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ORIGINAL RESEARCH

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Can Li-ESWT in the treatment of mild and mild/moderate erectile dysfunction affect the sexual functions of male patient and female partner?

Engin Özbay[1,*]

[1]Urology Department, Private Osmaniye İbni Sina Hospital, 80000 Osmaniye, Türkiye

***Correspondence**
enozbay63@gmail.com
(Engin Özbay)

Abstract

Background: This study retrospectively evaluated the efficacy of low-intensity extracorporeal shock wave therapy (Li-ESWT) in the treatment of mild and mild/moderate erectile dysfunction (ED) and compared changes in sexual function parameters of couples before and after the procedure. **Methods**: This study included 32 couples. The five-item International Index of Erectile Function (IIEF-5), the Erection Hardness Scale (EHS), and the male Arizona Sexual Experiences Scale (mASEX) were administered to patients who presented to the urology outpatient clinic with mild and mild/moderate ED. In addition, the female Arizona Sexual Experiences Scale (fASEX) was by their partners before the procedure. All male patients then underwent Li-ESWT. At the sixth month after the procedure, IIEF-5, EHS, and mASEX were again completed by the male patients, while fASEX was completed by their female partners. Pre-procedure and post-procedure values were compared statistically. **Results**: The differences between pre- and post-procedure IIEF-5 and EHS scores of male patients were statistically significant ($p < 0.05$). The total mASEX score and four sub-scores of male patients decreased compared to pre-procedure levels, and the differences were statistically significant ($p < 0.05$). However, the difference in the psychological stimulation score was not statistically significant ($p > 0.05$). The total fASEX score and all sub-scores of female partners decreased after the procedure compared to pre-procedure scores, and these differences were statistically significant ($p < 0.05$). The decrease in the number of cases of male/female sexual dysfunction in both groups after the procedure was also significant ($p < 0.05$). **Conclusions**: In young patients with mild or mild/moderate ED, Li-ESWT resulted in a high treatment success rate at six months after the procedure. Furthermore, both male and female sexual dysfunction improved simultaneously, with improvements observed in all female sexual function parameters. In male patients, improvements were observed in four different sexual functions, while psychological stimulation remained unchanged.

Keywords

Li-ESWT; Male patient; Female partner; mASEX; fASEX; IIEF-5; EHS; Erectile dysfunction; Sexual dysfunction

Puede Bi-TOCE en el tratamiento de la disfunción eréctil leve y leve/moderada afectar la función sexual del paciente masculino y su pareja femenina?

Resumen

Antecedentes: Este estudio evaluó retrospectivamente la eficacia de baja intensidad: terapia con ondas de choque extracorpóreas (Bi-TOCE) en el tratamiento de la disfunción eréctil (DE) leve y leve/moderada y comparó los cambios en los parámetros de función sexual de las parejas antes y después del procedimiento. **Métodos**: Este estudio incluyó a 32 parejas. Se aplicaron a los pacientes masculinos el Índice Internacional de Función Eréctil de cinco ítems (IIEF-5), la Escala de Dureza de la Erección (EHS) y la Escala de Experiencias Sexuales de Arizona masculina (mASEX). Además, la Escala de Experiencias Sexuales de Arizona femenina (fASEX) fue completada por sus parejas antes del procedimiento. Todos los pacientes masculinos se sometieron a Bi-TOCE. Al sexto mes posterior al procedimiento, los pacientes completaron nuevamente IIEF-5, EHS y mASEX, mientras que sus parejas femeninas completaron fASEX. Los valores pre- y post-procedimiento se compararon estadísticamente. **Resultados**: Las diferencias entre los puntajes pre- y post-procedimiento de IIEF-5 y EHS de los pacientes masculinos fueron estadísticamente significativas ($p < 0.05$). La puntuación total de mASEX y cuatro subpuntuaciones de los pacientes masculinos disminuyeron en comparación con los niveles pre-procedimiento, siendo estas diferencias estadísticamente significativas ($p < 0.05$). Sin embargo, la diferencia en la subpuntuación de estimulación psicológica no fue significativa ($p > 0.05$). La puntuación total del fASEX y todas las subpuntuaciones de las parejas femeninas disminuyeron respecto a los puntajes previos al procedimiento, siendo estas diferencias estadísticamente significativas ($p < 0.05$). La disminución en el número de casos de disfunción sexual (DS) masculina y femenina en ambos grupos después del procedimiento también fue significativa ($p < 0.05$). **Conclusiónes**: En pacientes jóvenes con DE leve o leve/moderada, Bi-TOCE resultó en una alta tasa de éxito terapéutico a los seis meses del procedimiento. Además, tanto los hombres como las mujeres con DS mostraron una mejoría simultánea y se observaron mejoras en todos los parámetros de la función sexual femenina. En los pacientes masculinos, se observaron mejoras en cuatro funciones sexuales diferentes, mientras que la estimulación psicológica permaneció sin cambios.

