

Radial Extracorporeal Shock Wave Therapy (rESWT) in Chronic Plantar Heel Pain - a RCT

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Aim:

The study has to determine the effectiveness of rESWT for chronic plantar heel pain.

Materials and methods:

A total of eight study centers enrolled 254 patients in this study, 252 patients were randomized, 251 patients received assigned treatment (129 active-ESWT, 122 Placebo-ESWT). All patients were suffering from painful heel syndrome for at least 6 months, all of them previously get unsuccessful conservative treatments. Basically the radial extracorporeal shock wave therapy was performed without local anesthesia. 2000 treatment-impulses were applied with the working pressure of 0.4 MPa (4 bar). Subjects received 3 shock wave treatments with 2000 therapeutical shock wave impulses each. Between each treatment, a treatment-free interval of 2 weeks was observed.

The primary Criteria were: Heel pain when taking the first steps of the day (VAS) and Heel pain while doing daily activities (VAS). Second criteria were defined as: Pain on pressure, measured with standardized pressure device (Dolormeter), Roles and Maudsley-Score, SF-36, physician's global judgment of effectiveness, subject's satisfaction with the outcome of the treatment, Subject's willingness to recommend treatment

The primary point in time for comparison of groups was three months after last treatment.

The patients of the ITT (intention-to-treat) population were defined in the final blind review report (individual listing) before blind was broken. A total of 125 ESWT patients (96.9% of all treated ESWT patients) and 118 placebo patients (96.7% of all treated placebo patients) were evaluated for the ITT analysis.

The size of the treatment effects were quantified using the Mann-Whitney superiority measure with associated confidence intervals. Efficacy was analysed by comparing the success rates between the treatment and placebo groups, with success being defined on a per patient basis for each of the two primary efficacy criteria as at least a 60% reduction in VAS pain scores from baseline to 3 month after ESWT.

The study was performed in accordance to GCP guidelines.

Results:

With regard to the demographic criteria, sex, BMI, age and other baseline characteristics including the baseline efficacy criteria, groups are well comparable, all effect sizes are denoting only marginal group differences, all p-values are statistically not significant ($p > 0.1$).

With regard to the primary criteria the analysis showed statistically significant results ($P = 0.0059$, one-sided, ESWT success rate 55.20% vs. placebo success rate 38.98%).

With regard to the secondary criteria the clinical relevant data criteria mental/physical health score of the SF36, the Roles and Maudsley Score, global judgment of effectiveness, therapy satisfaction and therapy recommendation all showed better outcome at the primary endpoint in favour to the ESWT group ($P < 0.025$ one-sided) and all effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group

The a priori ordered hypotheses of the final statistical analysis plan are statistically significant ($P < 0.025$ one-sided): Composite score (sum score) of heel pain (VAS) when taking first steps of the day, heel pain (VAS) while doing daily activities and heel pain (VAS) after application of the Dolormeter ($P = 0.0220$ one-sided, $MW = 0.5753$, $LB-CI = 0.5023$). Overall success rate with regard to heel pain defined as percentage decrease of heel pain larger than 60% from baseline at visit 7 for at least two of the three heel pain (VAS) measurements ($P = 0.0020$ one-sided, $MW = 0.5937$, $LB-CI = 0.5314$).

The other criteria also demonstrate superiority of the ESWT group with p-values below the level of significance. All effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group.

Only minor side effects as petechial bleeding, swelling and discomfort during treatment were detected.

Conclusion:

The radial shock wave therapy is effective and safe in treatment of chronic heel pain. The data showed high homogeneity, all other sensitivity analysis confirmed these findings in favour to radial shock wave therapy. The effect size reaches clinical relevance. No significant side effects were found but some minor findings could occur.