
Design: Randomized clinical trial

Study question: In patients with knee osteoarthritis (OA) for whom conservative treatment has failed, are there therapeutic benefits from radiofrequency neurotomy of the sensory nerves of the knee?

Population/sample size/setting:

- 35 patients (5 men, 30 women, mean age 67) who completed a randomized trial for knee osteoarthritis at a pain clinic in Seoul
- Eligible if they had moderate or greater knee pain for at least three months and radiographically confirmed grade 2 to 4 Kellgren-Lawrence tibiofemoral OA, and did not respond to oral analgesics, physiotherapy, or intra-articular injection with hyaluronic acid or steroids
- Exclusion criteria were previous knee surgery, recent (3 months) injection with steroid or hyaluronic acid, acute knee pain, sciatic pain, connective tissue disorders other than OA, anticoagulant medication, pacemakers, or prior electroacupuncture of the knee
- Before randomization, each candidate for treatment had a single diagnostic nerve block with 2 ml of 2% lidocaine under fluoroscopic guidance of the genicular nerves (superior lateral, superior medial, inferior lateral, inferior medial, and recurrent tibial nerve); a positive response was 50% decrease in pain for more than 24 hours

Interventions:

- 38 patients were originally randomized to either radiofrequency (RF) neurotomy or sham RF
  - A 10 cm 22 gauge RF cannula with a 10 mm active tip was guided to the contact areas; sensory stimulation at 50 Hz was done to identify the nerve position, and the nerve was tested for the absence of fasciculation in order not to affect motor nerves
  - The active RF group had the RF electrode raised to 70 degrees C for 90 seconds, once for each genicular nerve
  - The control group did not have the temperature of the cannula raised, but the procedure was otherwise the same
- After the procedure, all patients were directed to maintain the same dosages of medications they had been using for the 12 weeks following the procedure
Outcomes:

- Followup was done at 1, 4, and 12 weeks after the procedure
- Main outcome was the mean change from baseline knee pain as measured by a 100 mm VAS, and the proportion of patients with 50% pain relief at 12 weeks
- Secondary outcomes were the Oxford knee score, patient satisfaction with treatment, and adverse events
  - Oxford knee score has 12 items for the patient to fill out: pain, trouble with activities such as getting in and out of vehicles, standing up from a chair, walking down a flight of stairs, kneeling down and getting up again, interference with usual work, ability to walk before knee pain interferes, feeling that knee may suddenly give way, doing household shopping, limping, and night pain
- During the procedure, some patients (number not reported) transiently felt unbearable pain as the RF cannula touched the periosteum
- Data were missing from the analysis for two RF patients; one had fallen in the bathroom three weeks post-procedure, preventing collection of 4 week data; the other has hemarthrosis from walking up a hill, preventing collection of 12 week data
  - These two RF patients had no detectable weakness, paresthesia, or loss of proprioception, and the events were judged not to be related to the procedure
  - One control patient did not complete the study for logistical reasons
- 10 patients (59%) of the RF group had at least 50% pain reduction at 12 weeks; no control patient had 50% reduction in pain at 12 weeks
- At one week, both groups had decreased pain from baseline (33.7 point reduction for the control and 41.2 point reduction for RF), with no statistical difference
- The RF group was superior to the control group at 4 and at 12 weeks in pain reduction; pain returned to baseline for the control group but remained lower for the RF group at both time points
  - For the RF group, the baseline, 1 week, 4 week, and 12 week VAS scores were 78.2, 67.1, 33.5, and 42.4
  - For the control group, the corresponding scores were 77.2, 43.2, 72.6, and 77.9
- The secondary outcomes of Oxford knee scores and patient satisfaction were also superior in the RF group at 4 and 12 weeks

Authors’ conclusions:

- This is the first randomized study of RF for OA of the knee showing its clinical efficacy
- For three months, RF improved knee pain and function without adverse events
- Not all patients had benefit from RF; this may be related to the fact that only three main articular branches originating in the sciatic nerve were denervated, and other articular branches may be involved in pain generation.
- Most patients had degenerative pain of other joints, and it was not possible to select patients with only knee OA pain.
- RF neurotomy of the genicular nerves seems to be safe, effective, and minimally invasive, and could be an option for chronic OA pain refractory to other treatments.

Comments:

- The two RF patients who were not analyzed were judged not to have adverse events from the procedure, but this judgment is questionable.
  - The patient who fell may easily have had an alteration in proprioception not detected by the unspecified clinical test for same.
  - The patient who had a hemorrhage probably was not able to perceive the stresses placed on the joint by walking uphill, and should be considered to have had an adverse event from the procedure until proven otherwise.
- Three months is a fairly short observation period, and some effects of joint denervation (Charcot joint, for example) could develop later.
- The pain score for the RF group did increase from 33.5 at 4 weeks to 42.4 at 12 weeks; continued good pain relief cannot be assumed past that point.
- The study is best described as a small pilot study which cannot form the basis of a recommendation for RF neurotomy until larger and longer trials are done which give accurate accounting of all potential adverse events.

Assessment:

- Inadequate as evidence for RF neurotomy (observation period too short, likely adverse events dismissed without reason, and possible waning of pain relief between 4 and 12 weeks)