EFFECTS OF SHOCK WAVE THERAPY ON ERECTILE DYSFUNCTION – A PILOT STUDY

Ocena efektów leczenia terapii zaburzeń erekcji metodą fali uderzeniowej – badanie pilotażowe

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Abstract

Introduction and objective: Erectile dysfunction has become an increasingly common issue and is predictive of various cardiovascular and mental conditions. This study focuses on low-intensity extracorporeal shock wave therapy (Li-ESWT), which is recognised by the European Association of Urology as an adjunct to first-line treatment for erectile function. Li-ESWT can be an alternative to or complement pharmacotherapy (phosphodiesterase type 5 inhibitors). It is painless, non-invasive, and safe for the patient, as confirmed by numerous studies. **Material and methods:** The study included a group of 40 men receiving Li-ESWT treatment once a week. Treatment parameters were established based on the Motil algorithm following a qualifying appointment and exclusion of contraindications. Patients were assessed three times: before, immediately after, and six months post-treatment, using the International Index of Erectile Function-5 Questionnaire (IIEF-5). **Results:** The pre-treatment IIEF-5 score in the study group was 12.6 ± 3.9 increased to an average of 18.0 ± 3.4 points after treatment. Six months post-treatment, a further increase was noted to an average score of 18.9 ± 4.1 – statistically significant differences (p <0.05). A negative correlation was observed between the duration of erectile dysfunction and the results before treatment (−0.3526; p <0.05 – average correlation), immediately after (−0.0777; p <0.05 – low correlation), and six months after (−0.5180; p <0.05 – high correlation) the end of treatment. A positive correlation was observed between pre-treatment IIEF-5 scores and results immediately after treatment (0.6113; p <0.05 – high correlation) and six months (0.5207; p < 0.05 – high correlation) after the end of treatment (p <0.05). A negative correlation was observed between the number of shock wave pulses and IIEF-5 scores obtained before (−0.6963; p <0.05 – high correlation), immediately after (−0.5885, p <0.05 – high correlation), and six months after the end of treatment (−0.6884, p <0.05 – high correlation). **Conclusions:** 1. Low-intense extracorporeal shock wave therapy improves erectile function in patients with erectile dysfunction. 2. Positive effects on erectile function, as assessed by IIEF-5, were observed immediately after treatment and persisted at six-month follow-up. 3. Erectile dysfunction duration negatively affected IIEF-5 scores before, immediately after, and six months post-treatment. 4. Patient age had no impact on IIEF-5 scores at the end of the treatment and at six-month follow-up.

Streszczenie

Wprowadzenie i cel: Zaburzenia erekcji stają się coraz powszechniejszym problemem i są predyktorem różnych schorzeń sercowo-naczyniowych i psychicznych. Niniejsze badanie koncentruje się na terapii pozaustrojową falą uderzeniową o niskiej intensywności (Li-ESWT), która jest uznawana przez Europejskie Towarzystwo Urologiczne za leczenie pierwszego rzutu zaburzeń funkcji erekcyjnej. Li-ESWT może być alternatywą lub uzupełnieniem farmakoterapii (inhibitory fosfodiesterazy typu 5). Metoda ta jest bezbolesna, nieinwazyjna i bezpieczna dla pacjenta, co potwierdzają liczne badania. **Materiał i metody:** Badanie objęło grupę 40 mężczyzn otrzymujących leczenie Li-ESWT raz w tygodniu. Parametry terapii ustalono na podstawie algorytmu Motila po wizycie kwalifikacyjnej i wykluczeniu przeciwwskazań. Pacjenci byli oceniani trzykrotnie: przed, bezpośrednio po i sześć miesięcy po leczeniu, przy użyciu Międzynarodowego Kwestionariusza Funkcji Erekcji-5 (IIEF-5). **Wyniki:** Wynik IIEF-5 przed leczeniem w grupie badanej wynosił 12,6 ± 3,9 i wzrósł do średnio 18,0 ± 3,4 punktów po leczeniu. Sześć miesięcy po leczeniu odnotowano dalszy wzrost do średniego wyniku 18,9 ± 4,1 – różnice statystycznie istotne (p <0,05). Zaobserwowano ujemną korelację między czasem trwania zaburzeń erekcji a wynikami przed leczeniem (−0,3526; p <0,05 – średnia korelacja), bezpośrednio po (−0,0777; p <0,05 – niska korelacja) i sześć miesięcy po (−0,5180; p <0,05 – wysoka korelacja) zakończeniu leczenia. Zaobserwowano dodatnią korelację między wynikami IIEF-5 przed leczeniem a wynikami bezpośrednio po leczeniu (0,6113; p <0,05 – wysoka korelacja) i sześć miesięcy (0,5207; p <0,05 – wysoka korelacja) po zakończeniu leczenia (p <0,05). Zaobserwowano ujemną korelację między liczbą impulsów fali uderzeniowej a wynikami IIEF-5 uzyskanymi przed (−0,6963; p <0,05 – wysoka korelacja), bezpośrednio po (−0,5885, p <0,05 – wysoka korelacja) i sześć miesięcy po zakończeniu leczenia (−0,6884, p <0,05 – wysoka korelacja). **Wnioski:** 1. Terapia falą uderzeniową pozaustrojową o niskiej intensywności poprawia funk-

