
Design: Randomized clinical trial

Brief summary of results:
- 40 patients (12 men, 28 women, mean age 48) were treated for carpal tunnel syndrome at a family practice office or a physical medicine clinic somewhere in the United States
- Inclusion criteria were age 18 to 75, with median motor nerve distal latency greater than 4.10 msec or a median-ulnar sensory latency greater than 1 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 cervical radiculopathy, median nerve trauma, upper motor neuron disease, or significant thenar weakness
- Randomized in “strict consecutive order” to either lidocaine patch 5% (n=20) or to a single injection of lidocaine plus DepoMedrol 40 mg (n=20)
- 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
- Routine analgesic medication was not allowed, but was allowed prn during the 4 weeks of the study
- After baseline evaluation, follow-up was done at the end of week 1, the end of week 2, and the end of week 3
- Outcomes included pain intensity scores, a subscale of the Brief Pain Inventory dealing with interference with 7 dimensions of daily life (general activity, mood, walking work inside and outside the home, relations with other people, sleep, and enjoyment of life); also global assessment of pain relief and global assessment of treatment satisfaction
- Pain intensity, Brief Pain Inventory daily life scores, patient satisfaction, and clinician global assessment of improvement were statistically equal between the two groups; both groups experienced pain relief and less interference with activity
- 3 patients in each group had mild adverse events (skin rash, itching); one patient in the patch group discontinued the study due to the skin rash

Authors’ conclusions:
- Lidocaine patch 5% effectively relieved intensity of localized pain in patients with CTS, comparably to the more invasive steroid injection
- Lidocaine patch may be a useful option for some patients
- It was a small pilot study, with no allocation concealment and no blinding; further controlled trials are needed to confirm the results

Comments:
- Most of the limitations are pointed out by the authors; the randomization and blinding would not be sufficient to preclude bias in treatment assignment and outcome assessment, follow-up time was short, and the study was too small to compare adverse effect rates
- The entry criteria are somewhat vague; CTS pain and paresthesias (in addition to nerve conduction delay) were required for entry, but the distribution of the symptoms is not clearly specified
- In spite of not qualifying for an evidence statement, lidocaine patch could still be listed as a treatment option for patients who would prefer to avoid surgery and would rather not have a steroid injection
- If it is endorsed as an option, it would be off-label (postherpetic neuralgia is still the only FDA approved use)

Assessment: Inadequate for evidence statement (small, short follow-up time, unblinded pilot study without allocation concealment)