Efficacy and Safety Profile of a Topical Methyl Salicylate and Menthol Patch in Adult Patients With Mild to Moderate Muscle Strain:

A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study

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BACKGROUND

- Pain is one of the most common reasons for seeking medical care and a major cause of disability and patient suffering
- Numerous data sources support topical analgesics as a potentially safer alternative to systemic analgesics[1,2]
- With toxicity issues facing opioids and oral NSAIDs, it is more important than ever to identify safe options to treat pain
- As part of CDC's guidance for prescribing opioids, their online CME training module recommended topical agents as alternative first-line treatments[2]
- The benefits of topically applied analgesics include targeted delivery of medication to peripheral sites of pain, and a relative lack of systemic absorption compared to oral and transdermal agents

PURPOSE

- The purpose of this study was to support the hypothesis that topical application of counterirritants such as methyl salicylate and menthol has analgesic benefit in patients with musculoskeletal pain
- The main goal was to determine the efficacy and safety profile of a combination patch containing 10% methyl salicylate and 3% l-menthol compared with a placebo patch in adult patients with mild to moderate muscle strain

REFERENCES

1. Argoff C. Topical Analgesics in the Management of Acute and Chronic Pain. Mayo Clin Proc. February 2013;88(2):195-205
2. CDC Module 2: Treating Chronic Pain without Opioids; https://www.cdc.gov/drugoverdose/training/nonopioid/508c/index.html (accessed 8/27/19)
3. Higashi Y, et al in Clinical Therapeutics, Vol 32. No 1. 2010

METHODS[3]

- Eligible patients were aged ≥18 years with a clinical diagnosis of mild to moderate muscle strain; >70% met the inclusion criteria for "moderate" pain
- Patients were randomly assigned to receive either 1 active patch or 1 placebo patch applied to the skin at the affected area (i.e., shoulder, upper back, upper arm, etc.)
- Pain intensity was assessed on a 100-mm visual analog scale while at rest and with movement
- Pain levels were assessed at baseline and 30 minutes, and hourly at hour 1 through hour 12 after patch application
- The primary efficacy end point was the summed pain intensity difference score through 8 hours (SPID8) with movement
- Secondary efficacy analyses included SPID8 and SPID12 at rest, SPID12 with movement, pain relief and pain intensity difference (PID) and total pain relief (TOTPAR) scores at rest and with movement

FORMULATION

- The combination Methyl Salicylate and l-Menthol patch is the only OTC medicine that is indicated to treat moderate pain
- The patch formulation researched in this study was approved by the FDA and is currently available as the "Salonpas Pain Relief Patch Large"

RESULTS[3]

- A total of 208 patients were randomized to 1 of 2 study groups
  - 105 in the active-patch group [mean age, 37.3 years]
  - 103 in the placebo-patch group [mean age, 38.1 years]
- The primary efficacy analysis (SPID8 with movement) indicated that patients receiving the active patch experienced significantly greater pain relief (~40%) than those patients receiving a placebo patch (mean [SD], 182.6 [131.2] vs 130.1 [144.1]; P = 0.005)
- Analysis of the per-protocol population also found significantly more relief (P = 0.024) in the active-patch group (176.2 [131.4]; n = 92) versus the placebo-patch group (130.2 [144.0]; n = 96)
- Statistical analysis of secondary efficacy measures supported the primary end-point results
  - Significant differences in favor of the active patch were maintained throughout the 8 hour application for SPID8 at rest, TOTPAR at rest and with movement, and global patient satisfaction. Comparisons of pain relief with movement favored the active patch through 7 hours

ADVERSE EFFECTS[3]

- The number of patients experiencing any type of adverse event was comparable between study groups (active patch, 6.7% [7 events]; placebo patch, 5.8% [6 events])
- No serious adverse events were reported during the study

CDC GUIDELINES MODULE

For nonopioid chronic pain treatments, consider topicals as alternative first-line ANALGESICS- thought to be safer than systemic medications[2]

STUDY SUMMARY[3]

- Study met its primary endpoint
- Pain relief 40%> with active patch treatment VERSUS PLACEBO
- 70% of patients had moderate pain
- 58% rated satisfaction as good/very good/excellent

CONCLUSIONS

- A single, 8-hour application of a patch containing methyl salicylate and l-menthol provided significant relief of pain associated with mild to moderate muscle strain in these adult patients compared with patients receiving a placebo patch
- Considering the significant adverse effects noted with many over-the-counter and prescription analgesics, clinicians should consider topical analgesic therapies as first-line agents for pain relief

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