Study to determine the effectiveness of rESWT for chronic plantar heel pain regarding the short- and long-term outcomes

Author:
Ludger Gerdesmeyer, Lowell Weil jr, Lowell Weil sr, Carol Frey, Keith Fedder, Barry Scurran, John Stienstra, Johannes Vester, Mark Henne, Martin Russlies, Markus Maier

Institution:
MARE clinic Kiel; Dept. of Orthopedic Surgery and Sportstraumatology; Eckernforder Strasse 22; D-24119 Kiel, Germany

Device and producing company:
Swiss Dolorclast, EMS medical

Introduction:
RCT are needed to prove efficacy of treatment options. If rESWT showed significantly better outcomes at short-term follow-up (FU), long-time FU has to be analyzed as well

Methods:
A total of 254 patients were enrolled. All patients had been suffering from painful heel syndrome for at least 6 months. RESWT was performed without local anesthesia. Two thousand impulses were applied with the working pressure of 0.4 MPa (4 bar). Subjects received 3 shock wave treatments of 2000 therapeutical shock wave impulses each. 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 also defined. The endnoints were I and 12 months after rESWT. Efficacy was analyzed by comparing the success rates between the treatment and placebo groups and was defined as a 60% reduction in VAS pain scores. The study was performed in accordance to GCP guidelines.

Results:
With regard to the demographic criteria, groups are well comparable. At 3 months after rESWT treatment, overall therapeutic success was observed in 75 out of 123 ESWT patients and in 49 out of 116 placebo patients. The rate difference was statistically significantly better in favor of the rESWT treatment. The VAS composite score showed similarly significantly better outcomes. Thus, the difference between the groups (in favor of the ESWT group) at the primary endpoint (visit 7) was enlarged during the follow-up II period. Regarding the percent change of VAS pain reduction on the composite score 12 months after rESWT (end of the follow-up II period), the reduction in the ESWT group was 84.8%, whereas the placebo group showed a 43.2% reduction. The difference at the end of the follow-up II period is 41.6% in favor of the ESWT treatment. Thus, the group difference in favor of the ESWT group at the primary endpoint (visit 7) was also further enlarged during the follow-up II period. The same outcome was found in the secondary criteria as well. The a priori ordered hypotheses of the final statistical analysis plan were statistically significant ($P < 0.025$ one-sided. All effect sizes (Mann-Whitney) denote more than small superiority of the ESWT group. Only minor side effects, such as petecheal bleeding, swelling and discomfort during treatment, were detected.

Discussion:
RESWT is effective in treating chronic plantar heel pain after long-term FU. Another RCT is needed to compare focussed and unfocussed ESWT.

Conclusion:
Radial shock wave therapy is effective and safe for the treatment of chronic heel pain. The data showed high homogeneity and all analyses confirmed a more favourable outcome with radial shock wave therapy, the effects of which are clinically relevant. The significant difference between the groups increased with the length of the follow-up interval. No significant side effects were reported, but some minor side effects could occur.