

Thomson CE, Beggs I, et al. Methylprednisolone Injections for the Treatment of Morton Neuroma: A Patient-Blinded Randomized Trial. JBJS Am 2013;95:790-8.

Design: Randomized clinical trial

Purpose of study: to assess the effectiveness of a steroid injection on the symptoms of Morton neuroma

Population/sample size/setting:

- 131 patients (111 women, 20 men, mean age 53) treated for a diagnosis of Morton neuroma at a hospital in Edinburgh
- Eligibility based on a clinical diagnosis confirmed by a sonogram in participants over 18
 - o Clinical criteria meant at least six months of one or more of the following: pain/paresthesia in the second or third intermetatarsal spaces or toes, worsening of symptoms with weight-bearing, relief of symptoms by removing shoes and massaging the foot, a positive web space compression test, and a painful, palpable click
 - o Orthotic therapy had to have been tried for at least three months and failed
 - o Sonographic confirmation required a thickening of the plantar digital nerve in the web space and hypoechogenicity that was at least 5 mm in diameter
- Exclusion was based on pregnancy/breast feeding, peripheral vascular disease, bleeding disorders, a possibility of an inflammatory arthropathy, diabetes, possibility of peripheral neuropathy, local wound or skin lesion, previous surgery for Morton neuroma, or previous injection for Morton neuroma

Interventions:

- All patients were given an individually fitted ethylene-vinyl acetate shoe orthotic with a medial arch and metatarsal dome support
- Randomization was to a single ultrasound-guided injection using a plantar approach with either steroid with local anesthetic (n=64) or local anesthetic alone (n=67)
 - o Experimental injection was with 1 ml containing 40 mg methylprednisolone plus 1 ml of 2% lidocaine
 - o Control injection was with 2 ml of 1% lidocaine
 - o All injections were done by one radiologist who could not be blinded
 - o When multiple neuromas were on the same foot, all neuromas had the same injection

Outcomes:

- The ethics committee required that the control group be offered the experimental injection at three months if they desired, limiting the followup comparison time to three months
- The primary outcome was a global self-reported foot health thermometer, with a score of 0 for the worst imaginable health state and a score of 100 for the best imaginable health state, adapted from the EQ-5D scale for global quality of life
 - o Average scores at one month and at three months were compared with analysis of covariance (ANCOVA) in which the baseline score was entered as a covariate to control for any baseline differences
 - o At baseline, the scores for the experimental and control groups were 44.7 and 46.7
 - o At one month, the scores, adjusted for baseline differences, were 61.8 and 48.3, with a difference of 13.5 points between groups
 - o At three months, the scores were 64.8 and 50.7, with a difference of 14.1 points
- Several secondary outcomes, mostly derived from other foot pain and disability scoring instruments, were also generally in favor of the steroid over the anesthetic group, except for VAS pain, on which the groups did not differ at either one or three months
- 19 patients (32%) in the steroid group and 28 (43%) in the control group had subsequent surgery referrals; however, this information could not be used as a measure for comparison because the study patients had been unblinded before surgery took place and over one half of the control groups had had a steroid injection
- 2 patients in the steroid group had hypopigmentation of the dorsal skin over the injection, and 3 had atrophy of the plantar fat pad at 3 months
- The authors did an analysis which considered the size of the neuroma on treatment outcome, and size did not affect the main outcome

Authors' conclusions:

- Corticosteroid injection plus local anesthetic improved global assessment of foot health more successfully than the injection of local anesthetic alone
- Complete pain relief did not occur, but the steroid group did have a 38% decrease in mean pain scores between baseline and one month, which is a clinically meaningful change
- Because the duration of lidocaine is short, the injection of local anesthetic for the control group can be regarded as essentially a placebo injection

Comments:

- While the design of the study is adequate from the point of view of controlling biases which could threaten internal validity of the group comparison, the authors were

- working under constraints from their ethics committee which mandated that three month comparisons were the longest-term comparisons available
- As the authors note, this makes it uninformative to compare surgery rates between groups, and therefore no information is available for one of the outcomes of greatest interest for injection interventions, namely whether they prevent the need for surgery
 - The main outcome is a very global assessment of foot health, and there are no components or subscales to compare function and pain
 - There was a secondary outcome scoring instrument which compared pain VAS scores, and the group differences on this were not significant
 - The same instrument had a scale for “work/activities” and a scale for “walking/doing;” both of these scores did seem to show an advantage for the steroid over the local anesthetic alone
 - Foot pad atrophy with steroid was probably done by the patient self-report, since the clinicians in the study did not examine the patients at the end of the study
 - The sonograms for the diagnosis of Morton neuroma were “performed three months later;” this is probably referring to three months after potentially eligible patients were fitted with the shoe orthoses, but before any injections were given; no followup images were available to see if there had been any change in the size of the neuromas
 - Whether ultrasound guidance is necessary for the injection of a neuroma is a point for separate discussion; it was done for this study but it is not certain that it is required for clinical success

Assessment: adequate for some evidence that an ultrasound-guided injection of methylprednisolone improves global perception of foot health more effectively than an injection of local anesthetic at one month and at three months, but there is no information regarding the effectiveness of an injection for preventing the need for surgery at a later date