# The Efficacy of Low Intensity Shock Wave Therapy (LI-SWT) in Treating Erectile **Dysfunction: A Single Center Study**

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#### **Abstract**

Objective: To evaluate the effectiveness of low intensity shock wave therapy (LI-SWT) in the treatment of erectile dysfunction

Material and Methods: After ethics committee approval, male patients who applied to our clinic between March 2021 and July 2024 with the complaint of erectile dysfunction were retrospectively screened. Clinical data of 63 patients who met the inclusion criteria and underwent LI-SWT treatment were reviewed. Age, body mass index, International Index of Erectile Function (IIEF-5) and Erectile Hardness Score (EHS) score before LI-SWT treatment, previous erectile dysfunction treatment, smoking and alcohol use, benign prostatic hyperplasia (BPH) status and comorbidities were recorded. IIEF-5 and EHS scores at 3 and 6 months after LI-SWT were recorded and compared statistically. Subgroup analyses were also carried out according to comorbidities.

Results: Statistically significant improvements were observed in both IIEF-5 and EHS scores following Li-ESWT. The median IIEF-5 score increased from 13.0 at baseline to 15.0 at 3 months and 20.0 at 6 months post-treatment (p < 0.001). Similarly, the median EHS improved from 2.0 pre-treatment to 3.0 at 6 months (p < 0.001). Also significant improvements in IIEF-5 and EHS scores were observed across all subgroups at 6 months post-treatment

Conclusion: LI-SWT can be effective first line treatment option especially in mild and moderate erectile dysfunction. It can be used alternative to phosphodiesterase-5 (PDE-5) inhibitor treatment. In addition, it can be considered as single or combined with PDE-5 inhibitor treatment in severe erectile dysfunction patients with comorbid diseases.

Keywords: erectile dysfunction, EHS, IIEF-5, low intensity shock wave therapy (LI-SWT)

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#### INTRODUCTION

Erectile dysfunction is the inability to get or maintain an erection long enough to have sexual intercourse. The first line treatment for erectile dysfunction is phosphodiesterase-5 (PDE-5) inhibitor treatment (1). In patients unresponsive to PDE inhibitör treatment, intracavernosal injection therapy and penile prosthesis implantation can be prefered. But these treatment options are invasive and may not be applied to patient with comorbidities (2). In recent years, clinical use of regenerative treatment methods such as low intensity shock wave therapy (LI-SWT), platelet-rich plasma (PRP) and stem cells has increased with technological developments (3).

LI-SWT is a treatment modality that has been increasingly used in the treatment of erectile dysfunction. The mechanism of action of LI-SWT is endothelial cell proliferation, neoangiogenesis, reduction of smooth muscle atrophy, nerve regeneration and stem cell activation (4,5). Due to this mechanism of action, shock wave therapy has been used in musculoskeletal system diseases, diabetic ulcers and cellulitis for many years (6,7). The areas of use of LI-SWT in urology are mainly erectile dysfunction treatment, peyronie's disease and chronic prostatitis treatment (8). In current guidelines, LI-SWT treatment is recommended with a low recommendation level for patients with mild vasculogenic erectile dysfunction (9). In this study, we aimed to evaluate the efficacy of LI-SWT in patients with erectile dysfunction.

#### MATERIAL AND METHODS

# **Work Design**

The ethics committee approval of the study was obtained from Ordu University Non-Interventional Scientific Research Ethics Committee (Decision No: 2025/33, Date: 2025-02-07). After ethics committee approval, male patients who applied to our clinic between March 2021 and July 2024 with the complaint of erectile dysfunction were retrospectively screened. Clinical data of 63 patients who met the inclusion criteria and underwent LI-SWT treatment were reviewed. Data were extracted from medical records and questionnaires. In our clinic, Index of Erectile Function (IIEF-5) and Erectile Hardness Score (EHS) questionnaires are routinely performed at the time of diagnosis and during follow-up period. Age, body mass index, IIEF-5 and EHS scores before LI-SWT treatment, previous erectile

dysfunction treatment, smoking and alcohol use, benign prostatic hyperplasia (BPH) status and comorbidities were recorded. IIEF-5 and EHS scores were recorded at 3 and 6 months after LI-SWT.

#### **Inclusion and Exclusion Criteria**

Patients who were over 20 years of age, had regular sexual intercourse for more than 3 months, had an IIEF-5 score between 5-21 (mild, moderate, severe erectile dysfunction) and had erectile dysfunction for more than 6 months were included in our study. Testosterone replacement therapy, history of pelvic radiotherapy, history of anti-androgen hormone therapy, history of bilateral orchiectomy, use of 5-alpha reductase inhibitors, anatomical pathology in the penis or history of penile fracture, diagnosis of haemotological malignancy, spinal cord injury, polyneuropathy, stroke or neurodegenerative disease (Multiple Sclerosis, Parkinson, Multiple Atrophy), drug-induced erectile dysfunction (antipsychotics, anticonvulsives, antidepressants, thiazide diuretics, beta blockers) are exclusion criteria.