Palabras Clave

Bi-TOCE; Paciente masculino; Pareja femenina; mASEX; fASEX; IIEF-5; EHS; Disfunción eréctil; Disfunción sexual

1. Introduction

Erectile dysfunction (ED) is considered a male sexual dysfunction (mSD) due to the inability to achieve or maintain penile erection function [1]. mSD also includes lack of sexual desire or interest, sexual stimulation disorders, orgasm disorders, and pain disorders. ED constitutes a significant proportion of mSD. The causes of mSD may appear alone or in combination with other factors [1, 2].

ED is classified as mild, mild-moderate, moderate, or severe according to severity, and both physical and psychosocial health of the male patient are affected depending on the ED type [2, 3]. Therefore, sexual dysfunction (SD) may also be observed in the female partner of a male patient with ED [4]. Female SD (fSD) may manifest as sexual reluctance, lack of stimulation, orgasm disorders, vaginal dryness, and genito-pelvic pain/penetration disorder. The sexual quality of life is higher among couples without SD [4, 5].

The etiology of ED includes vasculogenic, neurogenic, anatomic, hormonal, drug-induced, psychogenic, and traumatic causes. Eliminating these causes plays an important role in the treatment of ED [1]. Current ED treatment options include lifestyle changes, phosphodiesterase type 5 inhibitors (PDE5i), topical/intraurethral alprostadil, vacuum devices, low-intensity extracorporeal shock wave therapy (Li-ESWT), and penile prosthesis implantation [6].

Li-ESWT has been used for the treatment of ED for the past two decades, but it has gained increasing popularity in the last decade. But there is no standardized treatment protocol for Li-ESWT application in ED. Li-ESWT appears to be a potential treatment option, particularly for patients who respond poorly to oral medications and prefer to avoid more invasive procedures [7]. Reported success rates of Li-ESWT range between 60% and 80% [8]. These rates may vary depending on the type of ED, patient age, and the energy density or pulse parameters of the Li-ESWT device used [7, 8].

This study aimed to re-evaluate male patients' ED complaints after receiving Li-ESWT as primary treatment for mild or mild/moderate ED and to present the changes in sexual function parameters of both male patients and their female partners during this period.

2. Methods

In this study, 32 male patients with either mild or mild/moderate ED underwent Li-ESWT as primary treatment at Private Osmaniye Park Hospital and Private Osmaniye İbni Sina Hospital between January 2021 and July 2024. The outcomes of the male patients and their female partners, recorded before the procedure and six months after the procedure, were analyzed retrospectively.

The medical history of each male patient who presented to the urology polyclinic with ED was taken, physical examination was performed, and blood tests were ordered. The five-item International Index of Erectile Function 5 (IIEF-5) was completed to determine the severity of ED, and the Erection

Hardness Scale (EHS) was administered to evaluate erection status. In addition, the male Arizona Sexual Experiences Scale (mASEX) and the female Arizona Sexual Experiences Scale (fASEX) were completed before Li-ESWT to evaluate the sexual function parameters of the couples. At the sixth-month follow-up after the procedure, IIEF-5, EHS, and mASEX were completed again by the male patients and fASEX by their female partners. All forms were administered by the same urologist.

The IIEF-5 questionnaire is used to determine the severity of ED in men. It contains five questions; each scored from 1 to 5. The total score is calculated by summing the scores of all responses. A score of 22 or above indicates no ED. Score between 17 and 21 indicate mild ED, 12–16 indicate mild-moderate ED, 8–11 indicate moderate ED, and 1–7 indicate severe ED [9].

