

The Effectiveness of Extracorporeal Shock Wave Therapy on Tendinitis of the Shoulder

Author:

L. Gerdesmeyer, S. Wagenpfeil, G. Handle, M. Loew, K. Lehmkuhler, S. Gassel, R. Seil

Institution:

Dept of Orthopaedic Surgery and Sportstraumatology, Technical University of Munich, Germany

Calcified lesions of the shoulder of the rotator cuff are a common problem in orthopaedic practice. The incidence varies from 2.5% to 20% in patients with asymptomatic shoulders and as much as 54% in patients with shoulder pain. The lesions are mostly located in the supraspinatus tendon close to the insertion area in the critical zone. Patients with calcifying tendinosis were usually treated conservatively (physiotherapy, analgesics, subacromial injection, ...). Uthoff described the circle of the disease which is mostly self-limiting and at least 10% of patients may require open or arthroscopic surgery.

Extracorporeal shock wave therapy (ESWT) in treatment of these calcified lesions was first described by Dahmen in Germany. Two different shock wave therapy techniques were known. The low energy one with a mean energy flux density lower than 0.08 mJ/mm² and the high energy one with energy levels of more than 0.28 mJ/mm² . Dahmen first used the low energy shock wave and described an analgetic effect. Loew used the high energy level and found a pain relief and also changes of the lesions in most cases.

There is an increasing number of clinical trials showing a success in 60% to 80% of patients. Mostly these trials were uncontrolled prospective designed. A better trial was published by Loew et al. They reported their results and stated the high energy ESWT is effective.

But at least there is no trial with a design in accordance to the ICH/GCP guidelines. Only these trials have the statistical power and evidence to show the efficacy of a treatment method.

Haake et al showed that the application of ESWT must be controlled to verify the position of the ESWT focus. Treatment techniques without control mechanism showed a worse outcome than techniques with an exact fluoroscopic controlled focussing application.

Materials and methods: First we completed a feasibility study to find out the treatment effect size and calculate the sample size. A prospective randomized placebo controlled study in accordance to the ICH and GCP guidelines was designed based on the results of the feasibility trial. We treated 48 patients in low energetic, high energetic and control group each to have the right statistic power.

One treatment group received 2 x 1500 high energetic shock waves with mean energy flux density of 0,32 mJ/mm² and the other one got 2 x 6000 low energetic shock waves with mean energy flux density of 0,08 mJ/mm² , 48 patients of the blinded placebo group received a sham therapy. We used the same device in all patients so we could exclude device related effects. The device we used called EPOS FLUORO®, manufactured by DORNIER MED TECH®. The primary criteria was the Constant-Murley-Score, second criteria the visual analogue scale and changes of deposit size in x-ray examination. The ESWT was indicated after failed complete conservative therapies. Between the two application settings we have an interval of two weeks. In all sessions the patients could get an analgesia if the pain was uncomfortable. An air chambered foil inhibits the transmission of the shock waves from ESWT emitter into the shoulder in the control group.

The clinical and radiological examinations were done by a blinded observer, during the whole trial phase an independent monitor guaranteed that the protocol was followed by the coworkers. The statistical evaluations, data monitoring and auditing were done independently from applicator and blinded observer. The patients were randomized after they have fulfilled the inclusion and exclusion criteria and after they have given a written informed consent to get the ESWT and to take part of the trial.

Comparative analyses were done on an intention-to-treat basis. No prospective cessation rules were defined and no interim analysis was planned. The study protocol was approved of by the ethics committee at the authors' institution.

Results: 24 weeks after ESWT the patients treated with high and low energetic ESWT have a significant better outcome as the sham group by scoring the Constant-Murley-Score ($p < 0.001$). The second criteria as the visual analogue scale and the morphological appearance of the deposits changed with high statistical difference ($p < 0.001$). No severe side effects caused by shock waves were observed. In some cases we observed a transient reddening and small cutaneous petechial bleeding but all of them disappeared within 6

weeks when the patients came to the first follow up visit. The comparison between high and low energetic ESWT showed significant better outcome after high energetic ESWT.

Discussion: The exact mechanisms of the therapeutic effect of extracorporeal shock wave therapy for treatment of calcified lesions of the shoulder are still uncertain. Although some investigations show a direct mechanical effect that leads to a mechanical disintegrating effect on the deposit. Other authors prefer a long-lasting hyperstimulation analgesia. The shock waves initiate an increase of blood flow with increasing oxygen supply of the critical zone. That can induce the further ongoing of the natural selfhealing cycle. In chronic calcified tendinitis of the rotator cuff, the cycle, described by Uthoff rests in the calcific stage. The application of extracorporeal shock waves pushes the cycle further to the postcalcific stage that leads to a complete restitutio. Because of the natural history and the normally self limiting disease of the tendinosis, the shock waves treatment should not used in acute patients. Most of these patients with an acute tendinitis still move from the calcific stage to the postcalcific stage and should only be treated in a symptomatic analgetic or antiphlogistic way. Compared to other published data regarding calcific tendinitis of the shoulder, no study fulfils the requirements of GCP guidelines to show efficacy.

Conclusion: The high energetic shock wave therapy is the best evidence based treatment in calcified lesions of the shoulder and must be indicated before operative intervention.