#### **Treatment Protocol**

The device used in LI-SWT treatment in our clinic is Modus ED-SWT (Inceler Medikal, Ankara, Turkiye) (Figure 1). We determined our treatment protocol as a total of 6 sessions with 3 day intervals. All sessions were done by the same clinican in outpatient clinic without anaesthesia. In order to prevent energy loss that may occur during shock wave therapy, we first applied ultrasound gel to the treatment areas. In each session, we applied 300 shock waves to 5 different regions of the penis (proximal and distal part of right corpus cavernosum, proximal and distal part of left corpus cavernosum and mid-dorsal penile region) with a total of 1500 shock waves per session (Figure 2). The frequency of the applied shock waves is 2/second and has a power of 0.15 mJ/mm<sup>2</sup>. Focal depth and penetration of Modus ED-SWT are 28.5 mm and 68.5 mm (Figure 3). Session durations were approximately 15-20 minutes. We do not discontinue anticoagulant therapy prior to LI-SWT, as there are no contraindications.

#### Statistical Analysis

Data analysis was performed using IBM SPSS Statistics version 22 (IBM Corp. Armonk, NY, USA). Continuous variables were presented as means ± standard deviations

depending on data distribution. Categorical variables were expressed as frequencies and percentages. The Wilcoxon signed-rank test was used to compare paired non-parametric data, including changes in IIEF-5 and EHS scores before and after treatment. Subgroup analyses were also performed using the Wilcoxon test to assess treatment response across clinical variables such as diabetes mellitus (DM), benign prostatic hyperplasia (BPH), cardiovascular disease (CVD) history and PDE-5 inhibitor use. A two-tailed p-value of <0.05 was considered statistically significant.



Figure 1. Modus ED-SWT device

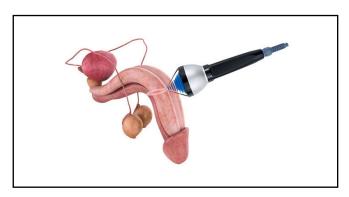


Figure 2. Application of LI-SWT



Figure 3. Penetration and depth of Modus ED-SWT

## **RESULTS**

The mean age of the participants was  $51.90 \pm 13.06$  years. Regarding body mass index, the majority were classified as normal weight (42.9%) and overweight (25.4%). The most common comorbidities included DM (33.3%), BPH (36.5%), hypertension (HT) (28.6%), CVD (22.2%), and hyperlipidaemia (20.6%). 30 (47.6%) patients had unresponsive treatment history to PDE-5 inhibitors. All demographic features of patients were summarised in table 1.

**Table 1.** Baseline characteristics and erectile function scores of the study population (n = 63)

the study population (ii = 65)					
	Value				
Age (years) (Mean±Sd)	51.90 ± 13.06				
BMI, n (%)					
- Underweight	12 (19.0%)				
- Normal weight	27 (42.9%)				
- Overweight	16 (25.4%)				
- Obese	8 (12.7%)				
Comorbidities, n (%)					
- Diabetes Mellitus	21 (33.3%)				
- Hypertension	18 (28.6%)				
– Hyperlipidemia	13 (20.6%)				
- Cardiovascular Disease History	14 (22.2%)				
- History of BPH	23 (36.5%)				
Lifestyle factors, n (%)					
- Smoking	33 (52.4%)				
- Alcohol Consumption	27 (42.9%)				
Previous treatment					
- Unresponsive to PDE-5 inh treatment	30 (47.6%)				
- No previous treatment	33 (52.4%)				

BMI: Body Mass Index, BPH: Benign Prostatic Hyperplasia, PDE-5 inh: Phosphodiesterase 5 inhibitor

Statistically significant improvements were observed in both IIEF-5 and EHS scores following Li-ESWT. Pre-treatment median IIEF-5 score was 13.0. Post-treatment 3th and 6th month IIEF-5 scores was 15 and 20 respectively There was statistically significant difference between pre-treatment, post-treatmant 3th and 6th months IIEF-5 scores (p < 0.001). In addition, pre-treatment median EHS score was

2.0. Post-treatment 6th month EHS score was 3.0. There was statistically significant difference between pre-treatment and post-treatmant 6th months EHS scores (p < 0.001). (Table 2). Before treatment, 30 (%48) patients have severe, 23 (%36) patients have modarete and 10 (%16) patients have mild erectile dysfunction. 6 months after LI-SWT treatment 4 (%6) patients have severe, 28 (%45) patients have modarete, 13 (%20) patients have mild and 18 (%29) patients have no erectile dysfunction. 4 patients from severe and 5 patients from modarete erectile disfunction group have no benefit after LI-SWT.

