

## SHOCK WAVE THERAPY IN PATIENTS WITH ERECTILE DYSFUNCTION

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### Abstract

Erectile dysfunction is a serious medical problem because it directly affects the sex life of a man, but it also has an overall effect on his self-esteem and social behaviour.

Pathophysiologically, erectile dysfunction may be due to factors of vascular origin, anatomical and structural features, neurological disorders, hormonal problems, drug-induced disorders, or iatrogenic trauma. The so-called psychogenic erectile dysfunction is not uncommon. In addition to the established therapy with phosphodiesterase inhibitors, there are a number of publications that focus on the effect of Shock wave therapy as an alternative for treating erectile dysfunction. However, this issue remains debatable. Extracorporeal shockwave therapy is used as a method of treating erection problems, as it induces neovascularization and improves blood flow to the cavernous tissue.

Our goal is to test the efficacy and safety of Shock Wave therapy and to determine its place in the treatment of patients with erectile dysfunction.

Clinical follow-up included 120 men between the ages of 30 and 75 (mean 55.68) diagnosed with erectile dysfunction. Patients were treated and monitored for a period of two years (January 2017 to April 2019). Detailed anamnestic data was taken, including sexual history, and full laboratory tests were performed. We used the following questionnaires to evaluate the extent of erectile

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dysfunction: International Index of Erectile Function (IIEF-5), Erection Hardness Score (EHS). All patients underwent shockwave therapy. Course duration was ten weeks, one procedure per week. Extracorporeal shock wave therapy equipment (BTL-5000) was used.

With regard to the Erection Hardness Score (EHS), there was a significant improvement in penis firmness, immediately after the first procedure, which persisted after the end of treatment until the third month after therapy. Improvement in firmness was mainly observed in patients with moderate and mild erectile dysfunction, while no significant improvement was observed in patients with complete inability to achieve erection.

With respect to the International Index of Erectile Function (IIEF-5), there is a significant improvement in erectile function, mainly in the groups with mild and moderate erectile dysfunction. The effect of therapy is maintained until the third month of treatment. No improvement in the condition was observed in patients with severe erectile dysfunction.

The mean value of IIEF-5 increased significantly from 14.54 to 18.85 after the end of treatment, and this value was sustained until the third month after the treatment – 18.55. The procedure was well tolerated by patients, with no side effects reported during and after the procedure.

The developments in modern technology and in the pharmaceutical industry have fundamentally changed the understanding of erectile dysfunction and the methods of treating it. More and more young people are rejecting the continued use of medication and looking for an alternative to effective treatment. Thus, there is a need for new methods of treating patients with erectile dysfunction. Based on publications in world literature, and on our own results, we have come to the conclusion that extracorporeal shock wave therapy may be an alternative to therapy with Phosphodiesterase 5 inhibitors (PDE5). Following the course of treatment, there was a significant increase in the number of patients without erectile dysfunction, and an increase in the total IIEF-5 score from 14.54 before treatment to 18.55 3 months after the end of therapy. This confirms the assumption of a lasting effect of the therapy 3 months after the end of treatment.

**Key words:** erectile dysfunction, shock wave therapy

**Introduction.** Erectile dysfunction is a serious medical problem because it directly affects the sex life of a man, but it also has an overall effect on his self-esteem and social behaviour. Currently, with increasing patient awareness and access to medical care, more and more people are looking for a solution to their problem. Erectile dysfunction is defined as a condition in which there is a lasting inability to obtain or maintain an erection (NIH Consensus Conference 1993). It is most commonly seen in men over the age of 40, and of course it increases with age. According to various studies, a frequency between 10 and 50% is reported depending on the research methods and the problem definition scale [2]. In developed countries, 25–30 men per 1000 suffer from erectile dysfunction annually [2,3]. Pathophysiologically, erectile dysfunction may be due to factors of vascular origin, anatomical and structural features, neurological disorders, hor-

monal problems, drug-induced disorders, or iatrogenic trauma [1,4]. The so-called psychogenic erectile dysfunction is not uncommon. Risk factors include some cardiovascular diseases, hypertension, diabetes mellitus, smoking, psychological and social problems. More and more young people are worried about the side effects of drug therapy, and second-line treatments are often rejected because of their unnatural characteristics.

