

Leclaire R, Fortin L, Lambert R, Bergeron YM, Rossignol M. Radiofrequency Facet Joint Denervation in the Treatment of Low Back Pain. Spine 2001;26:1411-17.

Design: Randomized controlled trial

Population/sample size/setting:

- 70 outpatients (25 men, 35 women, mean age 46) with 3 months or more of low back pain recruited from offices of physiatrists in Montreal area
- All patients required to have 24 hours of pain relief following fluoroscopically guided injection of lidocaine (0.5 ml of 2% solution) and 40 mg triamcinolone by referring physiatrist
- Excluded for sciatic pain or non-mechanical back pain (bone lesion/spondylitis) or history of low back surgery, allergy to local anesthetic, or medical comorbidity likely to interfere with study participation

Main outcome measures:

- Randomized to radiofrequency (RF) neurotomy (n=36) with catheter set to 80° C for 90 sec; control group (n=36) had identical procedure with catheter remaining at 37° C; procedures done at two vertebral levels (usually L4-L5 and L5-S1) involving both proximal and distal sections of facet nerve
- Primary outcome was the change in Roland-Morris (R-M), Oswestry, and 10 point Visual Analog Scores (VAS) at 4 and 12 weeks after procedure
- Additional measurements with triaxial dynamometry of low back to measure angular speed against resistance
- At 4 weeks, improvement in R-M was 8.4 % for RF group and 2.2 % for sham group, but statistical difference was borderline
 - o Oswestry showed no significant treatment effect at 4 or 12 weeks
 - o Pain VAS did not change significantly between baseline and followup times for either group
- Dynamometry measurements not different between groups
- Logistic regression was done, dichotomizing the R-M response as success if a 10 point change was observed, and failure otherwise
 - o Logistic regression adjusting for age, gender, number of children, and physical activities showed advantage for neurotomy group at 4 weeks (odds ratio was 3.14 with 95% confidence interval between 1.11 and 8.85 in favor of success in the RF group)
- Analysis for subgroups showed better response if patient smoked, was receiving workers' compensation, or older than sample median age of 47; however, the confidence intervals were very large due to the small numbers of participants in each subgroup

Authors' conclusions:

- Radiofrequency neurotomy did not change low back function in sample studied

- Sample may have contained patients who did not have facet origin of pain, since screening lidocaine injections were not placebo controlled and these injections done by community physiatrists with heterogeneity of methods
- Patient selection may be crucial in success of RF candidates

Comments:

- Sample recruited smaller than the 80 that authors calculated as needed to show a difference of 10 points between groups
- The adjustment for age, gender, number of children, and physical activities may not have been pre-planned; in addition, there is not a definition of “physical activities”
- The logistic regression model used a 10 point improvement in the R-M for the definition of success, but the number of successes is not clear
 - o Because there were three interaction analyses (age, smoking, and compensation status), the number of successful outcomes may have been too few to accommodate the number of variables in the model; the regression coefficients appear to be unstable with very wide confidence intervals
 - o These logistic regression analyses should be interpreted with great caution and are probably not credible
- The authors’ concerns about patient selection show uncertainty about criteria used to identify cases of low back pain originating in the facet joints

Assessment: Inadequate to support any conclusions about the effectiveness of RF neurotomy for lumbar pain