Efficacy and Safety of Diclofenac Diethylamine 2.32% Gel in Acute Ankle Sprain.

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Source

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Abstract

BACKGROUND.: Topical diclofenac diethylamine (DDEA) 2.32% gel achieves lasting efficacy in localized pain with two applications/day, while maintaining the favorable safety profile of topical diclofenac and potentially improving convenience and patient compliance. METHODS.: This randomized, double-blind, controlled study enrolled patients with acute ankle sprain treated with DDEA 2.32% gel two (n=80) or three (n=80) times/day or placebo (n=82). Efficacy (including pain and swelling) and local tolerability were evaluated over 8 (±1) days. RESULTS.: By Day 5, the reduction in pain-on-movement (POM) (primary efficacy variable) with DDEA bid and tid (49.1 mm and 49.7 mm, respectively; 100 mm visual analogue scale) was almost double that with placebo (25.4 mm) (p<0.0001). In patients with severe baseline POM (≥80 mm), mean change in POM from baseline to Day 5 with DDEA bid or tid was 30-40 mm greater than placebo, which was double the difference (15-20 mm) in patients with mild-moderate baseline POM (<80 mm). Over 70% of all DDEA patients experienced ≥50% reduction in POM between Days 1-5 versus 21% of placebo patients (p<0.0001). By study end (Day 8), ankle swelling in with DDEA (0.3 cm) was one-third that with placebo (0.9 cm) (p<0.0001), which had still not achieved the level of ankle joint function seen with DDEA on Day 5 (p<0.0001). At Day 5, treatment satisfaction was 'Good' to 'Excellent' in almost 90% of DDEA patients, but only 'Good' or 'Very good' in 23% of placebo patients (p<0.0001). DDEA 2.32% gel was well tolerated. CONCLUSION.: DDEA 2.32% gel twice daily (applied morning and evening) was well tolerated and provided lasting relief from pain, improved function and reduced symptomatic healing time in uncomplicated ankle sprain.