All these shortcomings indicate the need for another type of treatment method. There are numerous publications in the world literature that focus on the effect of Shock wave therapy as an alternative for treating erectile dysfunction. However, this topic remains debatable. External shockwave therapy is used as a method to treat erection problems, as it induces neovascularization and improves blood flow to the cavernous tissue [5-7]. In most cases, it is presented as a treatment method for patients with mild to moderate erectile dysfunction [7,8]. It is reported that only one-third of patients with severe erectile dysfunction would improve after shock wave therapy [9]. In these patients, a combination of Shock Wave Therapy and PDE5 is recommended for maximum treatment effect [10]. However, publications in this field are still too scarce, which requires further, in-depth studies in the field.

Our goal is to test the efficacy and safety of Shock Wave therapy and to determine its place in the treatment of patients with erectile dysfunction.

**Material and methods.** Clinical follow-up included 120 men between the ages of 30 and 75 (mean 55.68) with diagnosed erectile dysfunction. Patients were treated and monitored for a period of two years (January 2017 to April 2019).

We used the following methods to perform this study.

Taking detailed anamnestic data, including sexual history. All current and past illnesses, surgeries and medications taken in the last six months have been taken into account. All patients were in contact with a permanent sexual partner. Patients diagnosed with hypogonadism were referred to an endocrinologist to initiate hormone replacement therapy as needed. The emotional status of patients was significant – the presence of factors that adversely affect their psychological status.

Laboratory tests: Complete laboratory tests have been performed including assessment of lipid status, blood glucose testing, biochemistry and serum testosterone. The following distribution of patients was established according to the most common factors, which have a negative effect on erection: smoking – 65.83%; alcohol consumption – 28.33%; diabetes mellitus – 26.6%; arterial hypertension – 33.3%; dyslipidemia – 32.5%; benign prostatic hyperplasia – 39.1%; cerebrovascular disease – 2.5%; condition after prostate surgery – 4.16%; the presence of urinary infection in the last six months – 2.5%.

The following questionnaires were used to assess the extent of erectile dysfunction: International Index of Erectile Function (IIEF-5), Erection Hardness Score (EHS).

Patients were divided into the following groups according to the results obtained before treatment. According to IIEF: patients with normal erectile function – 0; patients with mild erectile dysfunction – 63; patients with mild to moderate ED – 28; patients with moderate ED – 18; patients with severe ED – 11.

According to EHS: The penis is completely rigid – Cat. 4 – 0 patients; the penis is hard enough to penetrate, but not completely rigid – Cat. 3 – 84 patients; the penis is hard but not enough to penetrate – Cat. 2 – 25 patients; the penis is enlarged but not rigid – Cat. 1 – 8 patients; the penis does not enlarge – Cat. 0 – 3 patients.

**Therapeutic protocol and equipment.** All patients underwent a treatment course of ten weeks, one procedure per week. External shock wave therapy equipment (BTL-5000) was used. No local or general anesthesia was used during manipulation. Three thousand and five hundred impulses are applied for each procedure, alternating 500 strokes for left lateral, right lateral and dorsal of the penis. The settings of the device are pressure of 1.5 bars at 13 Hz. The duration of the procedure is between 7 and 15 min. Patients were followed up one week after the first procedure, after the end of treatment and at the third month of treatment.

**Results.** All 120 patients were followed for a period of 3 months. With respect to the Erection Hardness Score (EHS), the data are summarized in Fig. 1.

There is a clear tendency of improvement to the condition of the patients in terms of penis firmness, and after the first procedure 25 men (20.83%) reported a significant effect and considered the erection to be quite sufficient – Category 4.