EHS is used to determine erection hardness status in men. The form includes options ranging from 0 to 4, where 0 indicates total impotence and 4 indicates full erection capacity [8].

ASEX has two different forms: mASEX and fASEX, which are used to identify mSD and fSD and to assess sexual function parameters. The ASEX form includes questions on sexual desire, psychological stimulation, physiological stimulation, orgasm status, and orgasm satisfaction. The validity of the Turkish version used in the current study was previously confirmed by Soykan [10]. The form contains five questions, each scored from 1 to 6, where 1 indicates the best sexual health and 6 indicates the worst. In this study, a total score of 19 or above was accepted as SD. SD was also defined if a patient scored 6 points on any question, 5 points on two questions, or 4 points on three questions [10].

The inclusion criteria for male patients were age <65 years, ED for more than six months, and a stable female partner for more than three months. Male patients with systemic disease, hypogonadism, psychiatric illness, moderate or severe ED, a history of radical pelvic surgery or pelvic radiotherapy, or PDE5i use were excluded. For female partners, women with systemic disease, menopausal women, and pregnant women were excluded.

The Li-ESWT procedure was performed in an outpatient setting. No medication was required before or after the procedure, and there were no physical restrictions afterward. The procedure lasted approximately 5–10 minutes. In this study, the BTL-6000 FSWT (low level laser machine, BTL Industries, MA, USA) device was used for Li-ESWT. The device consists of a machine generating focused shock waves and an applicator with a silicone pad measuring 15–20 mm in diameter at its tip. After applying gel to the penis, the silicone pad was placed at five different anatomical points (the tip, middle and lower parts of the dorsal side, and both lateral sides of the penis), and focused shock waves were delivered. Device photos and penile anatomical points are shown in Figs. 1,2,3.

In this study, a total of 3000 pulses (600 pulses per anatomical point) were applied to five different anatomical points on the penis at an energy density of 0.09 mJ/mm^2 and a frequency of 12 Hz in each session. A total of six sessions were administered over three weeks, with two sessions per week.

For descriptive statistics, mean, standard deviation, median, minimum, maximum, frequency, and percentage values were used. The distribution of variables was tested with the Kolmogorov-Smirnov and Shapiro-Wilk tests. The McNemar test, paired-samples *t*-test and Wilcoxon test were used for repeated measures analysis. Statistical analyses were performed using the Statistical Package (Social Sciences v. 27.0., IBM, Chicago, IL, USA).

3. Results

The study included 32 male patients and their 32 female partners. The median age of the male patients was 44 (27–61) years, and that of the female partners was 38.5 (21–49) years. No male patients reported complications following Li-ESWT.

The fASEX scores of female partners before and after the procedure are presented in Table 1. Post-procedure scores (desire, psychological stimulation, physiological stimulation, ability to reach orgasm, and orgasm satisfaction) showed a significant decrease compared to pre-procedure scores ($p < 0.05$) (Table 1).

The pre- and post-procedure mASEX, IIEF-5, and EHS scores of male patients are presented in Table 2. Post-procedure scores (IIEF-5, EHS, desire, physiological stimulation, ability to reach orgasm, and orgasm satisfaction) showed a significant improvement compared to pre-procedure scores ($p < 0.05$). Only the change in psychological stimulation scores was not statistically significant ($p > 0.05$).

According to fASEX scores, 17 (53.1%) female partners had fSD before the procedure, while 5 (15.6%) had fSD after the procedure. According to mASEX scores, 16 (50%) male patients had mSD before the procedure, while 6 (18.7%) had mSD after the procedure. The difference between pre- and post-procedure rates was statistically significant for both groups ($p < 0.05$). In addition, there was no significant difference in the overall rate of sexual dysfunction between male patients and female partners before and after the procedure ($p > 0.05$) (Table 3).

A significant decrease was observed in the rates of mild ED and mild/moderate ED, while the proportion of patients without ED increased. The changes in male patient rates across all ED groups were statistically significant ($p < 0.05$) (Table 4). The proportions of patients in the EHS 2 and EHS 3 groups decreased after the procedure, while the proportion in the EHS 4 group increased significantly. The rate of changes across all EHS groups were statistically significant ($p < 0.05$) (Table 5).

