

An Open-label Pilot Study Evaluating Heated Lidocaine/Tetracaine Patches in the Treatment of Patients with Carpal Tunnel Syndrome

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Purpose

To explore the potential usefulness of Synera® (lidocaine 70 mg and tetracaine 70 mg) topical patch for the off-label treatment of pain associated with carpal tunnel syndrome (CTS).

Method

Design: Open-label study, 2-week treatment duration. Setting: Outpatient clinic. Participants: 20 adult subjects with recent electrodiagnostic evidence of mild-to-moderate CTS and mean average pain VAS = 5.1 (range 4-7) in a single wrist. Interventions: Subjects applied 1 patch directly to the painful wrist region that overlies the carpal tunnel for 2 hours twice daily (morning and evening, approximately 12 hours apart) for 14 days. No other CTS pain medications were allowed. Main Outcome Measures: Visual analog scale (VAS) of pain intensity (average and worst pain over the last 24 hours and pain now) and pain interference with general activity, normal work, and sleep; Subject Global Assessment of Treatment Satisfaction (5-point scale); subject and investigator Clinical Global Impression of Improvement (7-point scale).

Results

The patch was generally well-tolerated by all subjects and 15 of 20 subjects completed treatment. Subjects were discontinued for protocol noncompliance (2, both applied only 1 patch/day), lack of efficacy (2), and adverse events (1, application site rash). VAS scores (mean ± standard deviation) for average pain, worst pain, and pain now decreased by 37% (±43%), 41% (±38%), and 34% (±53%), respectively, among all subjects. As well, pain interference with general activity, normal work, and sleep decreased by 49% (±46%), 47% (±47%), and 58% (±52%), respectively. Most subjects (75%) were satisfied or very satisfied with their treatment and 55% were much improved or very much improved based on the global impression of improvement by both the subjects and investigator.

Conclusions

In this open-label study, Synera was effective in reducing pain intensity and decreasing pain interference with activities of daily living, especially sleep.