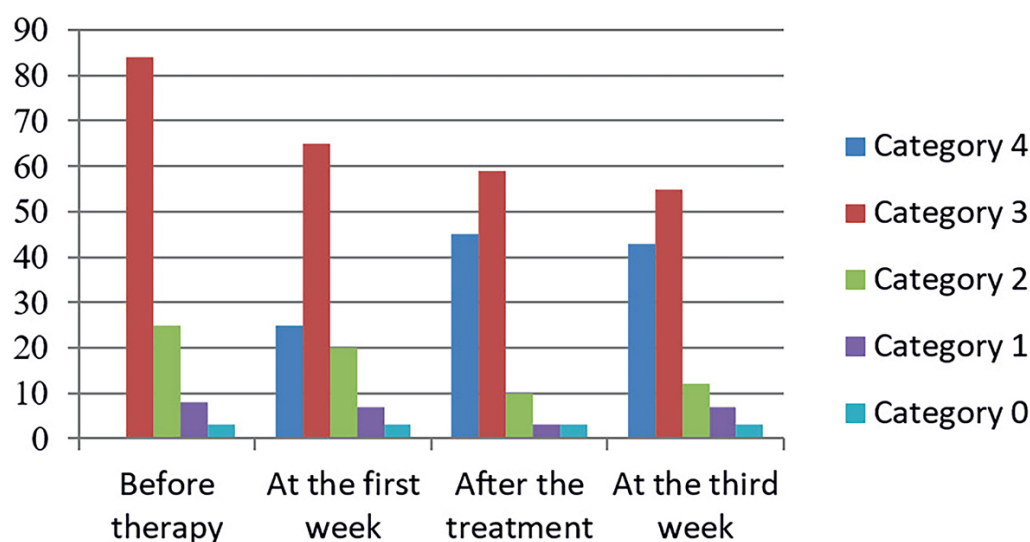


Fig. 1. Distribution of patients according to the possibility of achieving erection before therapy, at the first week, after the end of treatment, and at the third month

The rise was mainly in the patient group who classified themselves in Category 3 of Erection Hardness Score (EHS) before therapy – The penis is hard enough to penetrate, but not completely rigid. The increase in the total number of patients in Categories 3 and 4 immediately after the first week is also impressive (90 patients or 75%) compared to the number in these categories before therapy (84 patients or 70%). This trend persists after the end of treatment, with the highest percentage of patients in Category 4 accounting for 45 (37.5%) of all patients. The number of patients in categories 3 and 4 also increased from 84 (70%) before treatment to 104 (86.6%) after the end of treatment. Data received at the third month after therapy is commensurate with that obtained immediately after the end of treatment. The effect was maintained for 3 months after the end of therapy. In patients with complete inability to obtain an erection (Category 0 and 1), no significant improvement was observed in the condition – their number before treatment was 12 men (10%), with a percentage similar at the third month after therapy – 11 men (9.16%). The maximum effect of treatment is recorded at the tenth week from the start of therapy, and this effect is maintained until the third month.

With respect to the International Index of Erectile Function (IIEF-5), the distribution of patients is presented in Fig. 2.

Figure 2 shows the number of men who reported having good erectile function after the first procedure, namely 22 men (18.33%). The number of men without erectile dysfunction continues to increase and reaches a maximum after the end of treatment – 35 men (29.16%), the improvement of erectile function being most pronounced in those patients who reported mild and mild to moderate erectile