4. Discussion

The prevalence of ED in men between 40 and 80 years of age varies between 30% and 65% [11]. Aging, diabetes mellitus, hypertension, hyperlipidemia, hypogonadism, and cardiovascular diseases contribute to the high incidence and severity of ED [11, 12]. In our study, the median age of male patients was 44 years, and they had only mild or mild/moderate ED.

fSD may be observed at any age due to systemic diseases, vascular diseases, hormonal disorders, menopause, neurological conditions, and psychological factors (emotional or relational) [4]. Many studies have shown that the inability to engage in sexual intercourse due to male or female factors

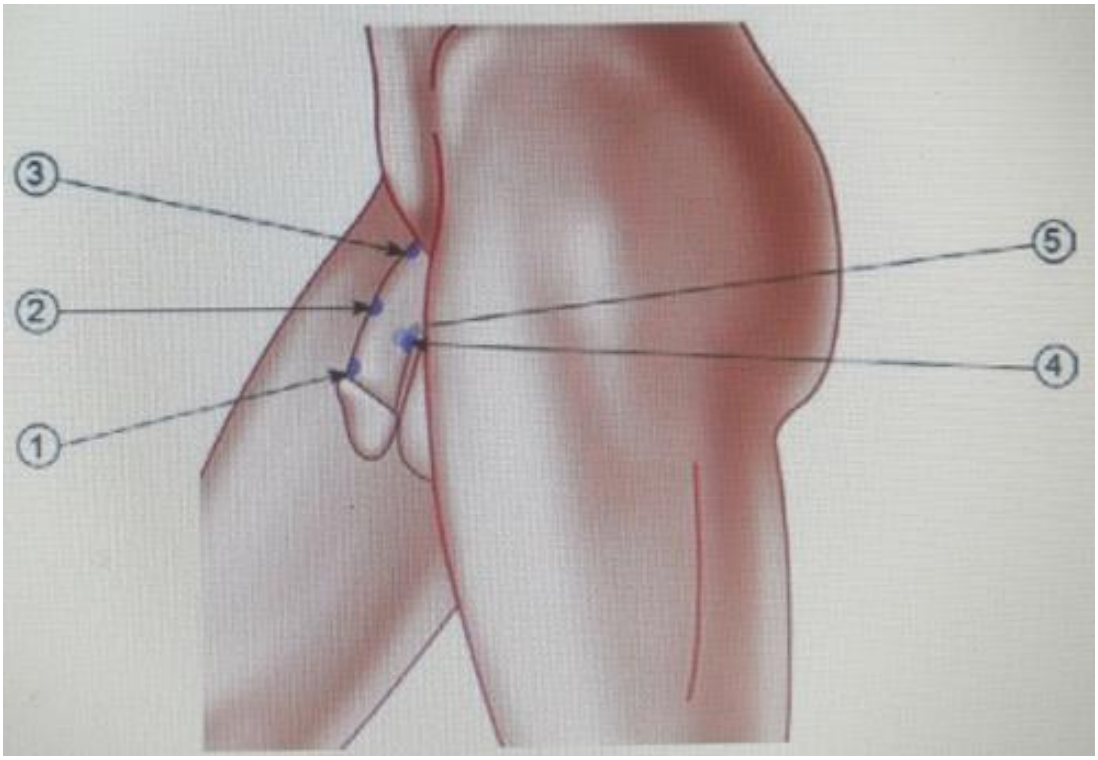

FIGURE 1. Penile anatomical points in Li-ESWT. The tip, middle and lower parts of the dorsal side are shown in the ①, ② and ③ numbers. Both lateral sides of the penis are shown in the ④ and ⑤ numbers.

FIGURE 2. BTL-6000 FSWT device.

