Efficacy and Safety of Diclofenac Epolamine Topical Patch, 1.3%, for the Treatment of Acute Back Strain

Joseph S Gimbel1, Craig A Paterson2, Glenn Pixton2, David Jacobs2
1Phoenix Orthopedic Surgeons, Phoenix, AZ, United States, 2King Pharmaceuticals, Inc., Bristol, TN, United States

Purpose

Back pain is a common medical problem often resulting in significant work absences and lost productivity.1,2 Diclofenac epolamine topical patch, 1.3% (DETP), indicated for the topical treatment of acute pain due to minor strains, sprains, and contusions,3 has not specifically been studied in the setting of acute back strain. This exploratory study was designed to evaluate the efficacy and safety of DETP in patients with acute back strain pain.

Method

This was a multicenter, open-label uncontrolled study in patients aged ≥18 years with acute non-radicular back strain pain, untreated or not responding adequately to conservative pain treatment regimens and/or opioids. Patients had onset of pain ≤10 days prior to study entry with a score of ≥4 (modified Brief Pain Inventory Questionnaire4 [mBPI], 0-10 scale; 0=no pain, 10=pain as bad as you can imagine) for average-pain over the last 24 hours. Patients could not have had another chronic pain condition within 3-months of study initiation. At Visit 1 (Screening), patients entered a 3-day observation/washout period and completed daily diary mBPI assessments. At Visit 2 (Baseline), patients with average pain intensity score of ≥4 at both Screening and Baseline started treatment with DETP every 12 hours applied at site of maximum discomfort. Patients returned to the clinic at Visit 3 (Day 8) after 7-days of DETP treatment. If pain resolved (average-pain score of 0 and investigator agreed that pain had resolved), treatment was discontinued and termination assessments conducted. Patients with unresolved pain continued DETP treatment for an additional week. Treatment emergent adverse events (TEAEs) were assessed throughout the study. The primary efficacy endpoint was mean change from baseline (CFB) to end-of-treatment in mBPI score for average-pain. Secondary efficacy endpoints included CFB in least, worst, and current pain scores; patient- and investigator-assessed patch satisfaction (very dissatisfied to very satisfied) and Global Pain Relief mean scores (no change to complete relief) at end-of-treatment.

Results

Patients (N=123) had a mean age of 38.8 years; 51% (63/123) were men, and 68% (84/123) were white. Ninety-eight percent (121/123) of patients completed the study. Baseline mean (SD) average-pain score was 6.5 (1.30). CFB in average pain intensity was -3.95 (2.51), p<0.0001. At end-of-treatment, 54% (67/123) of patients achieved ≥70% pain reduction from baseline. Similarly, mean worst, least, and current pain scores were also significantly reduced from baseline at end-of-treatment (p<0.0001). Eighty-seven percent (107/123) of patients rated global assessment of pain relief as moderate to complete at end-of-treatment. For 88% (108/123) of their patients, investigators rated global assessment of pain relief as moderate to complete at end-of-treatment. At end-of-treatment, 88% (107/122) of patients rated DETP as satisfactory or very satisfactory; investigators considered DETP satisfactory or very satisfactory for 85% (104/122) of their patients. During DETP treatment, 12% (15/123) of patients reported TEAEs. Most TEAEs were mild (63%, 12/19 events) or moderate (26%, 5/19) in intensity. Three AEs were considered treatment-related: application site rash, nausea, and tachycardia. One patient (0.8% [1/123]) had 1 serious AE, noncardiac chest pain, considered unrelated to DETP.
Conclusions

In this exploratory open-label uncontrolled study, DETP provided effective and well-tolerated relief for acute back strain pain with ≥85% of both patients and investigators expressing satisfaction with the treatment. Additional large, randomized, placebo-controlled studies are warranted to further evaluate the efficacy of DETP in this patient population.


2Stewart WF. JAMA. 2003;290(18):2443-2454.
