**Diclofenac Sodium 1% Gel in Patients With Hand Osteoarthritis: Effectiveness in Patients With First Carpometacarpal Joint Involvement**

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## Introduction

- Physical functioning of the hand can be severely compromised in patients with osteoarthritis (OA) localized to the hand.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended for the treatment of OA in the dominant hand.
- Typical NSAIDs are recommended over NSAIDs because they have similar efficacy in pain relief and a lower incidence of gastrointestinal and other systemic adverse events.
- In a randomized, vehicle-controlled trial, diclofenac sodium 1% gel (DSG) was effective and well tolerated in patients with OA of the hand.

## Objective

To evaluate the efficacy of diclofenac sodium 1% gel on pain, stiffness, and physical function in patients with osteoarthritis of the hand categorized according to involvement of the first carpometacarpal joint and intraphalangeal joints of the dominant hand.

## Methods

### Study Design
- Post hoc analysis of data by hand joint from an 8-week, multicenter, prospective, randomized, double-blind, placebo-controlled, parallel-group trial.
- The study received institutional review board approval, and all patients provided written informed consent.

### Participants
- Men and women aged 50 years or older with OA of the dominant hand diagnosed according to American College of Rheumatology criteria and radiographically staged as grade 3 or moderate to severe joint space narrowing (Kellgren-Lawrence grades 2–1).

### Inclusion Criteria
- Pain in the dominant hand for ≥12 months requiring use of an NSAID for ≥4 weeks.
- Pain in the dominant hand exceeding pain in the nondominant hand by >20 mm.

### Exclusion Criteria
- Secondary, rheumatoid arthritis, or other rheumatic or nonrheumatic diseases in the dominant hand.

### Treatment
- Diclofenac sodium 1% gel

### Outcomes
- AUSCAN = Australian/Canadian Osteoarthritis Hand Index
- CMC-1= first carpometacarpal joint
- DSG = diclofenac sodium gel

### Analysis
- Analyses were performed on an intention-to-treat basis.
- The occurrence of adverse events is summarized in Table 3.

## Results

### Patient Disposition
- 385 patients were randomized and included in the intent-to-treat population.
- Post hoc analysis of data by hand joint from an 8-week, multicenter, prospective, randomized, double-blind, placebo-controlled, parallel-group trial.

### Comparison of DSG and Vehicle

#### Efficacy
- Percentage reductions in AUSCAN pain were greater with DSG vs vehicle in patients with CMC-1 pain alone (41.3% vs 27.7%; p≤0.001) and in patients with pain in CMC-1 plus other affected joints (41.3% vs 27.7%; p≤0.001).

#### Safety
- No serious adverse events were reported.

## Conclusions

- Diclofenac sodium 1% gel improved pain, stiffness, and function in >900 patients with hand osteoarthritis (involving the first carpometacarpal plus other affected joints or involving the intraphalangeal joints only) and was well tolerated.
- In the small group (<10%) of patients with pain only in the thumbs (the carpometacarpal joint), diclofenac sodium 1% gel improved Visual Analog Scale pain but not Australian/Canadian Osteoarthritis Hand Index pain, stiffness, or function.
- The Australian/Canadian Osteoarthritis Hand Index may not be a sensitive instrument for measuring pain in patients with osteoarthritis limited to the thumbs.

## References


# Table 2: Baseline Characteristics According to Finger Joint Involvement

<table>
<thead>
<tr>
<th>Outcomes Measure</th>
<th>Outcome Category</th>
<th>Baseline Characteristics</th>
<th>DSG (n=187)</th>
<th>Vehicle (n=187)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age, yrs</td>
<td>Baseline</td>
<td></td>
<td>59.4 (8.8)</td>
<td>59.1 (9.1)</td>
<td>0.51</td>
</tr>
<tr>
<td>Mean BMI, kg/m²</td>
<td>Baseline</td>
<td></td>
<td>28.0 (5.5)</td>
<td>27.7 (5.4)</td>
<td>0.54</td>
</tr>
<tr>
<td>Mean baseline VAS pain, 100 mm</td>
<td>Baseline</td>
<td></td>
<td>70.2 (18.5)</td>
<td>67.5 (18.3)</td>
<td>0.35</td>
</tr>
<tr>
<td>Mean AUSCAN function, 100 mm</td>
<td>Baseline</td>
<td></td>
<td>65.1 (17.2)</td>
<td>66.9 (16.4)</td>
<td>0.39</td>
</tr>
<tr>
<td>Mean AUSCAN stiffness, 100 mm</td>
<td>Baseline</td>
<td></td>
<td>70.0 (18.2)</td>
<td>70.3 (18.5)</td>
<td>0.91</td>
</tr>
</tbody>
</table>

# Table 3: Most Frequent Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event, %</th>
<th>NSAIc (n=198)</th>
<th>Vehicle (n=187)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal adverse events</td>
<td>7.1</td>
<td>5.4</td>
<td>0.55</td>
</tr>
<tr>
<td>Application of rescue medicine</td>
<td>10.7</td>
<td>10.9</td>
<td>0.91</td>
</tr>
<tr>
<td>Serious adverse events*</td>
<td>1.0</td>
<td>0.5</td>
<td>0.50</td>
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<tr>
<td>Headache</td>
<td>11.1</td>
<td>10.2</td>
<td>0.70</td>
</tr>
<tr>
<td>Back pain</td>
<td>8.1</td>
<td>6.5</td>
<td>0.42</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>23.0</td>
<td>23.0</td>
<td>0.91</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>35.2</td>
<td>35.2</td>
<td>0.91</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>20.6</td>
<td>20.6</td>
<td>0.91</td>
</tr>
<tr>
<td>Nausea</td>
<td>20.6</td>
<td>20.6</td>
<td>0.91</td>
</tr>
<tr>
<td>Application site pruritus</td>
<td>23.1</td>
<td>23.1</td>
<td>0.91</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>22.7</td>
<td>22.7</td>
<td>0.91</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>20.1</td>
<td>20.1</td>
<td>0.91</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>15.3</td>
<td>15.3</td>
<td>0.91</td>
</tr>
</tbody>
</table>

*None of the serious adverse events was considered treatment related.

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