Predel HG, Giannetti B, et al. A randomized, double-blind, placebo-controlled multicentre study to evaluate the efficacy and safety of diclofenac 4% spray gel in the treatment of acute uncomplicated ankle sprain. J Int Med Res. 2013;41(4):1187-202.

Design: randomized clinical trial

Purpose of study: to determine the effectiveness of topical diclofenac in alleviating pain and swelling in acute ankle sprain

Reasons not to cite as evidence:

- While the study is randomized and has good followup, the reported advantages of diclofenac over placebo are small, and the statistical significance that arises between groups on measures of pain and swelling are likely to arise from the large sample sizes and narrow confidence intervals rather than from effect sizes of clinical importance
    - For example, in Table 2, the amount of ankle swelling decreases for both groups from baseline through day 14, and the statistically significant difference at day 14 is the difference between a mean of 3.0 mm of swelling and 2.1 mm of swelling
    - The similarity of effect sizes is also graphically displayed in Figures 2 through 5, where the response rates of the two groups remain close throughout the period of observation
    - In Table 5, there are no statistical differences in impaired mobility at any time, and the statistical differences with respect to Pain on Active Movement (POAM) are not large for most measured observations
- Therefore, the study would not warrant a statement that diclofenac spray has a clinically meaningful advantage over placebo spray for acute uncomplicated ankle sprains