, a history of pelvic surgery or radiotherapy, severe Peyronie's disease, or psychiatric disorders that could interfere with sexual activity or affect the reliability of patient-reported outcomes. By implementing these stringent inclusion and exclusion criteria, the study aimed to assemble a homogeneous cohort of men with primary vasculogenic ED, ensuring that the observed treatment effects could be confidently attributed to the intervention under investigation.

This careful patient selection allowed for a robust evaluation of Li-ESWT in a real-world population of men with ED refractory to standard pharmacologic therapy, while minimizing potential confounding factors that could otherwise compromise the validity of the study results.

Li-ESWT protocol

All enrolled patients underwent Li-ESWT administered once weekly over a period of six consecutive weeks. During each treatment session, a total of 3000 shocks were delivered using an electrohydraulic shock wave generator, with an energy flux density ranging from 0.10 to 0.15 mJ/mm² and a frequency of 120 shocks per minute. The therapy was applied systematically to both the penile shaft and the crura in order to maximize exposure of the corporal tissue to the mechanical stimulus.

The procedure was well tolerated, and no local or systemic anesthesia was required, reflecting the non-invasive nature of Li-ESWT. Patients were instructed to maintain their usual activities and medications during the treatment period, with no restrictions. The standardized treatment protocol was designed to ensure consistent delivery of energy across all participants, facilitating the evaluation of clinical outcomes while minimizing variability related to procedural technique.

This approach aimed not only to induce microvascular and tissue regenerative effects within the corpora cavernosa but also to provide a safe and reproducible treatment modality for men with erectile dysfunction refractory to pharmacological therapy.

Outcome measures

Clinical outcomes were assessed at baseline, 12 months, and 18 months using validated patient-reported instruments as the IIEF-5 and the *Erection Hardness Score* (EHS). The IIEF-5 is a widely used, self-administered questionnaire that evaluates the severity of erectile dysfunction over the preceding four weeks. It consists of five items focused on the ability to achieve and maintain an erection. Scores range from 5 to 25, with higher scores indicating better erectile function. An increase of three points or more on the IIEF-5 was considered indicative of a clinically meaningful improvement in erectile function.

The *Erection Hardness Score* (EHS) is a single-item scale that measures the rigidity of the penis during sexual activity, ranging from 0 (no enlargement) to 4 (completely rigid and fully penetrable). A score of 3 or higher corresponds to an erection sufficient for vaginal penetration and was therefore considered a positive treatment response. Patients meeting an IIEF-5 increase of ≥ 3 points and/or an EHS ≥ 3 were classified as responders. All adverse events, whether local or systemic, were recorded prospectively throughout the study period. This systematic assessment allowed for a comprehensive evaluation of both the efficacy and safety of Li-ESWT over an extended follow-up period, providing robust and clinically relevant outcome measures.

Statistical analysis

Continuous data are presented as mean ± SD. Differences between baseline and follow-up were analyzed using paired t-test or Wilcoxon signed-rank test. Categorical data were compared with chi-square or Fisher's exact test. Subgroup analyses evaluated the influence of age (< 45 *vs* ≥ 45 years), ED duration (< 12 *vs* ≥ 12 months), and baseline severity (moderate vs severe).

Multivariate logistic regression was used to identify independent predictors of response.

All analyses were performed using SPSS v27.0 (*IBM Corp., Armonk, NY*), with significance set at $p < 0.05$.

Results

Baseline characteristics

The study cohort consisted of 188 men diagnosed with vasculogenic ED who were refractory to optimal PDE5-I therapy. The mean age of participants was 66.6 years, with an age range spanning from 30 to 84 years, reflecting a broad representation of adult men affected by this condition. The mean duration of erectile dysfunction prior to enrollment was 24 months whith a range from 5 to 42, indicating a population with chronic and persistent disease.

All participants had a confirmed diagnosis of vasculogenic ED, as assessed by penile ultrasonography, and demonstrated insufficient response to PDE5-I therapy

despite adherence to recommended dosing regimens. The cohort also included men with varying degrees of disease severity, providing an opportunity to evaluate the efficacy of Li-ESWT across a spectrum of clinical presentations. These baseline characteristics offer important context for interpreting subsequent treatment outcomes and underscore the clinical relevance of evaluating novel, non-invasive therapies in patients with long-standing and pharmacologically resistant ED.

Efficacy

Treatment with Li-ESWT resulted in significant improvements in erectile function as measured by validated outcome tools (Table 1).

