EFFICACY OF LIDOCAINE PATCH 5% IN 4 CHRONIC PAIN CONDITIONS

The lidocaine patch 5% is a targeted transdermal analgesic that is applied directly to the area of painful intact skin. It is currently approved by the US Food and Drug Administration for the relief of pain associated with postherpetic neuralgia (PHN). Anecdotal reports of the patch's efficacy in other chronic pain conditions prompted the clinical investigation of its use in the 4 open-label pilot studies described below. Data from these preliminary studies suggest the topical lidocaine patch, either in combination with a centrally acting agent or as monotherapy, may be useful in treating several chronic and debilitating conditions. These preliminary findings have warranted additional investigation in randomized, controlled clinical trials, which are currently in progress.

IN COMBINATION WITH GABAPENTIN FOR PHN, DIABETIC NEURALGIA, AND LOW BACK PAIN

Based on a poster presented by Gimbel J,* Galer BS,† Hale M,§ et al.

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Complex and difficult-to-treat chronic pain conditions, such as PHN, painful diabetic neuropathy, and low back pain, often require multiple analgesics to achieve optimal pain relief. These pain conditions may be perpetuated by both peripheral and central nervous system pain processes. A rational pharmacotherapy approach for these conditions may involve the combination of a targeted peripheral analgesic with a centrally acting agent.

The first study, a randomized, open-label, multicenter 2-week pilot study, was designed to assess the efficacy of the lidocaine patch 5% (up to 4 patches administered every 24 hours) in patients with PHN (n = 11), painful diabetic neuropathy (n = 49), or low back pain (n = 47) who had experienced a partial response to their current gabapentin-containing analgesic regimen. Using the Brief Pain Inventory (BPI) to assess pain interference with quality of life, the investigators determined that the addition of the lidocaine patch reduced pain interference with most measures in the group with PHN (general activity, mood, normal work, sleep, enjoyment of life) and in all measures in the groups with diabetic neuropathy or low back pain (general activity, mood, walking ability, normal work, relations with other people, sleep, enjoyment of life; P < .0001). The results showed that application of up to 4 lidocaine patches every 24 hours with no "off period" was safe and well tolerated by the patients, with minimal risk of drug-drug interactions or systemic adverse effects. Clinical adverse events were few; most of these were mild to moderate. The most frequently reported treatment-related adverse events were somnolence and headache (2.8%). There were few reports of well-defined dermal reactions.
**AS MONOTHERAPY IN PATIENTS WITH PAIN FROM OSTEOARTHRITIS OF THE KNEE**

Based on a poster presented by Gammaitoni AR,* Galer BS,** Burch F,† et al
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The pathophysiology of osteoarthritis pain is complex and incompletely understood, but recent animal studies suggest that inhibition of T-cell activity,¹ inhibition of nitric oxide production in the knee,² and inhibition of dysfunctional sodium channels in peripheral nerves³ may reduce the pain and inflammation of osteoarthritis. Lidocaine inhibits the ability of damaged or dysfunctional sodium channels to interrupt pain signals and has also been shown to regulate T-cell activity⁴ and inhibit nitric oxide production⁵ in animal studies. This prospective open-label study assessed the effectiveness and safety of monotherapy with the lidocaine patch 5% in the treatment of moderate to severe osteoarthritis pain (average daily pain intensity >4 on a 0 to 10 scale), using up to 4 patches applied every 24 hours.

In this study involving 32 patients, each patient was treated with up to 4 patches (which covered as much of the painful areas as possible) every 24 hours; patients' use of all other analgesics was discontinued prior to entry in the study. Overall, 36% to 57% of patients experienced at least 50% improvement according to the Western Ontario and McMaster Universities Osteoarthritis Index and the BPI scales. Global assessments of patch satisfaction and pain relief showed 82% of patients and 76% of investigators rated treatment satisfaction as “satisfied” to “very satisfied” and pain relief as “moderate” to “complete.” One patient discontinued participation in the study due to moderate petechiae of both knees at the patch application sites. In one other patient, “very slight” erythema developed at the application site; after 2 weeks of patch application, there were no other reports of erythema, edema, or papules.