cje erekcji u pacjentów z zaburzeniami erekcji. 2. Pozytywne efekty dotyczące funkcji erekcji, oceniane według skali IIEF-5, obserwowano bezpośrednio po leczeniu i utrzymywały się podczas sześciomiesięcznej obserwacji. 3. Czas trwania zaburzeń erekcji negatywnie wpływał na wyniki skali IIEF-5 przed leczeniem, bezpośrednio po nim i sześć miesięcy po leczeniu. 4. Wiek pacjenta nie miał wpływu na wyniki skali IIEF-5 pod koniec leczenia i podczas sześciomiesięcznej obserwacji.

Keywords: angiogenesis; erectile dysfunction; vascular erectile dysfunction; low-intensity shock wave therapy

Słowa kluczowe: angiogeneza; zaburzenia erekcji; naczyniopochodne zaburzenia erekcji; niskoczęstotliwościowa fala uderzeniowa

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Epidemiology of erectile dysfunction

It is estimated that approximately 50% of men worldwide suffer from erectile dysfunction (ED), based on a study involving nearly 100,000 individuals aged 40–70 years from Brazil, China, France, Germany, Italy, Spain, the United Kingdom and the United States [1], and the issue is affecting increasingly younger men [2]. In Poland, 25–30% of men aged 30–50 years (approximately 3 million), experience problems with erectile function (EF) [3]. The risk factors for ED include hypertension, diabetes mellitus, and hypercholesterolaemia, which may have a direct effect on penile haemodynamics by generating changes in the vascular network. Furthermore, ED is now also recognised as a predictor of adverse cardiovascular events [4]. In the pathogenesis of ED, hormonal secretion is significant, in particular the hypothalamic-pituitary axis [5], which affects testosterone production in the testes [6]. Prostate-specific antigen (PSA) is another important indicator in the assessment of cancer-related ED [7]. Other risk factors comprise obesity and poor nutrition, as increased body fat promotes the formation of oestrogens, impairing metabolism and altering body composition [8]. These changes are associated with a decrease in daily physical activity, the lack or insufficient level of which promotes the development of endocrine, metabolic, and cardiovascular diseases [9]. Moreover, psychogenic factors, such as depression or prolonged chronic stress, may play a substantial role in the onset of sexual dysfunction in men [10].

Erectile dysfunction treatment modalities in men

According to the latest guidelines and international standards, the treatment of ED is a multidisciplinary issue. It involves not only an urologist and an andrologist, but also a broader team of healthcare professionals, consisting of a psychotherapist, an endocrinologist, a general practitioner and, if necessary, specialists from other medical disciplines.

