Clinical Area: Iontophoresis for TMJ

Keywords: iontophoresis, dexamethasone, TMJ


Study Type: Randomized controlled trial
Study Aim: To evaluate the effect of iontophoresis in a group of patients with documented painful temporomandibular joint (TMJ) pathologic conditions.

Outcomes
- Primary: Pain, mandibular range of motion.

Design
- Number of subjects: n=72 invited to participate; n=53 received treatment
- Description of study population: Patients recruited through newspaper advertisements and through local dentists. Treatment group: mean age=41.8 ± 15.9; 17 female/5 male; 7 disk replacement with reduction/7 disk replacement without reduction; 8 osteoarthritis. Placebo group: mean age=37.3 ± 13.4; 26 female/5 male; 14 disk replacement with reduction; 8 disk replacement without reduction; 9 osteoarthritis.
- Inclusion criteria: At least 18 years old; clinical and MRI evidence of a TMJ pathologic condition; focal preauricular pain on palpation and provocation of the TMJ; patient report of at least 1 month of persistent and focal preauricular pain; score of at least 2 cm on a 10 cm pain visual analog scale (VAS) obtained immediately before the first iontophoresis treatment.
- Exclusion criteria: Previous TMJ surgery (arthroscopy or arthrotomy); patients using analgesic, anti-inflammatory or other centrally acting pain medication; pregnancy; patients involved in litigation surrounding their pain.
- Power: Not discussed.
- Method of randomization: Not discussed.
- Intervention: Patients were randomly assigned to receive preauricular iontophoresis treatment with: 1) treatment group: 1.5 dexamethasone sodium phosphate 4 mg/ml combined with 40 mg/ml (4%) lidocaine hydrochloride or 2) placebo group: normal saline solution. Iontophoresis was done three times, with 1 day between each treatment.
- Blinding: Double-blind.
- Source of outcome data (e.g. patient self-report, doctor report, lab results): Patient self report: At baseline and immediately before each treatment, subjects recorded their pain level on a 10 cm VAS: Clinical examination: mandibular ranges of motion.
- Length of follow-up: 18 days.
- Completeness of follow-up: Appears to be 100%.

Validity
- Is the study type appropriate for the questions being asked? Yes.
- Was the study population typical of patients with this disease? Appear to be.
- Were the treatment/control groups comparable at baseline? Unclear, little information given.
- Was the intervention compared to placebo and/or best accepted intervention? Yes, placebo.
- 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? Repeated measurements may affect patients’ assessment of pain, but this would affect both groups.
- Intention to treat analysis? Did not specify.
Conclusions regarding validity of methods:
This was a relatively small RCT with short-term follow-up (2 weeks after the final treatment). It is unclear whether the 16 patients who did not meet the minimum VAS score on the day of the first treatment were excluded pre- or post-randomization. If excluded post-randomization, this could introduce a selection bias. The authors did not discuss the method of randomization or statistical power.

Results
Visual analogue scale (VAS) measurements$^{1,2}$ (mm)

<table>
<thead>
<tr>
<th>Day</th>
<th>Treatment group</th>
<th>Placebo group</th>
<th>p-value$^3$</th>
</tr>
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<tbody>
<tr>
<td>0$^4$</td>
<td>46</td>
<td>47.5</td>
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<tr>
<td>2</td>
<td>40</td>
<td>40.5</td>
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<td>4</td>
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<td>11</td>
<td>41</td>
<td>36</td>
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<tr>
<td>18</td>
<td>42</td>
<td>35</td>
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</tbody>
</table>

ns=not significant

$^1$Pain was measured on a 10 cm VAS that ranged from 0= “no pain” to 100= “the worst pain imaginable”. A score of 20 was required for study entry.

$^2$VAS values were estimated from figures given in the article (exact numbers not presented).

$^3$P-value comparing values for the treatment and placebo groups. p-values were only given for the comparisons on days 2 and 4.

$^4$The first treatment was given on day 0.

Both groups had significant (within group) decreases in VAS scores at days 2 and 5 (p<0.05)

There were no significant differences found between treatment groups for any of the mandibular range-of-motion measurements (vertical, lateral and protrusive) (no numbers were presented in the article).

Adverse effects
Not discussed

Authors’ Conclusions
“Our results do not provide evidence to support the conclusion that preauricular iontophoresis with dexamethasone and lidocaine has clinical efficacy when compared with placebo.”

Reviewer’s Conclusions
The authors did not find that iontophoresis improved self-reported pain measured by a VAS or mandibular range-of-motion compared to placebo. This was a relatively small study with no analysis of statistical power. There may not have been sufficient statistical power to detect clinically important differences. This is unlikely for the pain measurements because scores of the treatment and placebo groups were nearly identical at days 2 and 4 and the treatment group scores were slightly higher than the placebo group on days 11 and 18. The likelihood that there may have been clinically important although statistically non-significant differences between groups in mandibular range-of-motion cannot be determined because the authors did not report numbers for these outcomes (they only reported statistical significance). The authors mention that the lack of effectiveness of iontophoresis may be due to the heterogeneity of the sample (i.e. they included patients who had disk replacement with reduction; disk replacement without reduction and osteoarthritis). No data on adverse effects were presented.