Effectiveness of a heated lidocaine/tetracaine topical patch in reducing pain intensity and pain interference associated with myofascial trigger points: results of an open-label pilot study

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Purpose

Background: Myofascial trigger points (MTPs) are palpable nodules located within a taut band of skeletal muscle or in the muscle fascia that are painful on compression and can give rise to characteristic referred pain, motor dysfunction, and autonomic phenomena. Treatment approaches in myofascial pain include trigger point injections with local anesthetics. Synera® (lidocaine 70 mg and tetracaine 70 mg) heated topical patch is approved for use on intact skin to provide local dermal analgesia for superficial venous access and dermatological procedures. The depth and duration of analgesia suggest that it may be useful in the relief of pain from musculoskeletal structures lying close to the surface of the skin. Objective: To evaluate the potential usefulness of Synera for the treatment of pain associated with MTPs.

Method

This was a two-week, open-label, outpatient study in 20 adult subjects with pain (> one month duration) associated with ≤ 3 MTPs in the upper back, shoulder, and/or neck (identified by an experienced pain clinician using manual palpation, a currently accepted diagnostic technique) and reporting baseline pain intensity (average pain over the last 24 hours) of ≥ 4 on an 11-point Numeric Pain Rating Scale (NPRS). Subjects applied 1 patch directly over each MTP for 4 hours twice daily for 14 consecutive days. Subjects continued their previously prescribed analgesic dosing regimens. Outcome measures were NPRS of pain intensity, NPRS of pain interference with specific activities of daily living, and Patient Global Assessment of Treatment Satisfaction (5-point scale).

Results

Average pain intensity at baseline was 6.3 [range 4-8, N=20]. Seventeen subjects (85%) completed the study and their average pain intensity (±SD) decreased by 34% (±28%) after the 14-day treatment period. Overall, 7 of 20 subjects (35%) had a ≥30% decrease from baseline in pain intensity and 5 subjects (25%) had a ≥50% decrease. Pain interference (±SD) with general activity, normal work, walking, mood, relations with others, enjoyment of life, and sleep decreased by 52% (±33%), 40% (±53%), 42% (±58%), 59% (±34%), 52% (±41%), 60% (±35%), and 46% (±49%), respectively. Most subjects (76%) were satisfied or very satisfied with their treatment. The patch was well-tolerated by all subjects; the most common adverse events were application site erythema (50%), dryness (15%), and paraesthesia (10%). Three subjects discontinued for adverse events (one each for application site erythema, appendectomy, and sweats).

Conclusions

In this open-label pilot study, the majority of subjects suffering from pain associated with MTPs obtained clinically meaningful improvements in pain intensity and/or reported decreased pain interference with activities of daily living after 14 days of treatment with a heated lidocaine/tetracaine topical patch.