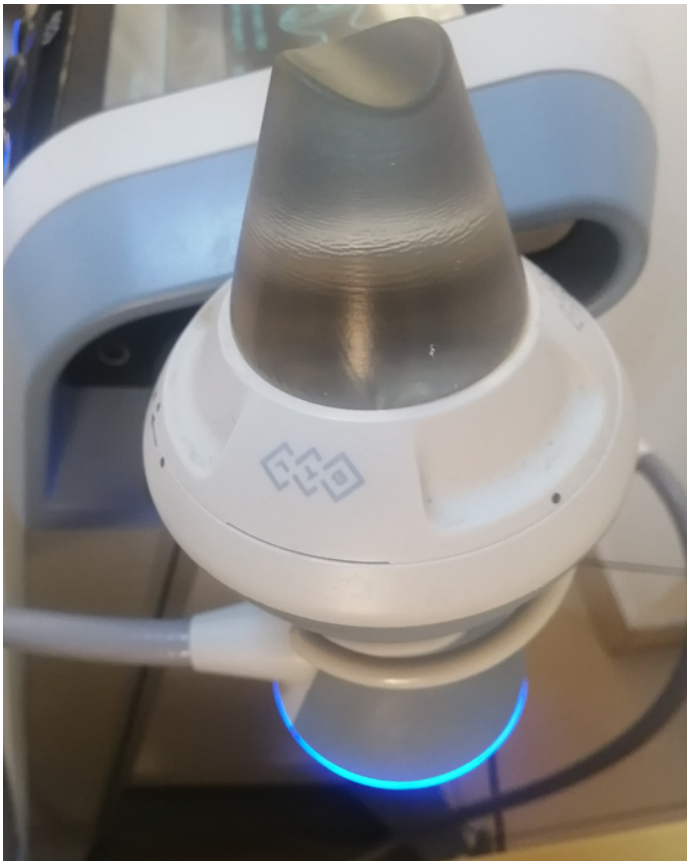

FIGURE 3. Device applicator with silicone pad (diameter: 15–20 mm).

TABLE 1. Comparison of pre- and post-procedure fASEX scores of female partners.

Female partner	Pre-Procedure		Post-Procedure		*p*-value
ASEX Scores	Mean ± SD	Median	Mean ± SD	Median	
ASEX 1. Desire Score	2.3 ± 0.9	2.0	2.1 ± 0.8	2.0	0.025
ASEX 2. Psychological Stimulation Score	2.3 ± 1.0	2.0	2.1 ± 1.0	2.0	0.025
ASEX 3. Physiological Stimulation Score	2.3 ± 1.0	2.0	2.1 ± 0.8	2.0	0.025
ASEX 4. Ability to Reach Orgasm Score	4.4 ± 0.9	4.0	2.4 ± 1.5	2.0	<0.001
ASEX 5. Orgasm Satisfaction Score	4.5 ± 1.0	4.0	2.4 ± 1.5	2.0	<0.001
Total ASEX Score	15.6 ± 1.9	15.0	11.0 ± 3.5	10.0	<0.001

Wilcoxon test, $p < 0.05$. fASEX: female Arizona Sexual Experiences Scale; SD: standard deviation.

TABLE 2. Comparison of pre- and post-procedure IIEF-5, EHS and mASEX scores of male patients.

Male patients	Pre-Procedure		Post-Procedure		*p*-value
ASEX Scores	Mean ± SD	Median	Mean ± SD	Median	
ASEX 1. Desire Score	2.5 ± 0.9	2.0	1.9 ± 0.9	2.0	0.014
ASEX 2. Psychological Stimulation Score	2.3 ± 1.1	2.0	2.5 ± 1.2	2.0	0.619
ASEX 3. Physiological Stimulation Score	4.0 ± 0.8	4.0	2.1 ± 1.1	2.0	<0.001
ASEX 4. Ability to Reach Orgasm Score	3.4 ± 1.1	3.0	2.3 ± 1.3	2.0	0.001
ASEX 5. Orgasm Satisfaction Score	4.3 ± 0.5	4.0	2.0 ± 1.3	2.0	<0.001
Total ASEX Score	16.5 ± 2.6	17.0	10.8 ± 5.0	9.0	<0.001
IIEF-5 Score	16.5 ± 3.8	16.0	22.7 ± 2.3	23.0	<0.001
EHS Score	2.6 ± 0.5	3.0	3.8 ± 0.4	4.0	<0.001

Wilcoxon test, $p < 0.05$. mASEX: male Arizona Sexual Experiences Scale, SD: standard deviation; IIEF-5: five-item International Index of Erectile Function; EHS: Erection Hardness Scale.