The 2021 European Association of Urology guidelines for the treatment of ED outline first-line treatment methods, which include phosphodiesterase type 5 inhibitors (PDE5i), vacuum erection devices (VEDs) and, in cases of vascular ED, low-intensity extracorporeal shock wave therapy (Li-ESWT), provided that patients have received proper pre-treatment counselling. In the absence of a positive response, second-line treatments, which include intracavernosal injections of vasoactive substances and combination therapy, are considered. Third-line treatment is based on penile implantation [11].

Early research into the use of Li-ESWT in ED dates back to the study by Gruenwald et al. [12] published a decade ago, which numerous subsequent authors have followed up on [13–17]. However, it was the pioneering work by Nishida et al. [18], Wang et al. [19], and Gotte et al. [20] on vascular angiogenesis and the mechanisms behind this process that initiated the entire debate. The effectiveness of Li-ESWT in the treatment of ED is most commonly assessed using subjective international questionnaires addressing issues with EF as well as self-perception. To objectify the results, methods such as ultrasound and plethysmography are used. Nevertheless, current research no longer focuses exclusively on assessing the applicability of Li-ESWT in the treatment of EF disorders in men, but rather on optimising the effects through the selection of appropriate parameters, type of equipment, and methodology of the procedure [21].

Furthermore, the assessment of long-term effects of Li-ESWT for ED is becoming a growing area of focus, as reflected in international guidelines and recommendations for further research in the field [11, 22]. Recent reports have suggested that attempts should be undertaken to extend the application of Li-ESWT for the treatment of EF disorders of non-vascular aetiology [23] and other uroandrological conditions [24].

The aim of the present study was to evaluate the effectiveness of Li-ESWT in the treatment of patients with ED, aged 30–80 years, in the Polish population, at a six-month follow-up.

The underlying mechanism of Li-ESWT

Li-ESWT is a mechanical wave characterised by high amplitude, lack of periodicity, pressure spikes, and low power and frequency, which is crucial for the treatment of patients with EF[25]. Numerous devices are used in clinical practice: electrohydraulic, electromagnetic or piezoelectric, converting electrical energy into mechani-

cal wave energy. Shock waves can be further subdivided according to the mode of propagation within the medium into focused shock wave therapy, radially propagating shock wave therapy, as well as planar shock wave therapy, which is less frequently used in ED patients [26].

Nevertheless, as emphasised at the 20th Congress of the European Society for Sexual Medicine and the 21st World Congress of the International Society for Sexual Medicine in 2018, there are no recommendations or guidelines in the available literature in terms of the apparatus models used to treat ED patients [22].

Porst et al. [21], in their study on the efficacy of Li-ESWT in the treatment of ED, analysed six types of Li-ESWT devices, which varied significantly in power density (0.09–0.55 mJ/mm^2). The team observed positive therapeutic effects with all the devices analysed, whether they generated the shock waves from electrohydraulic, electromagnetic, or piezoelectric sources. Interestingly, the study found significant differences with regard to the methodology of the treatment protocols. The authors suggested that higher energy levels might yield better therapeutic effects, although they require greater precision and focus in the area of the treatment protocol.

The underlying mechanism of Li-ESWT is the stimulation of the vascular endothelium and the activation of factors which promote blood vessel formation. One of the first studies addressing this topic was conducted by Nishida et al. [18], who observed that Li-ESWT application resulted in significant mRNA hyperexpression of potent angiogenesis ligands and protein expression in human umbilical vein endothelial cells (*in vitro*). They also reported a considerable improvement in regional myocardial blood flow (nine application sites, 200 impulses each; power density 0.09 mJ/mm^2, porcine studies – *in vivo*). Two possible mechanisms were identified: 1) enzymatic, which involves an increase in endothelial nitric oxide synthase activity [19], and 2) non-enzymatic, requiring the participation of L-arginine and hydrogen peroxide molecules [20]. Despite the obvious clinical effects of Li-ESWT, the exact mechanism by which it acts on tissues remains unknown. Li-ESWT exerts analgesic and anti-inflammatory effects, and it positively impact tissue remodelling by improving local blood circulation, thereby diminishing pathological processes directly associated with ischaemia of the corpora cavernosa. Furthermore, Li-ESWT is hypothesised to affect the cytoskeleton of the cell and, through a mechanotransduction mechanism, exert an effect on tissue metabolism [27]. Notably, immediately following Li-ESWT application, a reduction in the synthesis of pro-inflammatory cytokines, such as Il-1 beta, Il-6 and TNF-alpha is recorded [28], which may cause a transient decrease in temperature within the treatment site via a mechanism of primary vasoconstriction.