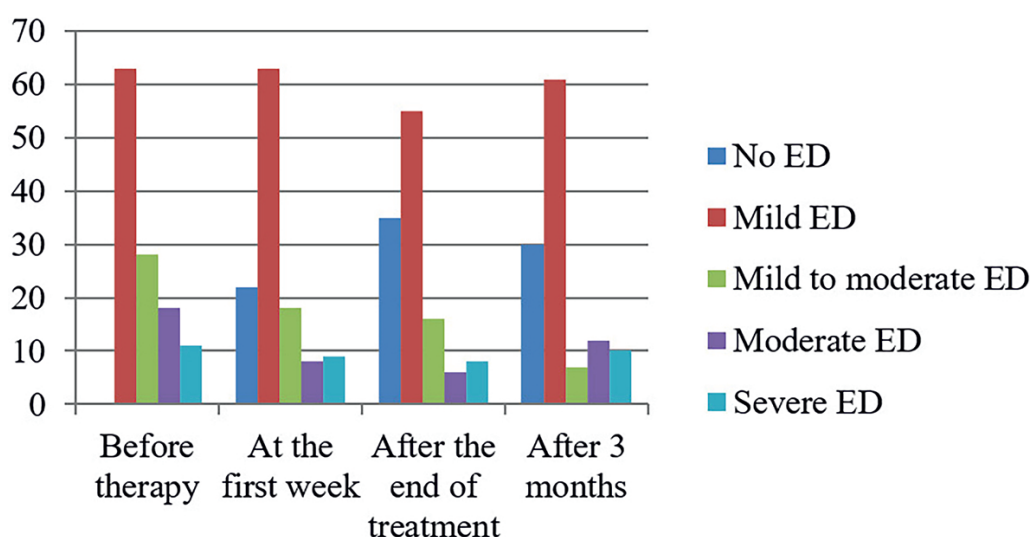


Fig. 2. Distribution of patients according to IIEF-5 for the follow-up period

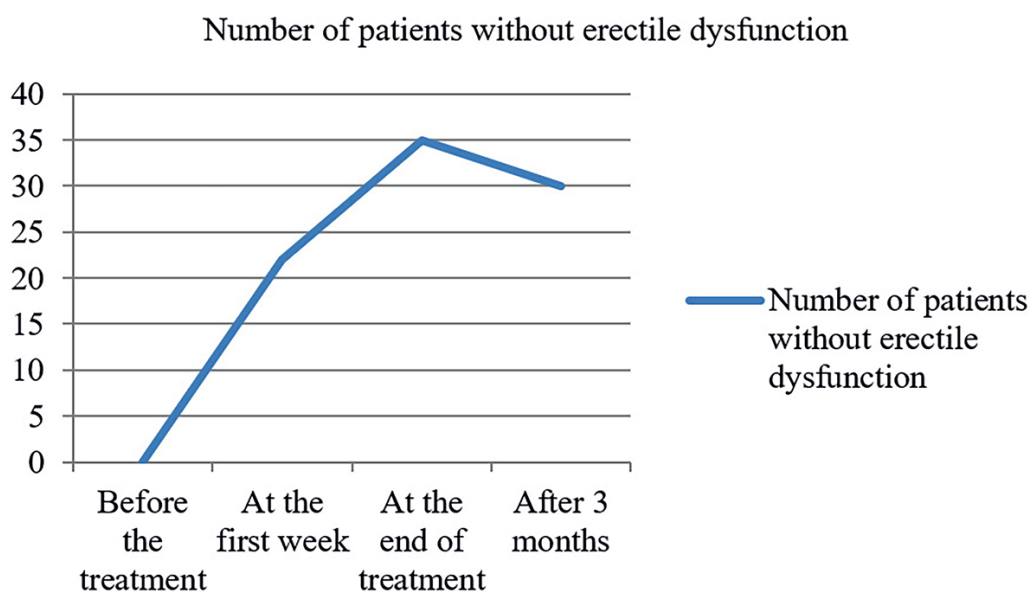


Fig. 3. Number of men without erectile dysfunction during the follow-up period

dysfunction before the onset of therapy. The total number of men without erectile dysfunction and those with mild erectile dysfunction increased gradually, with 63 patients (52.5%) before treatment and 90 (75%) after the end of treatment. This figure remains similar also 3 months after the therapy – 91 (75.8%). In patients with severe erectile dysfunction, no response to therapy has been observed. Their number is constant over the entire treatment period.

Figure 3 reports the change in the number of patients without erectile dysfunction before, during and after therapy. Before treatment, no patients were placed in the group without erectile dysfunction, whereas at the end of treatment, their number was 35.

With respect to the mean of IIEF-5 before, during and 3 months after therapy, the following change is presented in Fig. 4.

An increase in the mean IIEF-5 was reported from 14.54 points before treatment to 18.85 points after the end of treatment. This value is also maintained at the third month after therapy – 18.55 points.

Regarding the tolerability of the therapy, the course of treatment was completed in all patients without any adverse effects of the treatment. No pain, trauma, hematoma, or inflammatory changes were noted during and after the procedure.

