

## Abstract

**Background:** Currently, there are no effective therapy strategies for idiopathic, non-organic vulvodynia and dyspareunia in women. ESWT (extracorporeal shock wave therapy) is a nonsurgical/noninvasive technique widely used to treat musculoskeletal diseases, muscle spasticity, hypertonia, renal, biliary calculi and urological disorders.

**Aim:** The goal of our work is to investigate the possibility to eliminate chronic and acute forms of pelvic pain by a non-invasive physical method. We wanted to know if the extracorporeal shock wave technique could fulfill these requirements. Study design: The prospective, randomized, double-blind, placebo-controlled studies were conducted following feasibility studies.

**Methods:** The study 1. included 62 women with vulvodynia for at least 3 months. The women were randomly assigned to either a treatment group (n=31) or a placebo group (n=31). The patients in the treatment group received perineally applied ESWT weekly (3000 pulses each for four consecutive weeks). The position of the shock wave transducer was changed six times after every 500 pulses. Patients in the placebo group underwent the same treatment procedure, but the handpiece was provided with a placebo stand-off that disabled energy transmission. Subjective pain was evaluated by a visual analogue scale (VAS, 0-10) and a cotton-swab test (CST, Goetsch scale 0-4). Follow-ups were done 1, 4, and 12 weeks post-ESWT.

The study 2. included 62 women who reported dyspareunia. Patients in the treatment and placebo groups received perineally applied ESWT weekly for four consecutive weeks, placebo-patients with a placebo-stand-off. The grade of dyspareunia was estimated using the Marinoff-scale and subjective pain intensity on a visual scale (VAS), before and after treatment.

**Results:** In all, 61 women completed the vulvodynia study. We tested for differences in the VAS and CST within and between the treatment and placebo groups. The testing was between before treatment and particular follow-up. We found significant changes in the treatment group. Reductions in VAS ( $p<0.01$ ) and CST ( $p<0.01$ ) were observed at all three follow-ups. At all assessments, pain reduction was always  $>30\%$ . In the placebo group there were no statistically significant changes between before and after treatment. There were no differences between the treatment and placebo groups before treatment but statistically significant differences at all three follow-ups (VAS  $p<0.01$ ); CST  $p<0.01$ ). The dyspareunia study completed 61 women. We tested for differences in the Marinoff scale and VAS within and between the treatment and placebo groups. Significant differences were found in the treatment group but not in the placebo group. Differences before and after the treatment for within the groups were  $p<0.001$ , between the groups  $p<0.001$ . Pain reduction was always  $>30\%$ . The effect sizes were both large: Marinoff 0.825 and VAS 0.883.

**Conclusions:** In our study we have proved reducing chronic and acute pain perception in our treatment groups. The method is easily replicable, inexpensive, and without known side effects.

**Keywords:** vulvodynia; dyspareunia; extracorporeal shockwave therapy; ESWT; Pelvic pain