

Manchikanti L, Cash KA, et al. A Randomized, Double-Blind, Active Control Trial of Fluoroscopic Cervical Interlaminar Epidural Injections in Chronic Pain of Cervical Disc Herniation: Results of a 2-Year Follow-Up. Pain Physician 2013; 16:465-478

Design: Randomized clinical trial

Population/sample size/setting:

- 120 (67 women, 53 men, mean age 46) treated for chronic cervical pain at an interventional pain management center in Kentucky
- Eligible if they were over 18 and had at least 6 months of chronic, function-limiting neck and upper extremity pain and disc herniation with or without radiculitis
- All patients had to have utilized conservative treatment including, but not limited to physical therapy, structured exercise, and drug therapy
- Exclusion criteria were cervical spine surgery, radiculitis from spinal stenosis, discogenic pain without disc herniation, and uncontrolled psychiatric, medical, or opioid use disorders; pregnancy, lactation, and a history of adverse reactions to local anesthetic or steroids were exclusion criteria

Main outcome measures

- All patients received cervical interlaminar epidural injections done under fluoroscopy by one physician in an ambulatory surgery center using midazolam and fentanyl for sedation when needed
- Randomization was to either local anesthetic with 5 ml 0.5% lidocaine only (Group I, n=60) or to 4 ml of lidocaine plus 1 ml (6 mg) non-particulate betamethasone (Group II, n=60); injecting physician and patient were blinded
- Primary outcome was success as defined by a 50% improvement in both pain (Numerical Rating Scale, NRS) and function (Neck Disability Index, NDI)
- Follow-up was done at 6, 12 and 24 months with better than 90% retention of patients; numerous analyses were done, but for the primary outcome, there were no differences between Group I and Group II at 24 months
 - o For Group I, the criterion of success was met by 72% of patients, and in Group II the criterion was met by 68% of patients
 - o Group I had an average of 5.6 procedures in the two years; Group II had an average of 5.3 procedures
 - o Group I reduced its opioid intake in morphine equivalence from 57.0 mg to 35.8 mg; Group II reduced its intake from 53.8 mg to 31.3 mg

Authors' conclusions:

- Fluoroscopically guided cervical interlaminar injections of local anesthetic with or without steroid effectively treat chronic neck pain due to disc herniation and radiculitis
- A placebo group was not done; placebo interventions are frequently misinterpreted due to the multitude of effects when inactive substances are injected into active structures, Hawthorne effects [changes which occur in study populations simply from being observed], and the natural course of the disease

Comments:

- Numerous additional analyses were done, including an additional definition of success (having at least 3 weeks of relief from the initial two procedures); these appear to have been done post hoc and should not be interpreted as if they were planned analyses
- The analysis was said to have been done by intent-to-treat using either the last follow-up data or the initial data for patients who withdrew; sensitivity analysis was said to have been done in the Methods section but was not reported in the Results section
- The authors appear to have misunderstood the concept of allocation concealment; they report that this was done because the drugs were prepared to mask any identification of them
 - o This has to do with blinding the injecting physician
 - o Allocation concealment has to do with how patients are enrolled in the study
- On average, both groups had more than 5 procedures in the two year follow-up period; it is not clear whether the authors propose using spinal injections as a maintenance therapy for patients with chronic neck pain
- While there are always issues of interpretation in studies with placebo interventions, this is not a reason not to have placebo groups; the two injections may be of equal effectiveness, but the superiority of epidural injections over placebo is not shown
- There is a misprint in the flow diagram of Figure 1; “Caudal epidural” should be “Interlaminar epidural”
- All patients were expected to have used conservative treatment (including exercise), but the degree of participation does not appear to be a criterion for entry; patients may meet the criterion after attending one exercise class
- Some authors (Anderberg et al 2007.) reported more information about the nature of the herniated discs than are reported here; hard and soft discs may both have been present, and an opportunity to look at how different disc herniations respond to treatment was lost
 - o This does not mean a biased results section, but only a less informative description of the study population; the validity of the main conclusion is not affected
- Radiculitis was not a requirement for entry; it does appear that all patients had radicular problems (nerve conduction study results were not reported)

Assessment: Adequate for some evidence that there is no difference between lidocaine and lidocaine plus betamethasone in the effects of interlaminar injections for cervical herniated disc with radicular symptoms. Inadequate for evidence of superiority of cervical interlaminar injections over placebo