

# **Extracorporeal shockwave therapy (ESWT) for treatment of chronic pelvic pain syndrome (CPPS): First results of the randomised, placebo-controlled double-blind study**

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## **Introduction**

CPPS (classification 3A/B according to NIH-DIDDK) is associated with many different symptoms. The main complaints concern pain in varying locations with differing intensities of discomfort during urination. The men affected suffer from similar restrictions on their daily lives as do patients after a heart attack, for example. Given the unclear pathophysiology, there are no causally based approaches to a therapy, neither is any effective symptomatic treatment approach available either. This placebo-controlled study investigates the efficacy of ESWT for treating CPPS.

## **Patients and method**

60 patients with typical CPPS complaints of at least 3 months in duration with no signs of infection in their sperm or urine, and with normal prostate-specific antigen values were included in the prospective study following randomisation. ESWT was administered by perineal application at weekly intervals on a total of four occasions (3000 pulses per session, frequency 3 Hz, energy flux density 0.30 mJ/mm<sup>2</sup>), using a standard electromagnetic ESWT instrument without modifications (Storz Duolith, Storz Medical AG, Switzerland). For the purposes of the placebo treatment, the transmission of shockwaves was reliably interrupted by inserting a membrane into the standard shock transmitter. Follow-up examinations were performed 1, 4 and 12 weeks after ESWT. The pain was evaluated using the visual analogue pain scale (VAS, 0 – 10). The urination conditions were calculated using the international prostate symptom score (IPSS, 0 – 35), disease-specific discomfort using the chronic prostatitis symptom index of the National Institute of Health (NIH-CPSI, 0 – 43) and erectile function with the international index of erectile function (IIEF, 5 – 75). The statistical analysis was performed with the t-Test/Mann-Whitney rank sum test.

## **Results**

All 60 patients completed the treatment cycle without problems. 25 of them (11 verum, 14 placebo) have been evaluated so far on the basis of a complete follow up. The average duration of CPPS complaints was 7.7 months (3 – 24 months). Treatments were administered without problems as outpatient treatment without any analgesia whatsoever. The treatment duration in each case was 17 minutes. All investigated parameters revealed an improvement in the verum group as opposed to the placebo treatment, the values were statistically significant (IPSS  $p < 0.001$ , IIEF  $p = 0.005$ , CPSI  $p < 0.001$ , VAS  $p < 0.001$ ). No side effects were observed.

## **Conclusions**

For the first time, this study has revealed statistically significant improvements in CPPS patients using ESWT. ESWT of the prostate region by perineal application can be applied easily and safely. It was possible significantly to improve the patients' quality of life, in particular because of the alleviation of pain. The straightforward, rapid and safe perineal application means that ESWT has been found to be an ideal outpatient treatment option for this indication, offering good cost effectiveness. This is particularly the case because there have not been any side effects. The patients' everyday lives were not restricted by the ESWT application, the application is efficient in terms of time and cost. It will be necessary to check the duration of the effect following ESWT by means of a longer follow up. At this current time, however, ESWT can be regarded as one of the few placebo-controlled therapy options for the straightforward treatment of CPPS with proven effectiveness.