Table 1.
Mean IIEF, Mean EHS, Side effects follow-up.

Time (month)	Mean IIEF	Mean EHS	Side effects
0	11	1	0
12	21	4	0
18	18	3	0

The mean IIEF-5 score increased from 11 at baseline to 21 at 12 months, representing a substantial and clinically meaningful improvement in erectile function. At the 18-month follow-up, the mean IIEF-5 score was 18, a modest decline was observed relative to the 12-month assessment, suggesting some attenuation of the therapeutic effect over time (Figure 1).

Similarly, the *Erection Hardness Score* (EHS) demonstrated marked improvement, with 134 patients (71%) achieving erections sufficient for penetration at 12 months. Of these, 102 patients (54%) maintained their response at 18 months, indicating a sustained benefit in a majority of responders, albeit with partial reduction over extended follow-up (Figure 2). Consequently, the overall responder rate, defined as achieving an IIEF-5 increase of ≥ 3 points and/or an EHS ≥ 3, was 65% at 12 months and 54% at 18 months, highlighting the durable yet gradually waning efficacy of Li-ESWT in this patient population.

Figure 1.
Mean IIEF follow-up.

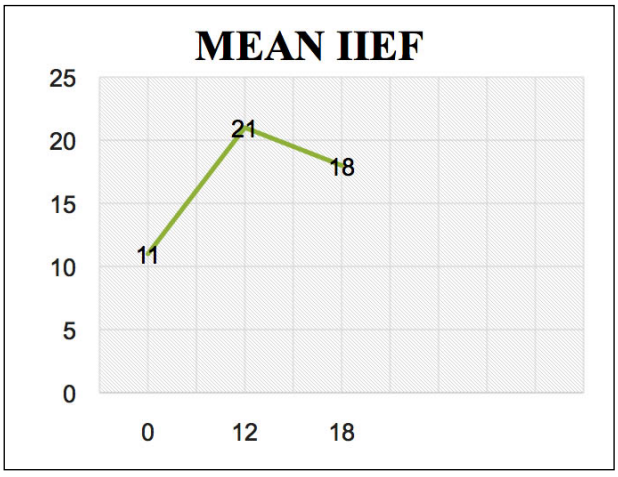
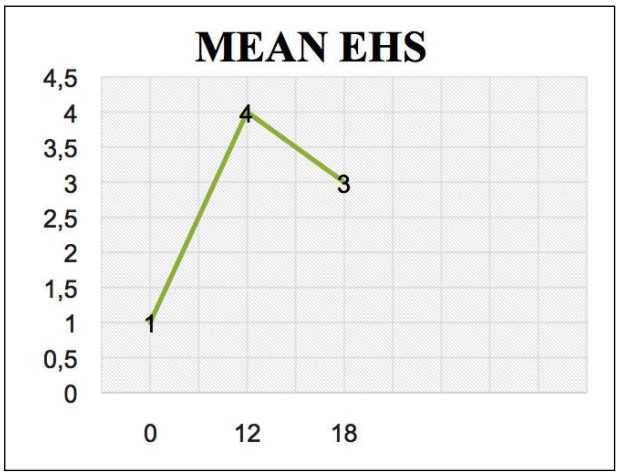


Figure 2.
Mean EHS follow-up.



Predictors of response

Subgroup analyses showed that younger age and shorter duration of ED were associated with higher likelihood of treatment success. Men younger than 45 years had an 82% response rate, compared with 59% in older patients. Patients with a shorter duration of ED (< 12 months) had a 12-month responder rate of 73% and an 18-month responder rate of 57%, whereas those with longer-standing ED (≥ 12 months) had rates of 63% and 54%, respectively.

Baseline severity also influenced outcomes: patients with moderate ED achieved a 12-month responder rate of 69% and an 18-month rate of 55%, while patients with severe ED had rates of 61% and 53%, respectively. Multivariate analysis confirmed that younger age and shorter ED duration were independent predictors of a favorable response. These results provide a clear overview of treatment success across subgroups defined by ED duration and severity.

Safety

Li-ESWT was well tolerated, and no treatment-related adverse events were reported throughout the study period. All participants completed the full course of therapy and the 12- and 18-month follow-up assessments. These findings underscore the excellent safety profile of Li-ESWT, reinforcing its suitability as a minimally invasive treatment option for men with vasculogenic ED refractory to conventional pharmacologic therapy.

