

Topical Diclofenac Solution (Pennsaid®) Compared With Oral Diclofenac in Osteoarthritis of the Knee: Pooled Analysis From 2 Controlled Clinical Trials

Sanford H. Roth¹, Fuller Philip²

¹Arizona Research and Education, Arthritis Research Laboratory, Arizona State University, Phoenix, AZ, United States, ²Covidien, Hazelwood, MO, United States

Purpose

The use of topical nonsteroidal anti-inflammatory drug (NSAID) formulations, which produce less systemic exposure to NSAIDs compared with oral formulations, is recommended in current guidelines for the management of osteoarthritis (OA). Several randomized clinical trials have shown that topical diclofenac solution (TDiclo) with penetration enhancer dimethyl sulfoxide (DMSO) is effective and well tolerated in the treatment of OA. Results of a pooled analysis of data from 2 trials comparing the safety and efficacy of TDiclo with that of oral diclofenac (ODiclo) are presented here.

Method

Pooled analysis was performed for two 12-week, double-blind, double-dummy, randomized, controlled, multicenter studies comparing the safety and efficacy of TDiclo with ODiclo in patients with radiologically confirmed symptomatic OA of the knee. Safety and tolerability assessments in both studies included recording of vital signs and adverse events (AEs), dermatologic evaluation of the knee, and clinical laboratory measurements. Primary efficacy variables were pain and physical function as measured by the Western Ontario and McMaster Universities Arthritis (WOMAC) Index and a patient global assessment.

Results

A total of 927 patients (randomized population) were included in pooled safety analysis, and 909 patients (intent-to-treat population) were included in the pooled efficacy analysis. AEs occurred in 312 (67.1%) patients using TDiclo vs 298 (64.5%) of those taking ODiclo. The most common AE with TDiclo was dry skin at the application site, reported in 24.3% of patients (vs 1.9% with ODiclo; $P<0.0001$). Fewer gastrointestinal-related AEs (25.2% vs 39.0%; $P<0.0001$) and fewer cardiovascular AEs (1.5% vs 3.7%; $P=0.037$) occurred with TDiclo compared with ODiclo. Efficacy as measured by WOMAC scales and patient global assessment was similar between treatment groups.

Conclusions

Although minor skin irritation at the application site was more common in patients using TDiclo, the incidence of gastrointestinal and cardiovascular AEs was significantly lower with TDiclo compared with ODiclo.