Significant difference in IIEF-5 and EHS scores were observed across all subgroups at 6 months post-treatment. There was statistically significant difference between pretreatment and post-treatment 6th month IIEF-5 scores

in patients with DM and without DM (p = 0.001 and p < 0.001 respectively). Also, significant diffrence between pretreatment and post-treatment IIEF-5 scores was detected in patients with BPH and without BPH (p < 0.001 respectively). In addition, both PDE-5 inhibitor users and non-users had statistically significant increase between pre-treatment and post-treatment 6th month IIEF-5 scores (p < 0.001 respectively). There was statistically significant increase in post-treatment 6th month IIEF-5 scores in patients with CVD (p = 0.008). In terms of erection hardness, There was statistically significant increase in post-treatment 6th month EHS scores in patients with DM, BPH or CVD (p < 0.001 respectively). (Table 3). 6 out of 9 patients who did not benefit from LI-SWT treatment have DM, CVD and BPH diseases. One patient has uncontrolled DM while the other 2 patients have CVD.

Table 2. Comparison of IIEF-5 and EHS scores before and after Li-ESWT treatment

	Pre-treatment Median	Post-treatment Median	Wilcoxon Z Value	p*
IIEF-5 (Pre vs 3 <sup>rd</sup> months)	13.0	15.0	0.0	< 0.001
IIEF-5 (Pre vs 6th months)	13.0	20.0	1.5	< 0.001
EHS (Pre vs 3 <sup>rd</sup> months)	2.0	2.0	0.0	< 0.001
EHS (Pre vs 6th months)	2.0	3.0	0.0	< 0.001

<sup>\*:</sup> Wilcoxon Test. EHS: Erection Hardness Score, IIEF-5: International Index of Erectile Function-5

Table 3. Subgroup analyses of IIEF-5 and EHS scores before and after LI-SWT treatment

	DM (+)	DM (-)	BPH (+)	BPH (-)	PDE-5i (+)	PDE-5i (-)	CVD (+)	CVD (-)
IIEF-5 (Preop)	11.0	14.0	12.0	14.0	13.5	12.0	9.0	14.0
IIEF-5 (Postop 6th months)	17.0	20.5	16.0	21.0	19.0	21.0	15.0	21.0
Z (IIEF-5)	0.0	1.5	0.0	1.5	1.5	0.0	0.0	1.5
p* (IIEF-5)	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	0.008	<0.001
EHS (Preop)	1.0	2.0	1.0	2.0	2.0	2.0	1.0	2.0
EHS (Postop 6th months)	3.0	3.0	3.0	3.0	3.0	3.0	2.0	3.0
Z (EHS)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
p* (EHS)	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

<sup>\*:</sup> Wilcoxon Test, EHS: Erection Hardness Score, IIEF-5: International Index of Erectile Function-5, DM: Diabetes Mellitus, BPH: Benign Prostatic Hyperplasia, CVD: Cardiovascular Disease, PDE-5i: Phosphodiesterase type 5 inhibitors

#### **DISCUSSION**

In our study, a significant response to treatment was observed at the 3rd month after the procedure in patients who underwent LI-SWT for erectile dysfunction. Treatment response continued to increase when the 6th month results were evaluated. The results of this study show that treatment efficacy was significantly higher in patients with DM, CVD and BPH. Another important result of our study is that LI-SWT treatment is effective in patients with PDE-5 inhibitor refractory erectile dysfunction. On the other hand, none of patient had treatment related complications.

The mechanism of action of LI-SWT has been studied in preclinical studies. In one of these studies demonstrated that endothelial cell regeneration and angiogenesis was increased as a result of nNOS, eNOS and VEGF activation (9). In another study, Ling G et al. found that schwann cell proliferation was increased via increased angiogenesis and activation of tissue regeneration in the penis of rats treated with LI-SWT in an age-induced erectile dysfunction model (10). The increase in angiogenesis has made LI-SWT valuable treatment option in vasculogenic type erectile dysfunction. In a systematic review of 11 studies by Brunchorst O et al, they found an average IIEF increase of 5.3 points in the 6th month after LI-SWT treatment in 799 vasculogenic erectile dysfunction patients (11). In a prospective study published in 2021 involving 66 patients, a significant increase was found in the 3rd and 6th month IIEF evaluations after LI-SWT treatment compared to the placebo group and it was stated that LI-SWT may be a useful treatment option especially in younger patients with mild vasculogenic erectile dysfunction (12). In our study the IIEF-5 values increased from 13.09  $\pm$ 4.04 before LI-SWT to 14.77 ± 3.96 in the 3rd month and  $18.53 \pm 5.03$  in the 6th month after the procedure, showing a statistically significant increase. In addition, the mean EHS score, which was 1.47 ± 0.83 before LI-SWT, increased to  $2.25 \pm 0.94$  at 3 months and  $3.07 \pm 0.92$  at 6 months after the procedure.

