

Geurts JWM, van Wijk RM et al. Radiofrequency lesioning of the dorsal root ganglia for chronic lumbosacral radicular pain: a randomized, double-blind, controlled trial. Lancet 2003;361:21-26.

Design: Randomized clinical trial

Population/sample size/setting:

- 83 patients (33 men, 50 women, mean age 46) treated for chronic lumbosacral pain at a university anesthesiology department in the Netherlands
- Inclusion criteria were age over 18 with lumbosacral pain with leg pain greater than back pain at or below the knee, with a positive straight leg raising test (30 to 60 degrees), lasting at least 6 months
- Exclusion criteria were previous radiofrequency (RF) treatment, conditions requiring urgent surgical intervention (cauda equina, progressive paresis, great pain), pregnancy, allergy to contrast, malignancy, neuropathic sensory or motor deficit, or non-segmental pattern of leg pain

Main outcome measures:

- Enrollment was done if a diagnostic nerve block was considered positive: when the nerve was identified by fluoroscopic injection of contrast and an infusion of 2% lidocaine reduced pain by 75%, with loss of pinprick and touch sensation in the dermatome
- Adjacent nerves were also injected; the patient was enrolled if only one positive nerve was identified
- Randomization was to either RF lesioning (n=45) or a control treatment (n=38)
- RF and control procedures were done by a single anesthesiologist; the nerve was identified under fluoroscopy and anesthetized with mepivacaine, with the RF patients undergoing lesioning of the dorsal root ganglion for 90 seconds at 67 degrees C, and the control patients receiving only the mepivacaine anesthesia
- The delivery or non-delivery of the RF was determined by a technician who operated the RF generator with the display turned away from the operating table, so that neither anesthesiologist nor patient could see or hear the display
- After the procedure, the patients recorded pain VAS scores two times per week, with separate scores for worst back pain and worst leg pain in the previous 24 hours; at the end of 3 months, these scores were analyzed in a blinded fashion
- In addition to pain scores, patients recorded their activity levels and analgesic use in the same diaries
- The primary outcome was "success" or "failure;" success was present when either (1) there was a 50% reduction in the VAS-leg score with no decline in activity level or increase in analgesic use, or (2) a 25% reduction in VAS-leg with both an increase in activity level of 25% and a decrease in analgesic use of 25%

- 3 patients (1 RF, 2 control) dropped out of the study because of disc herniation requiring immediate surgery; 44 RF and 36 control patients were assessed for the primary outcome
- Success was achieved by 7/44 (16%) of RF patients and by 9/36 (25%) of control patients; this difference was not statistically significant
- No clinically relevant differences in treatment effect were noted for VAS-leg or VAS-back, nor for physical activity scores or analgesic use

Authors' conclusions:

- RF of the dorsal root ganglion did not appear to be effective in reducing pain, increasing activity, or reducing analgesic use
- These results differ from those obtained in retrospective case series, in which 60% of patients reported substantial pain reduction
- RF for lumbosacral radicular pain should not be advocated

Comments:

- The principal outcome is derived from patient diary entries done twice per week, with pain levels, activity levels, and analgesic use
- It is not clear whether there were standardized instructions on when to make the diary entries; if some patients generally made entries during pain exacerbations and others made entries on the same calendar days, for example, then the significance of the diary entries may differ between participants
- The risk of bias appears low, and a treatment effect in favor of RF procedure appears unlikely

Assessment: Adequate for evidence that RF of the DRG in the lumbosacral spine is unlikely to be effective