

van Kleef M, Barendse GA, et al. Randomized Trial of Radiofrequency Lumbar Facet Denervation for Chronic Low Back Pain. Spine 1999;24(18):1937-1942.

Design: Randomized Clinical Trial

Population/sample size/setting:

- 31 patients (11 men, 20 women, mean age 44) who completed a randomized trial of radiofrequency at a pain management center in the Netherlands
- Eligible patients were between 20 and 60 years of age, had at least 12 months of nonspecific LBP, had not had satisfactory results from physical therapy, manipulation, electrical nerve stimulation, or medication, had mean pain VAS scores of more than 4, and absence of any neurological deficit, including lumbar radiculopathy
- Exclusion criteria were previous back surgery, diabetes, more than one pain syndrome, and specific lumbar diagnoses such as herniation, spondylolisthesis, spinal stenosis, malignancy, infection, or trauma
- Before randomization was done, patients who met the above criteria underwent a diagnostic block of the dorsal ramus of the segmental nerves at L3, L4, and L5
 - o Blocks were done under fluoroscopic guidance with 22 gauge needles directed to the medial branch of the nerve rami, using 1% lidocaine
 - o Patients who had at least 50% pain relief 30 minutes after the injection were eligible for randomization

Main outcome measures:

- Before the study began, 256 patients were screened, 92 met the basic eligibility criteria, 40 were eligible for randomization after having positive response to segmental nerve blocks, and 32 consented to the protocol for randomization, but one of these patients withdrew, leaving 31 patients to participate in the study
- Randomization was done in blocks of 2 to either true RF neurotomy (n=15) or to sham RF neurotomy (n=16)
- For both groups, the electrode was positioned by confirming its proximity to the dorsal ramus and avoiding the exiting nerve root, eliciting contraction of the multifidus muscle and avoiding contraction of the leg muscles
- After positioning the electrode, the true RF group had 1ml of 1% lidocaine, followed by a 60 second 80° C lesion at L3-L5 on one or both sides; the sham RF group had the same procedure, except that no RF lesion was made

- Patient and operator were both blinded to the type of RF performed; after positioning the electrode, the operator left the room and an independent investigator operated the probe and monitored the patient response
- Outcome data was obtained by a blinded investigator, rating pain by three measures of VAS: the mean, the high, and the low pain levels averaged over three days
 - Global perceived effect was scored by the patient on a 7 point Likert scale, ranging from much worse (-3), no effect (0), and complete relief (+3)
 - Physical impairment was measured on a similar scale, ranging from 0 (no impairment) to 7 (maximum impairment)
 - Disability was assessed on the Oswestry scale
 - Quality of life was recorded with a questionnaire divided into 7 items, each rated on a 5 point scale
- Main outcome was measured at 8 weeks, and success was predefined as requiring (1) at least a 2 point reduction on the VAS scale (VAS mean or VAS high), (2) at least a 50 % pain reduction on global perceived effect; all other treatment outcomes were considered failures
 - Additional outcome measurements were conducted at 3, 6, and 12 months after the procedure
- At 8 weeks, the true RF group had a success rate of 66.7% (n=10), compared with a success rate of 37.5% (n=6) in the sham RF group
 - The success comparisons were tested for statistical significance at the 90% confidence interval with two logistic regression models, one model with only the treatment received, and a second model adjusted for other patient factors which were likely to be confounders because the study size was too small to ensure that the randomization would equally distribute the differences in prognostic factors such as age, gender, duration of pain, average pretreatment pain intensity, and Likert scores after the diagnostic nerve blocks
 - The unadjusted odds ratio was 3.33, but the 90% confidence interval was from 0.97 to 11.5, which includes the null value of 1.0
 - The adjusted odds ratio was 9.53 with 90% confidence intervals from 1.50 to 60.5, which excluded the null value of 1.0
 - The change in the odds ratio was mostly attributable to including the response to the diagnostic nerve blocks which preceded the randomization; this showed that patients who had complete relief from those nerve blocks were more likely to have successful RF neurotomy than patients whose pain relief was above 50% but not quite complete
 - After 3, 6, and 12 months, the number of successes in each group declined from the 8 week assessment; the success numbers for the true RF group were 9, 7, and 7; the success numbers for the sham RF group were 4, 3, and 2

- In addition to the success rate comparisons, other analyses were done for the Oswestry and VAS average scores, and these comparisons also favored true over sham RF

Authors' conclusions:

- Although the study had a relatively small sample, the results show that RF neurotomy can reduce pain in a selected group of patients whose pain arises from the facets
- The treatment effect tends to decline over time, perhaps because of regeneration of the lesioned nerves
- The definition of lumbar facet syndrome is problematic; clinical history and physical examination do not provide an effective diagnosis, radiographic imaging does not help the diagnosis, and full relief of pain with diagnostic nerve blocks appears to correlate well with success of treatment

Comments:

- Most of the requirements of a high quality study are met; risks of bias were controlled with randomization and blinding, the procedures for diagnosis and treatment were well documented, and the time course of pain relief was extended up to one year
- The analyses used a 90% confidence interval rather than the more commonly used 95% confidence interval for statistical significance, and this may underestimate the role of chance in generating the differences in outcome; however, this does not necessarily invalidate the results
- Logistic regression produces estimates of odds ratios, whose calculation is straightforward but whose interpretation is not straightforward
 - o When the "event" of interest, namely treatment success, is common in a study sample, the odds ratio will inflate the actual "risk ratio" for success
 - o For example, the unadjusted odds ratio for success in table 2 was 3.33, but the success ratio (66.7/37.5) is only 1.78
 - o Logistic regression coefficients can become unstable as additional parameters are added to the model, as evidenced by the very wide 90% confidence interval in the adjusted model in Table 2 (OR of 9.53 with 90% CI from 1.50 to 60.5)
- Overall, the study was well planned and executed, and the main limitation to its interpretation is the small sample size with which it was working, leaving considerable uncertainty in the estimate of treatment effect; it does remain adequate for evidence that RF neurotomy in carefully selected patients has the potential to improve function and decrease pain

Assessment: Adequate for evidence that RF neurotomy of the lumbar facet joints can improve function and decrease pain in patients who respond well to medial branch blocks of the affected joints, though the effect is likely to decline over the course of one year