



Evaluation of SWT Efficiency in Treatment of Erectile Dysfunction

K. Kazalakova, MD, PhD

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The results of the study show that the ESWT device BTL-6000 SWT is safe and efficacious to improve erectile function. **57% improvement at 90-day follow-up**

Abstract

Purpose & Primary Objective:

The main objective of the study was to investigate and prove the effectiveness and safety of extracorporeal shock wave therapy (ESWT) in treatment of erectile dysfunction (ED) caused by vascular disorders.

The primary efficacy outcome is set to be a minimum increase in IIEF-EF ≥ 5 points in 50% of subjects after the last treatment with results remaining at the same level at 90-day follow-up.

Materials and Methods:

We treated 8 middle-aged men 48-65 years old (average age: 55.5 \pm 6.3 yr) with vasculogenic ED existence for more than 6 months. Patients underwent 8 treatments every 3 - 4 days with BTL-6000 SWT unit.

Assessment of erectile function was performed at screening, after the last treatment and at the 3- and 6-month follow-up examinations using the International Index of Erectile Function (IIEF) questionnaire. Outcome measures used are changes in the International Index of Erectile Function-erectile function domain (IIEF-EF) scores. Safety assessment was based on complications and reported adverse events.

Results:

All patients completed the treatment protocol of 8 consecutive procedures, 30 and 90-day follow-up visits. Pre- and post-treatment collected parameters from 5 patients (62.5%) met the primary efficacy criteria of IIEF-EF increase ≥ 5 points.). At 90-day follow-up examination, the IIEF-EF scores remained at the same level.

Conclusion:

The main object of the study was to investigate the effectiveness and safety of extracorporeal shock wave therapy (ESWT) in treatment of erectile dysfunction (ED) caused by vascular disorders. The results of the study show that the ESWT device BTL-6000 SWT is safe and efficacious to improve erectile function. Patients tolerate the treatment sessions well.