



## New Treatments in Erectile Dysfunction and First Clinical Trial Results

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### **Abstract:**

**Objectives:** Extracorporeal shock wave application (ESWA) has been reported as an effective treatment in different urological indications and newly for erectile dysfunction (ED). We aimed to investigate the efficacy of ESWA in ED patients who were poor responders to phosphodiesterase type 5 inhibitors (PDE5i).

**Methods and Tools:** This was an open-label single-arm prospective study on ED patients with an IIEF-ED score (International Index of Erectile Function) of less than 15 and with a duration of more than 6 months at baseline. All patients were non-responders to PDE5i and with multiple cardiovascular risk factors. 30 patients were enrolled from July until October 2014. The protocol comprised one treatment session per week for 5 weeks. Patients were followed at 1 month, and only then an active PDE5i medication was provided if needed for additional 2 months until final follow up visit (after 12 weeks). At each treatment session, 5000 shock waves were applied using the *Dornier Aries* (*Dornier MedTech GmbH, Wessling, Germany*) on the penile shaft and crus in different anatomical sites at an energy level 4 with an energy flux density (EFD) of 0.051 mJ/mm<sup>2</sup>. Each subject underwent a full baseline assessment of erectile function using validated questionnaires and objective penile hemodynamic testing before and after treatment.

**Results:** All patients (mean age of 53; range 40-66) completed the study and tolerated the novel therapy very well without side effects. The mean IIEF-ED score at baseline was 11±1. At the end of the treatment 26 of the 30 males (86.6%) reached an improvement of at least 7 points and an average increase of 11 points (p<0.001). 10 patients achieved an increase to IIEF-score higher than >25 and 16 patients were able to achieve full sexual intercourse after taking PDE-5i. These results were lasting for 12 weeks until the second follow up. A significant improvement (p < 0.001) in penile hemodynamics was detected after treatment and this improvement significantly correlated with increases in the IIEF-ED (p < 0.05). No patients reported pain associated with any adverse events during or after the treatment.

**Discussion:** Penile ESWA is a new modality that can improve treatment of severe to moderate ED patients non-responding to PDE-5i or with multiple cardiac risks. The effect of ESWA on angiogenesis and microcirculation seems to be essential for the vast improvement in erectile function. These results were significantly shown using the IIEF-ED scores, and the three parameters of penile hemodynamics and endothelial function.

**Conclusion:** The new treatment represents a valid option to conservative strategies for the management of patients with erectile dysfunction. These preliminary data need to be reconfirmed by multicenter sham controlled studies in a larger group of ED patients.