Van Wijk RMAW, Geurts JWM et al. Radiofrequency [RF] Denervation of Lumbar Facet Joints in the Treatment of Low Back Pain. Clin J Pain 2005;21:335-344.

Design: Randomized Clinical Trial

Population/sample size/setting:

- 81 patients (mean age 47, 23 men, 58 women) with low back pain (LBP) treated at 4 pain clinics in the Netherlands, selected from 462 LBP patients screened for inclusion into study
- Eligible if over 17, more than 6 months of LBP with focal tenderness over facet joints, with or without leg pain
- Excluded if they had radiculopathy, prior RF treatment, coagulation disturbances, psychiatric conditions precluding adequate communication, or "indication for low back surgery"
- Diagnostic 2 level intra-articular facet block with 2% lidocaine; 50% or greater reduction in pain VAS was considered positive block
- Randomized to RF denervation (n=40) or sham RF (n=41)

Main outcome measures:

- All patients received local anesthesia with 2% mepivacaine for placement of thermocouples "at the level concerned;" RF group treated at 80°C for 60 seconds, with sham RF group had similar positioning of probes without switching on current
- Primary outcome measure was a combined outcome measure (COM), which was a combination of (1) change in VAS-back, (2) change in daily physical activity, and (3) use of analgesics; "success" defined as (1) reduction in VAS of 50% with no drop in daily activity or rise in analgesic use, or (2) reduction of 25% in VAS with 25% rise in activity and 25% drop in analgesic use
- A secondary measure was Global Perceived Effect (GPE), a self-report of relief of pain (complete relief, >50% relief, no relief, or increase in pain)
- Analysis of success/failure done at 3 months; if not a "success," case was unblinded and, if sham RF was done, real RF was offerec
- Cost analysis of treatment in Euros also done
- COM showed 30% success rates in both groups (27.5% in RF and 29.3% in sham RF) at 3 months; the other 70% were unblinded at this point
- Both groups had decrease in VAS-back; RF group only had decrease in VAS-leg
- GPE of 50% or more pain relief was greater in RF group (61.5%) than in sham RF group (39%)
- Separate components of COM (VAS, physical activity, and analgesic use) were correlated in expected manner (e.g., lower VAS meant more physical activity and less analgesic use)
- Several secondary analyses reported; one showed that less psychological distress meant better self-reported GPE, and others showed RF more effective in women, older pts, pts with longer pain history, employed pts

Authors' conclusions:

- Long-term analyses are compromised by the fact that the blinding was broken at 3 months in 70% of participants who were treatment failures at that point
- No differences in primary outcome between RF and sham RF were seen at 3 months; lack of improvement in physical activity and analgesic use accounted for most failures
- Controlled diagnostic blocks not done, which reflects dominant practice pattern in Netherlands; this may have had a bearing on the results
- Prolonged analgesic effect from local anesthetic infiltration may account for some of the observed improvement in VAS-back in both groups seen post-procedure
- RF may account for reduction in VAS-leg
- GPE was in favor of RF group
- Success of RF reported in some previous clinical trials may have resulted from use of steroid injection added to local anesthetic; this trial did not include steroid injection
- RF may be better than sham RF for selected group of patients, but the profile of the most appropriate patient requires further research

Comments:

- Good quality trial methodologically, with randomization and concealment of allocation with complete follow-up; authors also show appropriate skepticism towards some of their own secondary analyses
- One inclusion criterion was "no indication for low back surgery," but this is not specified
- Comparison of RF with sham RF is not equivalent to comparing RF with no treatment
- 95% confidence interval for success in RF group (sample percent is 27.5%) is between and 14% and 41%; this sample size is sufficient to rule out a large success rate using the criteria of pain reduction with increased physical activity and reduced analgesic use
- Power calculation for binary outcome is accurate, but it is not clear why Kaplan-Meier was used to compare groups, since it is a time-to-event analysis, and the "event" is not clearly specified
- The superior response of the RF group on the GPE outcome may be unbiased, but it is not the primary designated outcome and does not qualify for inclusion for an evidence statement
- Overall, the study is inconclusive regarding the effectiveness of RF neurotomy of the lumbar facet joints

Assessment: Inadequate for evidence for RF neurotomy for lumbar facet pain (inconclusive results)