TABLE 3. Comparison of pre- and post-procedure male/female sexual dysfunction rates based on mASEX and fASEX scores.

	Male (n = 32) n (%)	Female (n = 32) n (%)	*p*-value
Pre-procedure sexual dysfunction	16 (50.0%)	17 (53.1%)	1.000
Post-procedure sexual dysfunction	6 (18.8%)	5 (15.6%)	1.000
Intra-group change *p*-value	<0.001	<0.001	

McNemar test, $p < 0.05$. mASEX: male Arizona Sexual Experiences Scale; fASEX: female Arizona Sexual Experiences Scale.

TABLE 4. Comparison of pre- and post-procedure ED types of male patients based on IIEF-5.

ED type	Pre-procedure Male (n = 32) (n, %)	Post-procedure Male (n = 32) (n, %)	*p*-value
Mild ED	18 (56.3%)	5 (15.6%)	<0.001
Mild/Moderate ED	14 (43.8%)	2 (6.3%)	<0.001
No ED	0 (0.0%)	25 (78.1%)	<0.001

McNemar test, $p < 0.05$. ED: erectile dysfunction; IIEF-5: five-item International Index of Erectile Function.

TABLE 5. Comparison of pre- and post-procedure EHS scores of male patients.

EHS Score Groups	Pre-procedure Male (n = 32) (n, %)	Post-procedure Male (n = 32) (n, %)	*p*-value
EHS 2	15 (46.9%)	0 (0.0%)	<0.001
EHS 3	17 (53.1%)	6 (18.8%)	<0.001
EHS 4	0 (0.0%)	26 (81.3%)	<0.001

McNemar test, $p < 0.05$. EHS: Erection Hardness Scale.

negatively affects the sexual function and quality of life of couples [2, 4]. In our study, the mean age of female partners was 36.8 years, and there was no significant difference in the rate of sexual dysfunction between male patients and female partners before and after the procedure ($p > 0.05$, Table 3).

Li-ESWT is a safe and well-tolerated procedure without clinically significant side effects. Its success depends on energy density, pulse number, and adherence to treatment protocol (duration, frequency, and localization) [7]. Fojecki *et al*. [13] reported that two cycles of linear Li-ESWT was not superior to one cycle at 6- and 12-month follow-up. Evidence from radial ESWT studies suggest that intensified treatment protocols with higher energy levels (10,000 shocks per treatment at 90 mJ and 15 Hz) may yield better results in ED treatment [14]. A meta-analysis showed that treatment plans with an energy density of 0.09 mJ/mm^2 and 1500–2000 pulses were most beneficial for improving IIEF scores in patients with ED. However, the same analysis also reported effective outcomes with protocols using an energy density of 0.16 mJ/mm^2 and up to 5000 pulses [15]. In our study, piezoelectric energy was concentrated by an electroacoustic method and applied to patients at the recommended energy density with 3000 pulses, and no complications were observed after the procedure.

IIEF-5 and EHS have been widely used in studies to evaluate the success of Li-ESWT for ED. Several meta-analyses have shown that Li-ESWT leads to significant increases in IIEF scores [16, 17]. In addition, in many studies, the increase in IIEF scores of patients with mild-moderate ED was significant [15, 18, 19]. In contrast, patients with severe ED did not experience statistically significant improvements in IIEF scores following Li-ESWT [3, 12, 19]. Moreover, three different metanalysis demonstrated that both IIEF and EHS increased simultaneously in patients undergoing Li-ESWT [8, 17, 20]. Consequently, in 2020, the Asia-Pacific Society of Sexual Medicine recommended Li-ESWT as an effective treatment option for mild-to-moderate vascular ED [21]. In our study, a statistically significant improvement was observed in both IIEF-5 scores (median increased from 16.0 to 23.0, $p < 0.001$) and EHS scores (median increased from 3.0 to 4.00, $p < 0.001$) of patients with mild or mild/moderate ED (Table 2). In addition, 25 male patients (78.1%) had an IIEF-5 score of 22 or above and 26 (81.3%) achieved an EHS score of 4 ($p < 0.05$) (Tables 4 and 5).