Discussion

The present prospective observational study provides additional evidence supporting the clinical value of Li-ESWT in men with vasculogenic ED refractory to PDE5-Is. Our findings demonstrate that Li-ESWT yields significant functional improvements at 12 months, with partial yet sustained benefits persisting at 18 months. These clinical outcomes are consistent with previous reports sug-

gesting that the therapeutic efficacy of Li-ESWT is mediated by durable regenerative processes within penile tissues, particularly involving neovascularization, endothelial repair, and nerve regeneration in the corpus cavernosum.

Several experimental and translational studies support the biological plausibility of these effects. Prior research has shown that Li-ESWT can enhance penile blood supply, although the exact mechanisms are still being elucidated. In vitro and animal models indicate that shock waves promote neovascularization through upregulation of angiogenic biomarkers and vascular remodeling. This regenerative response has been attributed to increased cell proliferation, endothelial repair, and cavernosal tissue regeneration. Correspondingly, LI-ESWT is thought to stimulate neovascularisation, improve penile microcirculation, and enhance oxygenation by inducing mechanical shear forces that trigger the release of growth factors such as VEGF and *endothelial nitric oxide synthase* (eNOS) (16). Animal models of diabetic and nerve-injury-induced ED similarly demonstrate endothelial and smooth muscle regeneration following Li-ESWT (17), although the role of *neuronal nitric oxide synthase* (nNOS) remains debated (18). Additional evidence indicates that Li-ESWT may facilitate nerve repair, with reports of regeneration of damaged nerve fibers mediated by VEGF and transforming growth factor-β pathways (19).

Beyond angiogenesis and neuroregeneration, shock wave-induced microtrauma may activate endogenous repair mechanisms, including recruitment of stem cells and initiation of tissue remodeling (20). Clinical evidence has further demonstrated increased neovascularization in functional penile arteries following Li-ESWT (21).

Another potential downstream effect involves upregulation of neuronal and endothelial nitric oxide synthase, leading to sustained increases in nitric oxide, a key mediator of cavernosal smooth muscle relaxation (22). Li-ESWT has also been shown to modulate sympathetic tone in the corpus cavernosum, reducing age- and diabetes-related hyperactivity through altered expression of α-adrenergic receptors (23), thereby improving hemodynamic function.

Taken together, these biological mechanisms offer a coherent explanation for the improvements we observed in erectile function, supporting the hypothesis that Li-ESWT acts as a regenerative therapy capable of addressing the vascular and neurogenic deficits underlying vasculogenic ED.

A key observation in our cohort is the marked improvement in IIEF-5 scores from baseline to 12 months, accompanied by a significant increase in EHS, with 71% of patients achieving clinically relevant erection hardness. These findings are consistent with earlier clinical trials showing that Li-ESWT enhances sexual function by promoting penile hemodynamics and improving cavernosal blood flow. Several studies have confirmed similar response rates in PDE5-I non-responders, reinforcing the concept that shockwave therapy targets the underlying vasculogenic pathology rather than merely alleviating symptoms.

Despite the encouraging mid-term outcomes, we observed a progressive decline in treatment efficacy at 18 months, with responder rates decreasing from 65% to 54%. This trajectory mirrors previously reported patterns, where initial improvements tend to attenuate over time, possibly due to progressive vascular aging, ongoing endothelial dysfunction, or the cumulative impact of comorbidities. Nonetheless, more than half of the treated men maintained clinically meaningful benefits at 18 months, supporting the notion that Li-ESWT provides sustained but not permanent functional recovery.

Our analysis also identified younger age and shorter ED duration as independent predictors of therapeutic response (24). These findings indicate that early-stage vasculogenic ED, before extensive structural degeneration of penile tissues, responds more favorably to regenerative modalities. Younger patients may possess greater vascular plasticity and better endothelial recovery potential, while a shorter disease course may reflect less fibrotic remodeling of the corpus cavernosum. From a clinical standpoint, these insights underscore the importance of timely intervention. Of particular relevance, these observations are in line with randomized placebo-controlled evidence demonstrating that ESWT produces significantly greater improvements in erectile function than placebo in relatively young men with mild vasculogenic ED, thereby reinforcing that age and disease chronicity strongly influence treatment responsiveness (25).

Multiple clinical studies consistently report the absence of significant complications. A meta-analysis of eight randomized controlled trials including 595 patients demonstrated significant improvements in IIEF and EHS scores, with no adverse events reported (26). Similarly, a systematic review assessing short-term outcomes found no treatment-related complications across all included trials (27). Overall, these findings reinforce that Li-ESWT has a strong safety profile, with available clinical evidence showing no meaningful adverse effects in controlled settings.

