Evidence Table

Clinical Area: Shockwave therapy for epicondylitis

Study Type: Randomized controlled trial.
Study Aim: To evaluate the efficacy of extracorporeal shock wave therapy (ESWT) for treatment of lateral epicondylitis.

Outcomes
- **Primary:** Success rate after 12 weeks.
- **Secondary:** Roles and Maudsley score; intensity of pain, grip strength.

Design
- **Number of subjects:** N=272 (n=135 ESWT, n=137 control)
- **Description of study population:** Multicenter trial conducted in Germany. **ESWT group:** 54% female; mean age=46.9 ± 8.5 years; mean duration of symptoms=27.6 ± 35.5 months; 
  **Control group:** 52% female; mean age=46.3 ± 9.6 years; mean duration of symptoms=22.8 ± 21.4 months.
- **Inclusion criteria:** At least 18 years old; clinical diagnosis of lateral epicondylitis; Roles and Maudsley score of 3 or 4; at least 6 months of unsuccessful conservative therapy (e.g. physical therapy, local steroid injections); at least 2 weeks since the last conservative treatment.
- **Exclusion criteria:** Local arthritis; pathological neurological findings; pregnancy; infection or tumor of affected extremity; thrombopathy, anticoagulant therapy or manifest hyperthyroidosis; known allergy to local anesthetic.
- **Power:** 80% power to detect a 20% difference in success rates between groups, with 136 patients per group.
- **Method of randomization:** Computer-generated randomization lists.
- **Intervention:** “Low-energy” ESWT with 3 treatments of 2000 pulses each (0.04 to 0.22 mJ/mm²), applied after administration of local anesthesia (3mL of 1% mepivacaine). There was an interval of 7 ± 1 days between treatments. Continuous ultrasound guidance was used to focus the shock waves at the insertion of the muscles at the lateral epicondyle of the humerus. Patients in the control group received the same regimen, but a polyethylene foil filled with air and fixed with ultrasound gel was placed in front of the coupling cushion to reflect the shock waves. Several shock wave devices were used including the Dornier Epos/Ultra and the Siemens Sonocur. The authors reported that the manufacturers arrived at a set of shock wave parameters with which the devices could be compared. Patients were not restricted from using other treatments after active or sham ESWT. In addition, they could cross-over to the other intervention after 3 months.
- **Blinding:** Double-blind (patients and outcome assessors were blinded). Patients were unblinded at 3 months if treatment was not successful.

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Source of outcome data (e.g. patient self-report, doctor report, lab results): Clinical examination, patient self-report.

Length of follow-up: 12 months. Assessments at baseline, 6 and 12 weeks and 12 months post-treatment.

Completeness of follow-up: 242/272 (89%) completed the 12 week follow-up (primary outcome); 206/272 (76%) completed the 12 month follow-up.

Validity

Is the study type appropriate for the questions being asked? Yes.

Was the study population typical of patients with this disease? Yes.

Were the treatment/control groups comparable at baseline? Yes.

Was the intervention compared to placebo and/or best accepted intervention? Yes, to sham intervention.

Was there compliance with the intervention? Yes.

Was there equal intensity of observation of study and control subjects? Yes.

Was the process of observation likely to affect the outcome? No.

Intention to treat analysis? No.

Conclusions regarding validity of methods:
The investigators did not use intention to treat analysis for the primary outcome; 11% of patients were excluded.

Results

Primary outcome: Success* rate 12 weeks after intervention, No. (%)

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>ESWT</td>
<td>(n=124)</td>
<td>(n=122)</td>
</tr>
<tr>
<td>32 (25.8)</td>
<td>31 (25.4)</td>
<td>1.00</td>
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</table>

* Success was defined as Roles and Maudsley score of 1 or 2 and no additional conservative or operative treatment in the observed time-interval. Roles and Maudsley pain score: 1=excellent (no pain), 2=good (occasional discomfort), 3=fair (some discomfort after prolonged activity), 4=poor (pain limiting activities).

Secondary outcomes

There were no significant differences between groups at any time point (6 weeks, 12 weeks, 12 months) on pain-free grip strength, or pain ratings. There was improvement in both groups compared to baseline. (Exact numbers not available because data were presented in Figures).
**Adverse effects affecting at least 5% of study population, No. (%)**

*Note: Statistical significance not reported*

<table>
<thead>
<tr>
<th></th>
<th>ESWT (n=134)</th>
<th>Control (n=136)</th>
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<tbody>
<tr>
<td>Reddening of skin</td>
<td>42 (31.3)</td>
<td>11 (8.1)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>10 (7.5)</td>
<td>4 (2.9)</td>
</tr>
<tr>
<td>Swelling</td>
<td>9 (6.7)</td>
<td>8 (5.9)</td>
</tr>
<tr>
<td>Pain</td>
<td>15 (11.2)</td>
<td>6 (4.4)</td>
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**Authors’ Conclusions**

“Extracorporeal shock wave therapy as applied in the present study was ineffective in the treatment of lateral epicondylitis. The previously reported success of this therapy appears to be attributable to inappropriate study designs. Different application protocols might improve clinical outcome. We recommend that extracorporeal shock wave therapy be applied only in high-quality clinical trials until it is proved to be effective.”

**Reviewer’s Conclusions**

The investigators did not find a significantly higher rate of success at 12 weeks (the primary outcome) between the group receiving ESWT and the group receiving a sham treatment. The study was designed to have sufficient power to detect a clinically meaningful difference in success rate between groups. 11% were excluded from the primary outcome analysis.