ASEX and the Female Sexual Function Index (FSFI) are reliable and practical tools for identifying and measuring SD in clinical practice [22]. While the ASEX form can be applied to both men and women, the FSFI is used only for women and also assesses sexual pain [23]. In one study evaluating sexual

function in men receiving testosterone replacement therapy for hypogonadotropic hypogonadism, the median total mASEX score decreased significantly from 18.0 before treatment to 14.0 after treatment, which was statistically significant ($p < 0.001$). According to the ASEX evaluation, the proportion of individuals with ED decreased from 70.2% before treatment to 38.3% at six months after treatment [24]. In another study, Anğın *et al*. [25] evaluated female sexual function in pregnant and non-pregnant women and found that tASEX scores were higher in the pregnant group (12.1 *vs*. 9.2, $p < 0.001$), while total Female Sexual Function Index (tFSFI) scores were higher in the non-pregnant group (18.5 *vs*. 27.4, $p < 0.001$). Gittens *et al*. [26] investigated the sexual life of couples after penile prosthesis implantation (PPI) and reported that the FSFI scores of spouses of patients with high implant satisfaction were significantly higher than those in the low-satisfaction group (25.09 ± 6.79 *vs*. 13.67 ± 12.70, $p < 0.001$). In another study evaluating couples after PPI, the total mASEX score was recorded as 21.55 ± 1.95) and the total fASEX score as 21.83 ± 2.74 preoperatively, while postoperatively, the total mASEX and fASEX scores were 11.00 ± 3.24 and 10.00 ± 2.74), respectively ($p < 0.001$) [27]. In addition, physiological stimulation, ability to reach orgasm, and orgasm satisfaction score were found to be lower in both male patients and their partners in the postoperative period ($p < 0.05$) [27].

Gokalp F *et al*. [23] analyzed sexual parameters of male patients who underwent bariatric surgery and their partners. They reported postoperative increases in both the total IIEF scores of male patients (63 *vs*. 73, $p < 0.001$) and total FSFI scores of their female partners (20.40 *vs*. 26.70, $p < 0.001$), with all subscores improving in both groups ($p < 0.001$). In another bariatric surgery study evaluating couples, the total mASEX score decreased from 15.8 to 8.0, the total fASEX score decreased from 15.0 to 10.5, and the proportion of patients without ED increased from 25% to 77.5% ($p = 0.001$) [28]. In the current study, the total mASEX score decreased from 16.5 to 10.8 ($p < 0.05$) (Table 2), while the total fASEX score decreased from 15.6 to 11.1 at six months after the procedure ($p < 0.05$) (Table 1). Furthermore, all fASEX scores and four mASEX subscores decreased significantly at six months ($p < 0.05$) (Tables 1 and 2). However, no statistically significant difference was observed between the pre- and post-procedure psychological stimulation scores of male patients ($p = 0.619$) (Table 2). In addition, the reduction in the rate of participants with SD in both groups was statistically significant ($p < 0.05$) (Table 3).

The small sample size and absence of a control group are the main limitations of this study. However, it is uncommon common to find studies with sufficient numbers of patients treated with Li-ESWT for mild or mild/moderate ED. To generalize our findings, further studies with larger patient cohorts and control groups are necessary.

5. Conclusions

Li-ESWT is a safe procedure. In young with mild or mild/moderate ED, Li-ESWT achieved a high success rate at six months after the procedure. Furthermore, mSD and fSD improved simultaneously, with improvements observed in all female sexual function parameters. In male patients, improvements were observed in four different sexual functions, while psychological stimulation remained unchanged. However, to generalize these results, there is a need for randomized controlled trials with larger patient populations.

AVAILABILITY OF DATA AND MATERIALS

The author declares that all data supporting the findings of this study are available within the paper, and the raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

EÖ—designed and conducted the study; supervised data collection; analyzed and interpreted the data; prepared the manuscript for publication; and reviewed the manuscript draft. The author has read and approved the final version of the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Ethics Committee of Adana State Hospital (06/02/2025-10/340). Since there is no medical ethics committee in the province where the hospital I work at is located, we applied to the nearest ethics committee and obtained approval. The Adana State Hospital Ethics Committee did not require written consent forms from patients and their relatives for the retrospective study we wrote.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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