

Kanai A, Kumaki C, et al. Efficacy of a Metered-dose Lidocaine Pump Spray for Patients with Post-herpetic Neuralgia. Pain Medicine 2009;10(5):902-909.

Design: Randomized crossover trial and open label study

Population/sample size/setting:

- 24 patients (11 women, 13 men, mean age 70) treated for post-herpetic neuralgia in a university anesthesiology department in Japan
- Inclusion criteria were pain persisting for 3 months after resolution of cutaneous lesions, typical pain intensity of at least 4 on a 10 point VAS
- Exclusion criteria were other neurological/psychological/chronic conditions, or oral medication changes within 1 week of the study
- In an additional study, 100 patients were enrolled in an uncontrolled, open-label study (not analyzed here)

Main outcome measures:

- All patients received both 8% Xylocaine pump spray (XPS) and placebo pump spray (PPS) in random order: 12 had XPS/PPS and 12 had PPS/XPS
- Dose was individually determined to the dose which covered the painful site, with a maximum dose of up to 30 sprays
- Pain at rest and tactile allodynia were assessed by the patient using VAS 15 minutes before and 15 minutes after application of spray
- Patients also were asked to rate pain relapse and to record the latency period for recurring pain
- After 7 days of treatment, the patients crossed over from one spray to the other spray (there does not seem to have been a washout period)
- All 24 patients completed both phases of the study
- Median single dose was 9 sprays
- XPS decreased pain scores from a mean of 6.1 to a mean of 2.3; PPS only decreased pain scores from 6.1 to 5.7
- None of the 24 patients had a 2 point decrease in pain scores using PPS, but 19 of 24 patients had a 2 point decrease in pain scores using XPS, and 9 patients had a disappearance of pain using XPS
- The median duration of XPS analgesic effect was 4.5 hours
- No carry-over or period effects were present when treatments were switched
- The instructions for repeated application in the crossover study are not clearly explained, but in the open label study, the patients were instructed to wait 2 hours for a second application of the spray
- In the open label study, the mean frequency of use was 3.1 times per day
- Lidocaine levels were not measured in the crossover study, but in the open label study, the lidocaine levels were below the lower limit of measurement in all patients who used more than 30 sprays daily
- No adverse effects were reported in the crossover study; 7 of the 100 patients in the open label study reported local adverse effects which abated within a few hours

- Blood pressure and pulse were measured at the clinic visits, and no effects of either vital sign were noted

Authors' conclusions:

- Topical application of lidocaine 8% spray produces analgesia within 15 minutes without serious side effects
- It is unlikely that blinding was compromised by the lack of an irritant effect of saline spray, since none of the patients in the crossover study reported an irritant effect of XPS
- The effects of treatment beyond 2 weeks are not known

Comments:

- Most sources of bias were well controlled, and the risk of bias is low
- The description of the administration of the spray was left unclear for the crossover study; the number of applications per day was 3.1 for the open label study, but the number of applications for the crossover study is not given
- The difference in pain scores between XPS and PPS is reported as significant ($p < 0.001$), but the means and standard deviations of the differences are not given; this precludes using the data from this study to combine with other topical lidocaine studies in a meta-analysis
- There is a description of co-interventions in the text, concerning the use of previously used medications during the treatment period, but this description is not clear

Assessment: Adequate for evidence that topical spray of 8% lidocaine provides prompt short-term analgesia (period of observation is short, and description of intervention could have been clearer)