Nath S, Nath CA, Pettersson K. Percutaneous Lumbar Zygapophyseal (Facet) Joint Neurotomy Using Radiofrequency [RF} Current, in the Management of Chronic Low Back Pain. Spine 2008;33(12)1291-7.

Revised, conclusions revised January 2017

Design: Randomized clinical trial

Population/sample size/setting:

- 40 patients (15 men, 25 women, mean age 55) treated for low back pain at a pain clinic in Sweden
- Eligibility criteria were at least 2 years of low back pain not responding to previous treatment and paravertebral tenderness at one or more facet joints
- Exclusion criteria were pregnancy, malignancy, coagulopathy, infection, and mental handicap or psychiatric disorders; also motor deficits "or any other indication for surgical treatment"
- 376 patients were initially screened with medial branch blocks using 1 ml of 0.5% bupivacaine at segmental levels corresponding to points of paravertebral tenderness; 261 patients had at least 80% relief from the blocks, and were invited to participate in the next phase of the study
    - These 261 patients next had controlled, blinded blocks using lidocaine and bupivacaine, recording the degree and duration of pain relief hourly for 6 hours
    - 150 of these patients were not considered eligible for RF treatment after these blocks; another 71 did not participate for other reasons, leaving 40 patients in the study sample for randomization

Main outcome measures:

- Randomized to active RF (n=20) or placebo RF (n=20)
- Both procedures were identical except that no current was applied to the placebo RF group; the operator was unaware of the current level, which was operated by another person, leaving the operator and patient unaware of whether true or sham RF had been applied
- The electrode tip was placed under guidance of a radiograph beam, using 4 views: the tunnel view, the posterolateral view, the cephalad view, and the lateral view
    - After cannula placement, 2 ml of 0.5% bupivacaine was injected, and a total of 5 lesions of 60 second duration were made at the level of the target nerve
    - For the true RF, the probe was heated to 85° C; for the placebo RF, no current was applied
- All patients were seen again by the blinded operator 6 months after the procedure for outcome evaluation
- Primary outcomes were global improvement, relief of generalized pain, relief of low back pain, and pain in the lower limb

- Secondary outcomes were range of motion in the lumbar spine, hip movements, and quality of life variables
- At baseline, the RF group had more generalized pain, low back pain, and referred pain to the leg when compared to the placebo RF group
- At 6 months, the active RF group had greater improvement on the 6-point global assessment scale (1.1 points) than the sham RF group (0.3 points)
    - Active RF had greater improvement on the 11-point generalized pain scale (1.9 points) than the sham RF group (0.4 points)
    - Back pain was reduced in the active RF group by 2.1 points, greater than the reduction for the sham RF group (0.7 points)
    - Leg pain was reduced in the active RF group by 1.6 points, greater than the reduction for the sham group (0.13 points)
- No complications were reported; the treatment was well-tolerated

Authors' conclusions:

- RF neurotomy provided significantly better pain relief than sham RF in a group of patients who could identify a particular component of their pain that was relieved by controlled medial branch blocks
- RF neurotomy is not a total treatment; it provides relief for only one component of the patients' pain
- The study was not designed to measure effects beyond 6 months, but the procedure may be repeated to reinstate relief if pain recurs
- The success of the procedure depends on operator expertise in precise placement of the electrodes, which require training in fluoroscopy and interpretation of images

Comments:

- Some of the criteria for having patients proceed to randomization for RF were not clear
    - 261 patients had controlled blocks with lidocaine and bupivacaine, of whom 45 were "negative" and 105 had "prolonged" responses to blocks
    - The medial branch block protocol was modeled on Dreyfuss 2000, who required one hour of 80% pain relief from lidocaine and 2 hours of 80% relief with bupivacaine given one week apart
- A large number of secondary outcomes were tested, but these results should be interpreted cautiously, since there appears to be no adjustment for multiple comparisons, making it more likely that some differences could be due to chance
- The active RF group had higher scores at baseline on measures of pain; this means that comparison of improvement scores can be partly explained by regression to the mean, unless this phenomenon is controlled for
    - MANOVA was used in the analysis, and presumably the baseline score was entered as one of the variables controlled for; if this were done, then regression to the mean was probably controlled for, although this is not explicitly stated

- The authors draw their conclusions with appropriate limits; the RF procedure is not a pain cure, but alleviates only one component of back pain, namely the component arising from the facet joint
- A recent Cochrane Review (Maas 2015) included this study in its meta-analysis of the topic, but downgraded it based on two considerations: imprecision and lack of difference between final pain scores between RF and the control group
    - The downgrading for imprecision was based on the small sample size, with 20 patients in each group, and these small sample studies frequently do provide imprecise estimates of the effect of an intervention
    - However, the population which was recruited for the study was fairly large (n=376) and was narrowed down to a much smaller group of patients who back pain patients who demonstrated a clear response to controlled medial branch blocks, creating a precisely defined study population in which the distinction of "signal" from "noise" offsets much of the imprecision arising from a fairly small absolute number of randomized patients
    - In addition, Maas (Analysis 1.3) judged analgesic effectiveness by comparing RF with placebo in terms of mean pain scores on the 10 point VAS at 6 months, where the group differences were statistically equivalent
    - However, the primary outcome for the Nath study was based on a more appropriate measure of effectiveness when analyzing data which are collected in a longitudinal study, namely MANOVA, and that analysis favored the RF intervention
    - For these reasons, the study remains adequate for evidence of the effectiveness of RF neurotomy, but only for patients who respond to controlled medial branch blocks, attaining at least one hour of 80% pain relief with lidocaine and two hours of 80% relief with bupivacaine

Assessment: Adequate for evidence that RF neurotomy may provide relief of facet joint pain in patients who have demonstrated pain relief with controlled medial branch blocks providing one hour of 80% pain relief with lidocaine and two hours of 80% pain relief with bupivacaine, where the blocks are done one week apart

References:

Dreyfuss P, Halbrook B, et al. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. Spine 2000;25:1270–7.

Maas ET, Ostelo RW, et al. Radiofrequency denervation for chronic low back pain. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD008572.