

**Nalamachu S, Crockett RS, et al. A Comparison of the Lidocaine Patch 5% vs Naproxen 500 mg Twice Daily for the Relief of Pain Associated With Carpal Tunnel Syndrome: A 6-week, Randomized, Parallel-Group Study. MedGenMed 2006;8(3);33.**

Design: Randomized clinical trial

Brief summary of results:

- 100 patients (25 men, 75 women, mean age 53) with carpal tunnel syndrome were treated at 2 centers in the United States
- Inclusion criteria were age 18 to 75, with median motor nerve distal latency greater than 4.2 msec or a median-ulnar sensory latency greater than 0.6 msec, with persistent or recurrent pain, paresthesias, or positive Phalen's or Tinel's signs
- Exclusion criteria were carpal tunnel injection in previous 8 weeks, carpal tunnel release within the past 6 months, concomitant use of lidocaine patch for any other reason, or another peripheral neuropathy in the same limb, were pregnant, or were breastfeeding
- Randomized "in strict consecutive order" to lidocaine patch (n=52) or oral naproxen 500 mg bid (n=48)
- Patch was to be worn 24 hours per day, was to be changed at least once and up to 3 times per day, covering volar aspect of wrist
- Primary efficacy measure was the mean change in average daily pain from baseline to week 6; secondary endpoint was the investigator global impression of improvement and a comparison of patient satisfaction
- By week 6, both treatment groups reported significant decreases in pain; there was no significant difference between groups in pain relief
- At 6 weeks, the investigator global impression of improvement was significantly greater for the lidocaine group (51/1%) than for the naproxen group (24.3%)
- Overall patient satisfaction was statistically similar in both groups: 71.8% in the lidocaine group and 63.2% in the naproxen group
- Adverse effects were of mild-to-moderate intensity; 2 patients in the lidocaine group reported treatment-related adverse effects (skin rash or dyspepsia); 7 patients in the naproxen group reported adverse effects (GI disturbances of appetite loss, dyspepsia, nausea)
- Patient withdrawals due to adverse effects were 3 in the lidocaine group and 2 in the naproxen group
- Total reporting of adverse effects (treatment-related and non-treatment related) were equal: 13 in each group

Authors' conclusions:

- Lidocaine patch may be an effective and safe form of therapy for mild-to-moderate CTS
- This was a brief pilot study with an open label design, so that investigator bias cannot be ruled out

- Lidocaine patch may offer physicians a choice of a noninvasive topical analgesic if avoidance of systemic effects of NSAIDs is desired

Comments:

- As the authors note, this is a brief pilot open-label study of lidocaine vs. naproxen, and more controlled studies are necessary to assess the efficacy of topical lidocaine
- The “strict consecutive order” of the randomization is likely to mean that allocation concealment was not done; this is what that term meant in the other lidocaine patch pilot study by the same authors (J Fam Pract 2006;55(3):209-214) comparing topical lidocaine with steroid injections
- The basis for the investigators’ “global impression of severity” is unclear; in Table 1, it is called “severe” for 32.7% of the lidocaine group and 39.6% of the naproxen group
- Generally, “severe” CTS is expected to involve denervation and some degree of thenar atrophy; it is difficult to believe that this patient population presented with such advanced findings of CTS, and the significant difference in the investigators’ impression of improvement (favoring the lidocaine group) is not highly credible
- Although not adequate to support an evidence statement for the use of topical lidocaine for CTS, topical lidocaine could still reasonably be listed as a treatment option when avoidance of systemic NSAIDs is desired
- If it is endorsed as an option, it would be off-label (postherpetic neuralgia is still the only FDA approved use)

Assessment: Inadequate for an evidence statement (lack of concealment of allocation or blinding, “global impression of severity” seems dubious)