**IN PATIENTS WITH LOW BACK PAIN**

Based on a poster presented by Gimbel J,* Hale M,† Linn R,‡ et al
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Recent data suggest treatment with the lidocaine patch 5% is effective in patients with nonneuropathic pain, such as myofascial pain. Thus, researchers hypothesize that the lidocaine patch may be effective in the treatment of both neuropathic and nonneuropathic components of low back pain. This 2-week, prospective, open-label, nonrandomized pilot study was conducted to assess the effectiveness and impact on pain-related quality of life of patients with low back pain who were treated with the lidocaine patch.

Patients with nonradicular acute/subacute (<3 months duration; Group 1, n = 21), short-term chronic (3-12 months duration; Group 2, n = 33), or long-term chronic (>12 months duration; Group 3, n = 76) low back pain were treated for 2 weeks with up to 4 lidocaine patches applied every 24 hours to the area of maximal peripheral pain; patients continued their current analgesic regimen without dosage adjustment. The lidocaine patch produced statistically significant improvements in pain intensity and relief in Group 1 (P < .001) and in Group 3 (P < .0001) as measured by the BPI. In Group 2, significant improvements were seen in worst pain (P < .001), average pain, and immediate pain (P < .01). Groups 1, 2, and 3 had statistically significant reductions in BPI composite scores for pain interference with quality of life (P < .0001); significant reductions in Beck Depression Inventory scores were also shown for Group 1 (P < .05), Group 2 (P < .0001), and Group 3 (P < .0001). There were no serious systemic adverse events or drug-drug interactions related to patch use.
IN PATIENTS WITH PAINFUL DIABETIC NEUROPATHY WITH OR WITHOUT ALLODYNYA

Based on a poster presented by Dworkin RH,* Hart-Gouleau S,† Galer BS,‡ et al

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Painful diabetic neuropathy—occurring in 20% to 24% of patients with diabetes—includes a variety of painful sensations, such as tingling or burning of the lower extremities, either with or without alldynia. Recent evidence suggests that hyperexcitability and altered expression of sodium channels in peripheral nerves may contribute to the early pathophysiology of diabetic neuropathy. A prospective, nonrandomized, 3-week, open-label study involved 56 patients with diabetic neuropathy who had painful distal sensorimotor polyneuropathy. Patients were treated with up to 4 lidocaine patches applied for 18 hours per day to areas of maximal peripheral neuropathic pain. Patients could continue their current analgesic regimens throughout the study if dosing remained stable. Regardless of the presence or absence of alldynia at baseline, treatment with the lidocaine patch 5% significantly improved patients' average daily pain ratings and all other BPI measures of pain intensity and pain relief. From baseline to week 3, the average daily pain ratings, on a scale of 0 to 10, decreased from 6.5 to 3.6 (P < .001). The McGill Pain Inventory sensory, affective, and total scores also significantly improved from baseline to week 3. Sensory scores decreased from a baseline score of 12.1 to 7.6 at week 3 (P < .001); affective scores, from 1.9 to 0.9 (P < .01); and total scores, from 14.0 to 8.5 (P < .001). Significant improvements were also reported in the secondary outcome measures of BPI composite score for pain interference with quality of life, the Beck Depression Inventory score, and the sleep quality score. Application site pain and application site burning considered to be related to the lidocaine patch resulted in 2 patients withdrawing from the study.

CONCLUSION

Findings from these studies suggest the lidocaine patch 5% may provide clinicians with another option for treating chronic pain in a variety of conditions. The topical application of the patch causes negligible systemic drug absorption and, therefore, does not contribute to adverse drug-drug interactions or systemic side effects. The patch may prove particularly useful in older patients taking multiple medications. Randomized placebo-controlled trials are currently under way to confirm the observations from these pilot studies.

REFERENCES