

**Spacca G, Cacchio A, et al. Analgesic Efficacy of a Lecithin-Vehiculated Diclofenac Epolamine Gel in Shoulder Periarthritis and Lateral Epicondylitis: A Placebo-Controlled, Multicenter, Randomized, Double-Blind Trial. *Drugs Exptl Clin Res* 2005;31(4):147-154.**

Design: Randomized clinical trial

Brief summary of results:

- 155 patients (74 men, 81 women, mean age 50) with either shoulder periarthritis (n=115) or lateral epicondylitis (n=40) treated at 3 centers in Italy and one center in Hungary
- The patients had periarthritis or epicondylitis in an acute phase (pain present for less than 5 days); further inclusion and exclusion criteria not stated
- Randomized to diclofenac gel (n=79) or placebo gel (n=76), at a dose of 5 g tid for 10 days, applied by gentle massage until gel completely absorbed
- Main outcome was based on the movement (lifting a weight, shaking hands, turning a key, opening a door, etc) that was most painful to the patient at the outset of the study; the pain provoked by doing the movement was scored on a 100 mm VAS
- Pain was scored by performing the aggravating movement at the same time each day, recording the pain VAS, and recording it in a diary for each of the 10 days of the trial
- Baseline pain scores were about 73 mm for both groups, judging from Fig. 1
- The daily pain VAS showed a steady decrease, beginning on day 1, for both groups, with a faster decline for the diclofenac group
- On days 3 and 6, the patients applying diclofenac gel had pain improvements which were greater than the improvements in the placebo group, but by day 10 the pain reductions were equal (mean of 32.6 mm for diclofenac gel and 35.7 mm for placebo gel)
- The use of acetaminophen as a rescue medication was the same for the two groups
- Seven items from the 21-item DASH questionnaire (administered on day 1 and day 10) showed greater improvement for the diclofenac gel than for the placebo gel: these included opening a tin, arranging lunch, carrying a bag, carrying a heavy item, and using a knife during lunch

Authors' conclusions:

- Diclofenac gel and placebo gel produce significant pain reduction when applied topically for 10 days, with a large placebo effect
- Diclofenac gel is an effective product for relief of shoulder periarthritis and lateral epicondylitis
- The DASH questionnaire had not previously been used in Italian or Hungarian populations, and its use in these populations is experimental

Comments:

- Eligibility criteria are not clear: all patients had less than 5 days of pain, but this may have been either the onset of the condition or an acute exacerbation of an existing condition
- The advantage of diclofenac over placebo on days 3 and 6 is of unclear importance: it is not possible to tell if these comparisons were part of the study protocol before the trial began, or if they were discovered after the data were collected
- Similarly, the DASH criteria that differed in favor of the active gel may have been selected after the data were collected, and without adjusting for the multiple comparisons that were made
- The “placebo” effect may be due to at least 2 sources: (1) there may be some therapeutic ingredient in the lecithin-based vehicle, or (2) the act of massaging the gel into the elbow or shoulder may be therapeutic

Assessment: Inadequate for an evidence statement that diclofenac gel is superior to placebo for lateral epicondylitis (entry criteria too vague to define a patient population, several analyses appear to have been post hoc)