Study group

The study involved 40 men with a mean age of 54.5 years (35–78 years ± 9.1 years), presenting with ED of an average duration of 2.9 years (0.5–12 years ± 2.5 years) (tab. 1). Exclusion criteria comprised laboratory results outside the reference range (LH, FSH, PSA, oestradiol, prolactin, testosterone), prostate and/or penile cancer, a history of cancer within the past two years, radical prostatectomy, and prior radiotherapy. The study was approved by the Bioethics Committee at Poznan University of Medical Sciences (resolution no. 110/21).

Methods

The treatment cycle consisted of six Li-ESWT sessions performed every 5–12 days (on average once a week), with the following parameters: electrohydraulic source, average number of impulses: 6,725 (5,000–8,000 ± 960 impulses), average treatment time: 20 minutes, delivered via a BTL device.

The parameters were selected using the Motil algorithm [29] which considers the International Index of Erectile Function-5 (IIEF-5) score, the duration of symptoms, and patient comorbidities. All subjects (n = 40) completed the full treatment cycle, with no drop-outs or adverse effects reported.

Patient assessments were conducted at three intervals: 1) before starting treatment (n = 40), 2) at the end of the treatment cycle (n = 40), and 3) six months after the

Table 1. Characteristics of the study group

Variable	Number of subjects (n)	Mean	Median	SD	Minimum	Maximum
Age (years)	40	54.5	56	9.1	35	78
ED duration (years)	40	2.9	2	2.5	0.5	12
Number of Li-ESWT impulses	40	6725	7000	960.4	5000	8000
ED – erectile dysfunction; Li-ESWT – low-intensity extracorporeal shock wave therapy						

Table 2. IIEF-5 scores before, immediately after, and six months after erectile dysfunction treatment

Variable	Number of subjects (n)	Mean	Median	SD	Minimum	Maximum
IIEF-5 (pre-treatment) (pts)	40	12.6	12	3.9	6	20
IIEF-5 (post- treatment) (pts)	40	18	18	3.4	10	25
IIEF-5 (six months post-treatment) (pts)	21	18.9	20	4.1	9	24
IIEF-5 – International Index of Erectile Function-5						

Table 3. Statistical analysis of IIEF-5 scores before, immediately after, and six months after erectile dysfunction treatment

Pairs of variables	*N*	T	Z	*p** level
Pre-treatment IIEF-5 vs post-treatment IIEF-5	40	0.00	5.30	0.0000
Pre-treatment IIEF-5 vs IIEF-5 at six months post-treatment	21	0.00	3.82	0.0001
Post-treatment IIEF-5 vs IIEF-5 at six months post-treatment	21	0.00	2.33	0.0196

* Statistically significant results at $p < 0.05$ are underlined; IIEF-5 – International Index of Erectile Function-5

completion of treatment ($n = 21$) (the remaining subjects ($n = 19$) did not respond to follow-up contact) (tab. 2). The validated version of the IIEF-5 was used for the assessments. The IIEF-5 consists of five questions, each of which can be rated from 0 to 5 points (where '0' indicates the most severe impairment and '5' means no impairment) [30].

Results

Statistica 9.0 was used to assess the results obtained. The analysis involved IIEF-5 scores recorded before and after treatment, as well as at a six-month follow-up (Wilcoxon Test; $p < 0.05$).