**Discussion.** The development of modern technology and the pharmaceutical industry have fundamentally changed the understanding of erectile dysfunction and the methods for its treatment. As a first line of treatment for erectile dysfunction, drugs from the group of phosphodiesterase 5 inhibitors have been used

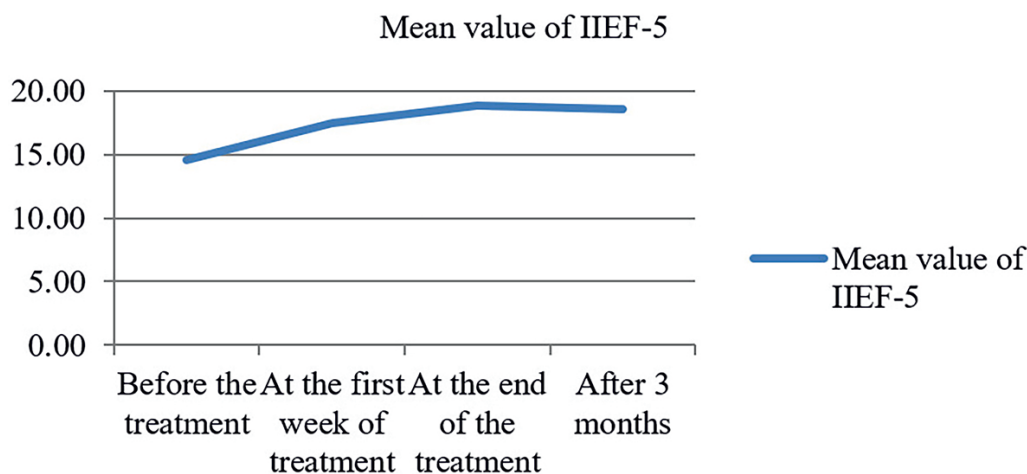


Fig. 4. Change in the average of IIEF-5 for the follow-up period

with great success. The positive results from the use of this type of medication and the lack of serious side effects are causing more and more people to turn to a specialist in the hope of quickly and easily treating their problems. On the other hand, more and more young people are rejecting the continued use of medication and looking for an alternative to effective treatment. The myth of the risk of serious cardiovascular accidents after taking this type of medication still persists. The methods used as second and third line of treatment (vacuum pumps, penis prostheses) are usually associated with positive results, but patients often stay away from these types of treatment because of the inconvenience of use, the invasive and unnatural characters of the methods. Thus, there is a need for a new method of treating patients with erectile dysfunction. In 2010, VARDI et al. [6] conducted therapy on 20 men, reporting significantly improved erections using IIEF-5 as early as the first month after therapy. At an IIEF-5 average of 13.5, after the first month it rises to 20.9. In a study of 31 men with mild to moderate erectile dysfunction, RUFFO et al. [11] reported a significant increase in IIEF score from 16.54 at baseline to 21.13 after the first month of therapy. Our experience shows similar results. There was a significant increase in the number of patients without erectile dysfunction after treatment, as well as an increase in total IIEF-5 score from 14.54 before treatment to 18.55 3 months after the end of therapy. This confirms the assumption of a lasting effect of the therapy even 3 months after the end of treatment.

### Conclusions.

1. With regard to the Erection Hardness Score (EHS), there is a marked improvement in penis firmness immediately after the first procedure, which persists after the end of treatment until the third month after therapy. Improvement in firmness was observed mainly in categories 2, 3, 1, while no

significant improvement was observed in patients with complete inability to obtain an erection.

2. With regard to the International Index of Erectile Function (IIEF-5), there is a significant improvement in erectile function, mainly in the groups with mild and mild to moderate erectile dysfunction. The effect of therapy is maintained until the third month after treatment. No improvement in the condition was observed in patients with severe erectile dysfunction.
3. The mean value of IIEF-5 increased significantly from 14.54 to 18.85 after the end of treatment, and this value was maintained until the third month after the treatment – 18.55.
4. The procedure is well tolerated by patients, with no side effects reported during and after the procedure.

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