Similarly, Li-ESWT demonstrated an excellent safety profile in our population, with no adverse events reported and full adherence to follow-up. This aligns with the current body of evidence positioning Li-ESWT as a minimally invasive, well-tolerated therapy with a complication rate substantially lower than that of intracavernosal injections or penile prostheses (27). Its non-invasive nature and absence of systemic side effects make it an attractive option particularly for men who are unable or unwilling to use pharmacological therapies. Notably, these observations are supported by a double-blind, sham-controlled randomized trial in which no patients reported pain or other adverse events throughout treatment and follow-up (28).

Nevertheless, the study is subject to limitations intrinsic to its design. The absence of a control group prevents definitive causal inference, and the reliance on patient-reported outcome measures, while validated, introduces subjectivity. Additionally, objective functional assessments such as post-treatment penile Doppler parameters were not performed, limiting mechanistic interpretation. Finally, although an 18-month follow-up provides meaningful mid-term data, long-term durability beyond this timeframe remains uncertain.

Future randomized controlled trials with standardized treatment protocols, sham controls, and extended follow-up periods are essential to refine patient selection criteria and identify optimal dosing parameters. Studies integrating combination therapies, such as Li-ESWT with PDE5-

Is or biological treatments like platelet-rich plasma, may further clarify strategies to enhance and prolong therapeutic efficacy.

Conclusions

Li-ESWT is a safe and effective treatment for men with vasculogenic erectile dysfunction unresponsive to PDE5-Is. Significant improvements in erectile function were observed at 12 months, with a majority of patients maintaining clinically relevant benefits at 18 months. Younger age and shorter duration of ED were associated with superior outcomes, highlighting the potential value of early intervention.

Further multicenter randomized trials are needed to refine treatment protocols, clarify patient selection, and assess long-term efficacy, in order to establish Li-ESWT as a reliable, minimally invasive option in routine clinical practice.

Declarations

Ethical approval and consent for participate: *This study did not require formal approval from an Ethics Committee according to local regulations, as it involved a non-experimental therapeutic procedure routinely used in clinical practice. However, all participants provided written informed consent prior to undergoing Li-ESWT, after receiving a detailed explanation of the treatment, its mechanism of action, expected benefits, potential risks, and alternative therapeutic options. The consent form specifically described the biological effects of low-intensity shock waves, the treatment procedure, the expected outcomes, and the possible side effects. All procedures were carried out in accordance with the principles of the Declaration of Helsinki.*

Consent for publication: *Not applicable.*

Availability of data and material: *The clinical datasets generated and analyzed during this study are not publicly available due to patient confidentiality and institutional data protection policies. Nevertheless, anonymized data supporting the findings of this study are available from the corresponding author upon reasonable request.*

Competing interests: *The authors declare that they have no competing interests.*

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Authors' contributions: *Conception and Design: Giuseppe Saitta and Giuseppe Di Paola contributed to the conception and design of the study and were involved in the interpretation of the data; Manuscript Drafting: Simone Di Salvatore and Benedetto Calabrese drafted the manuscript and contributed to its critical revision for important intellectual content; Critical Revision: Franco Mantovani, Attilio Luigi Meazza, and Mauro Seveso critically revised the manuscript, providing substantial intellectual input and ensuring the accuracy of the scientific content; Final Approval and Accountability: All authors reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately addressed.*

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Correspondence

Giuseppe Saitta (Corresponding Author)
gsaitta@hotmail.it
ICCS Milano, Istituto Clinico Città Studi, Milano, Italy
via Palmanova 72, 20132, Milan (Italy)

Giuseppe Di Paola
giuseppe.dipaola@ic-cittastudi.it
Andrea Simone Ceresoli
andrea.ceresoli@ic-cittastudi.it
Franco Mantovani
franco.mantovani@ic-cittastudi.it
Attilio Luigi Meazza
attilio.meazza@ic-cittastudi.it
Mauro Seveso
mauro.seveso@ic-cittastudi.it
ICCS Milano, Istituto Clinico Città Studi, Milano, Italy

Simone Di Salvatore
simone.disalvatore@ic-cittastudi.it
Benedetto Calabrese
benedetto.calabrese@ic-cittastudi.it
IRCCS Humanitas Research Hospital, Rozzano, Milan, Italy