In the study group, the baseline IIEF-5 score averaged 12.6 ± 3.9 pts (6–20 pts). It increased to an average of 18.0 ± 3.4 pts (10–25 pts) upon treatment completion, and further to an average of 18.9 ± 4.1 (9–24 pts) at six months post-treatment (tab. 2). The observed increase was statistically significant in comparison to the pre-treatment ED status, both immediately following ED treatment and at the six-month follow-up (Wilcoxon Test, $p < 0.05$) (tab. 3).

The study evaluated the effects of age, ED duration, and the number of Li-ESWT impulses applied on IIEF-5 scores obtained before and after ED treatment, as well as at a six-month follow-up (Spearman's R test, $p < 0.05$). A negative correlation was observed between ED duration and patient scores both before treatment (−0.3526, $p < 0.05$ – moderate correlation), upon its completion (−0.0777, $p < 0.05$ – low correlation), and at six months post-treatment (−0.5180, $p < 0.05$ – high correlation). Additionally, a positive correlation was found between the pre-treatment versus post-treatment IIEF-5 scores (0.6113, $p < 0.05$ – high correlation) and six months after the treatment (0.5207, $p < 0.05$ – high correlation) (tab. 4).

No impact of the age of the patients on their IIEF-5 scores was observed before treatment, upon its completion, and six months post-treatment ($p > 0.05$). However, a negative correlation was noted between the number of Li-ESWT impulses and IIEF-5 scores obtained before (−0.6963, $p < 0.05$ – high correlation), immediately after (−0.5885, $p < 0.05$ – high correlation), and six months after the end of treatment (−0.6884, $p < 0.05$ – high correlation). This finding may be related to the fact that, according to the Motil therapeutic protocol, a greater number of Li-ESWT impulses were administered to patients in a poorer clinical condition. Consequently, the baseline severity of their condition influenced the final treatment outcomes (tab. 4).

Discussion

Despite the observed positive effects of Li-ESWT in the treatment of ED, there are no conclusive guidelines with regard to treatment parameters and standards in various male populations [12–17, 21].

In 2012, Gruenwald et al. [12] conducted one of the first studies investigating the efficacy of Li-ESWT for ED in a group of 29 men (mean age: 61.3 years), who showed minimal response to PDE5i treatment (mean duration of erectile dysfunction: 5 years). After nine weeks of therapy (3,000 impulses per session, 2Hz, 0.09 mJ/mm^2) and one month of follow-up, a significant increase in IIEF scores was noted (8.8 points vs. 12.3 points after therapy) – without the use of pharmacotherapy. After another month, a further increase to 19.8 pts was recorded, following the administration of pharmacotherapy. No ad-

Table 4. Correlation analysis of the variables

Spearman's R coefficient*	Age	ED duration	Number of Li-ESWT impulses	PDE5I	Pre-treatment IIEF-5	Post-treatment IIEF-5	IIEF-5 at 6 months post-treatment
Age	x	0.2609	0.3887	0.1553	−0.0882	−0.2723	−0.3464
ED duration	0.2609	x	0.4539	0.2010	−0.3526	−0.0777	−0.5180
Number of Li-ESWT impulses	0.3887	0.4359	x	0.0870	−0.6963	−0.5885	−0.6884
PDE5I	0.1553	0.2010	0.087	x	0.0371	−0.0302	−0.1852
Pre-treatment IIEF-5	−0.0	−0.3526	−0.6963	0.0371	x	0.6113	0.5206
Post-treatment IIEF-5	−0.2723	−0.0777	−0.5885	−0.0302	0.6113	x	0.6241
IIEF-5 at 6 months post-treatment	−0.3464	−0.5180	−0.6884	−0.1852	0.0526	0.6241	x

* Statistically significant results at $p < 0.05$ are underlined
ED – erectile dysfunction; PDE5i – phosphodiesterase type 5 inhibitors; Li-ESWT – low-intensity extracorporeal shock wave therapy; IIEF-5 – International Index of Erectile Function-5

verse reactions were reported. In this study, one of the research tools used to assess EF improvement was the IIEF questionnaire. An abbreviated version of this questionnaire (IIEF-5) was also employed in our study.