The patient groups in which LI-SWT treatment is most frequently used in daily clinical practice are those who are unresponsive to PDE-5 inhibitor treatment, who cannot continue PDE-5 inhibitor treatment. Up to 50 per cent of those with severe erectile dysfunction due to comorbid diseases especially DM and CVD, do not benefit from PDE-

5 inhibitor treatment (13) LI-SWT is one of the treatment modalities to be used in this patient group. In a prospective multicentric study, significant differences were found in IIEF-5, EHS and SQOL (Sexual Quality of Life-Male) indexes and penile doppler ultrasound results after LI-SWT applied to patients unresponsive to PDE-5 inhibitor treatment (14). According to our study results, the mean IIEF-5 score increased from 13.5 to 19, while the EHS score increased from 2 to 3 on average after LI-SWT treatment in the PDE-5 inhibitor unresponsive patient group. LI-SWT treatment is an alternative treatment for PDE-5 inhibitor refractory patients and has been shown to increase the efficacy of PDE-5 inhibitor treatment. Ibis MA et al. obtained higher IIEF-5 and EHS scores in patients who received PDE-5 inhibitor treatment combined with LI-SWT compared to those who received only LI-SWT treatment (15). These results further support that LI-SWT can be used as an alternative treatment method for patients who can not use PDE-5 inhibitor.

Intracavernosal injection therapy and vacuum erection devices, which are alternative treatment methods used in the treatment of erectile dysfunction, cause treatment non-compliance in patients because these are invasive treatment options. The last-line treatment method of erectile dysfunction is penile prosthesis implantation. This is a high cost treatment option and has some crucial complications such as prosthesis infection and mechanical problems (16).

In addition to treatment efficacy, LI-SWT also has different advantages in clinical use. Low side effect profile, noninvasiveness, reapplication, painless procedure and easy application are the most important advantages. Also Its relatively low cost compared to alternative treatment methods in patients with long-term effect is another advantage. Because of these advantages, it has started to be used in patients with non-vasculogenic type erectile dysfunction. In a systematic review of 9 clinical and 10 animal studies, Mason MM et al. stated that LI-SWT treatment is a safe and effective treatment method in patients with moderate erectile dysfunction with controlled DM (17). In another systematic review involving patients with erectile dysfunction after radical prostatectomy, the potential therapeutic effect of SWT treatment has been emphasised (18). Apart from erectile dysfunction, recent studies showed that LI-SWT is also effective in patients with chronic prostatitis and

peyronie's disease (19,20).

One of the most important clinical problems related to LI-SWT treatment is the lack of standardisation. In clinical practice, there are different devices. Also, number of sessions, session intervals, frequency, number of pulses and power applications are not certain yet. On the other hand there is still not certain indications of LI-SWT. Although the European Society of Urology recommends LI-SWT treatment in patients with mild vasculogenic erectile dysfunction, we think that the current recommendations may change as preclinical and clinical studies increase. Ghahhari J et al. (21) reported in their multicentric study that LI-SWT treatment is an effective and safe treatment method independent of device type, power, frequency, treatment protocol and erectile dysfunction type.

The first limitation of our study is its retrospective design, which is inherently prone to selection bias and unmeasured confounding. In addition, the relatively small sample size may have reduced the statistical power, particularly in subgroup analyses. Another limitation is the lack of long-term follow-up data, which prevented us from evaluating the sustained efficacy of LI-SWT. Moreover, if penile doppler ultrasonography findings available, they could have contributed to the evaluation of LI-SWT success. Finally, many patients had comorbidities requiring various medications, which may have influenced treatment outcomes and complication rates.

#### **CONCLUSIONS**

According to our retrospective short-term results, LI-SWT can be effective first line treatment option especially in mild and moderate erectile dysfunction. It can be used alternative to PDE-5 inhibitor treatment. In addition, it may be considered as single or combined with PDE-5 inhibitor treatment in severe erectile dysfunction patients with comorbid diseases. Surely, prospective larger scaled randomized controlled studies with a long follow-up period will contribute to the establishment of ideal protocols regarding the indication and application method of LI-SWT treatment.

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**Informed Consent:** Informed consent was obtained from all participants included in the study

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**Ethical Approval:** The ethics committee approval of the study was obtained from Ordu University Non-Interventional Scientific Research Ethics Committee (Decision No: 2025/33)

**Author Contributions:** Concept and Design: EO, MK. Supervision: MK. Data Collection and/or Analysis: EO. Analysis and/or Interpretation: EO, MK. Literature Search: EO. Writing: EO, MK. Critical Review: MK.

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