Similar treatment parameters were applied by Pelayo-Nieto et al. [13], who investigated the effects of Li-ESWT in a group of 15 men (mean age 59.6 years). The improvement in EF was verified using the IIEF score, which changed significantly (p <0.05) from 14.23 pts to 19.69 pts in 80% of patients. Four treatment sessions were conducted, once a week, with a wave energy of 0.09 mJ/mm^2, with 5,000 impulses per session. Similar clinical outcomes were obtained in our study, which demonstrated a significant improvement both immediately after therapy completion and at the six-month follow-up, compared to the baseline values (pre-treatment – 12.6 ± 3.9 pts, immediately after therapy – 18.0 ± 3.4 pts, at the six-month follow-up– 18.9 ± 4.1 pts). Our study followed a similar therapeutic regimen with one treatment/week for a total of six weeks.

Fojecki et al. [14] conducted a study in a group of 126 patients divided into a study group (n = 63) and a control group receiving sham treatment (n = 63). At the end of therapy, one month after the five-week treatment cycle ended, no significant differences were demonstrated between the two groups. The baseline IIEF scores in the sham and study groups were 10.9 pts and 11.5 pts, respectively. Four weeks after completing the five-week treatment, an increase in IIEF scores was observed (study group – 13.1 pts, control group – 13 pts), and after another four weeks, following the completion of another cycle, IIEF scores decreased in the study and control groups to 11.8 pts and 12.6 pts, respectively. This study yielded less promising results compared to those obtained in our analysis and in the studies by other authors cited above, which may be attributed to the use of planar shock wave therapy – a method less commonly applied for improving EF in men.

Palmieri et al. [15] analysed a group of men (n = 109) suffering from ED, not responding to PDE5i. The authors administered 3,000 impulses with a power density of 0.25 mJ/mm^2 and a frequency of 4–6 Hz, twice a week for three weeks. Following treatment, a significant (p <0.001) increase in IIEF scores was demonstrated (mean: 13.47 ± 4.61 pts vs 22.07 ± 5.27 pts; p < 0.0001) after a one-month follow-up period. The treatment parameters used in their study, both in terms of power and frequency settings, were similar to those employed by our team (1.5b, 5 Hz), with a greater number of impulses (mean: 6,725) and twice as long treatment duration (six weeks).

Vinay et al. [16] investigated 76 men with ED responding poorly to PDE5i pharmacotherapy, who were divided into a study group (n = 40, Li-ESWT) and a control group (n = 36, sham treatment). In the study group, four Li-ESWT treatments (once a week; 5,000 impulses; 0.09 mJ/mm^2) were administered using an electromagnetic source. Following treatment, the median increase in IIEF values in the study and control groups was 3.5 and –0.5 (p <0.05), respectively. The findings demonstrated that Li-ESWT, delivered via an electromagnetic source, provided a a modest therapeutic effect in patients poorly responding to pharmacotherapy. This therapy offers an alternative for patients rejecting more invasive therapies in the treatment of vascular ED.

It is vital to bear in mind that the beneficial effects of Li-ESWT have been highlighted not only in individual randomised controlled trials, but also in numerous meta-analyses. One such analysis, conducted by Kałka et al. [17], focused specifically on patients with diabetes and associated risk factors. The authors concluded that the application of Li-ESWT was beneficial, as reflected by a significant increase in EF. Nevertheless, they also highlighted that the observations were short-term and incomplete due to the lack of standardised therapeutic parameters, and therefore recommended further studies involving larger study groups.

Campbell et al. [31] summarised the results of seven randomised control trials (RCTs) conducted on a group of 607 patients, assessed using the IIEF and Erection Hardness Score (EHS). In their analysis, they observed significant heterogeneity among the groups and a low degree of accuracy in terms of both quality and quantity of the data (with inconsistencies in treatment protocols, a variety of equipment and treatment parameters). After a one-month follow-up, the IIEF score varied between 12.8–22.0 in the study group vs. 8.2–16.4 in the sham therapy group, showing a significant increase of 4.24 pts, (p = 0.012). The authors concluded that Li-ESWT represented a safe therapeutic option in patients with vascular ED and could provide short-term effects. In our study, positive treatment effects persisted (and even improved) over a six-month follow-up period.

Capogrosso et al. [32] analysed 11 RCTs and 5 meta-analyses regarding the use of Li-ESWT in the treatment of uroandrological disorders, which were sourced from the Medline and Embase databases. They concluded that Li-ESWT was a non-invasive and safe treatment for ED and, through the available studies, presented questionable effects in terms of EF improvement due to high heterogeneity among the study groups. The authors emphasised the need for further multicentre studies involving larger groups of patients to clarify the efficacy of this treatment.

Bocchino et al. [33] reviewed 52 studies on the use of Li-ESWT in patients with vascular ED, diabetes mellitus, following pelvic floor surgery, as well as cases of undetermined aetiology. Therapeutic effects were determined with regard to improvement in the IIEF-5 index and EHS. The mean age of the patients was 55.87 ± 7.91 years, with an ED duration of 4.36 ± 2.08 years. The IIEF-5 score before therapy was 12.04 ± 2.67 pts, while three months after treatment completion it was 16.12 ± 5.72 pts. At six months, the score was 16.30 ± 3.26 pts, whereas one year after the treatment onset it was 16.85 ± 1.63 pts. EHS was 2.00 ± 0.46 pts at baseline, which increased to 2.58 ± 0.60 pts after three months of treatment, and amounted to 2.75 ± 0.46 pts after six months. After one year, a further increase to 2.87 ± 0.16 pts was observed (indicating an improvement in erectile rigidity sufficient for satisfactory sexual intercourse). These findings indicate that Li-ESWT represents a non-invasive and safe therapeutic alternative for well-counselled ED patients. Similarly to our study, none of the patients reported adverse effects.

Our study also analysed the impact of factors such as patient age, number of impulses applied, and ED duration. A negative correlation was found between ED duration and patient outcomes before (−0.3526, p <0.05; moderate correlation), immediately after (−0.0777, p <0.05; low correlation), and six months after treatment completion (−0.5180, p <0.05; high correlation), which indicates that the earlier the treatment is initiated, in terms of the development of ED symptoms, the better the clinical outcomes.

Furthermore, a positive correlation was observed between the IIEF-5 scores before and after treatment (0.6113, p <0.05; high correlation) and at the six-month follow-up (0.5207, p <0.05; high correlation) (Spearman's R test, p <0.05). This suggests that in terms of EF symptoms, the better the patient's condition prior to the treatment, the more favourable the prognosis and greater treatment efficacy.

Patient age showed no effect on the IIEF-5 scores before, after, or six months after the end of the treatment (p >0.05). Moreover, in our study, we found no impact of age on therapeutic outcomes. This contrasts with the majority of scientific reports, which clearly indicate that EF impairment progresses with age [34]. Additionally, numerous authors emphasise that the effectiveness of ED treatment decreases with age due to the onset of cardiovascular comorbidities associated with the ageing process [35]. Thus, the evaluation of the therapeutic effects of Li-ESWT in the elderly requires further studies on larger patient groups.

Finally, a negative correlation was found between the number of Li-ESWT impulses and IIEF-5 scores obtained before (−0.6963, p <0.05; high correlation), immediately after (−0.5885, p <0.05, high correlation) and six months post-treatment (−0.6884, p <0.05; high correlation). This may be due to the fact that, according to the treatment protocol, patients in poorer clinical condition received more Li-ESWT impulses.

Conclusions

- Li-ESWT improves EF in patients suffering from ED.
- Positive EF scores, as assessed using the IIEF-5, were observed immediately after treatment completion and persisted at the six-month follow-up.
- A negative impact of ED duration on IIEF-5 scores was found before and after therapy, as well as six months after treatment.
- Patient age showed no impact on IIEF-5 scores following treatment and at the six-month follow-up.

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