

Patel N, Gross A, et al. A Randomized, Placebo-Controlled Study to Assess the Efficacy of Lateral Branch Neurotomy for Chronic Sacroiliac Pain. Pain Med 2012;13:383-398.

Design: Randomized clinical trial

Population/sample size/setting:

- 51 patients (14 men, 37 women, mean age 57) treated for chronic low back pain at a private pain practice in Florida or Wisconsin
- Eligibility criteria were predominant axial back pain below L5 lasting longer than 6 months, 3 day average pain Numerical Rating Scale (NRS) between 4 and 8, age over 18, failure of treatment with nonoperative interventions such as activity alteration, NSAIDs, PT, manual therapy, fluoroscopically guided steroid injection into SIJ or SI ligaments, and reasonable exclusion of fracture, hip joint pathology, spondylolisthesis, tumor, and other regional soft tissue structures
- Exclusion criteria were disc or facet joint disease, Beck Depression score >20, irreversible psychological barriers to recovery, scoliosis, stenosis, cervical or thoracic pain greater than 2, inflammatory arthritis, active radicular pain, workers compensation, litigation or disability payments, narcotic use, current smoking
- Before entry into study, patients meeting these criteria had to be screened with two sets of diagnostic blocks
 - o Lateral branches of S1-S3 were blocked under C-arm fluoroscopy and L5 dorsal ramus was blocked using ISIS guidelines for needle placement
 - o 0.5 cc of 0.5% bupivacaine was injected without steroid, without sedation, and with encouragement not to take any pain medication around the time of the diagnostic block
 - o Positive response required patients to report at least 75% of their index pain for between 4 hours and 7 days after injection
 - o Same blocking protocol was repeated on a separate day after return to baseline pain, with positive response defined the same way
 - o Patients with 75% relief on both blocks had to return to baseline pain before entry into study

Main outcome measures

- Randomization was to either true RF neurotomy (n=34) or to sham RF (n=17)
- Both true and sham RF were done with sedation and a local anesthetic, and patients remained communicative throughout the procedure
- Randomization code was broken after the patient was sedated, when the code was revealed to the machine operator and physician; the patient remained blinded through use of typical equipment noises
- The physician doing the procedure was not involved with the follow-up or assessment of outcomes

- RF was delivered with a cooled RF probe which applied RF energy for 150 seconds at 60° C, monitoring for any new symptoms, targeting L5 dorsal ramus and lateral branches of S1, S2, and S3
- Outcome measures were changes from baseline in NRS for pain (primary measure); secondary measures were the Oswestry for disability, SF-36 body pain and physical function subscales, Global Perceived Effect (GPE) of procedure on pain using a 7 point scale
 - o Positive GPE was defined as patient reporting pain “decreased a lot” or “completely gone”
- All outcome assessments were administered by a study coordinator blinded to patient randomization
- Scores were measured at baseline, and again at 1, 3, 6, and 9 months after the procedure
 - o Assessment was blinded at 1 and 3 months, with unblinding at 3 months, when patients in the sham RF group were invited to cross over to true RF
- True RF group had greater decrease in pain NRS at 3 months (2.4 points vs. 0.8 points), and also had greater improvement on Oswestry (decrease of 11 points vs. increase of 2 points) than the sham RF
 - o Pain change scores appeared to be bimodally distributed (Figure 2); Oswestry changes also appeared to be bimodal
- At 3 months, a positive GPE was reported by 47% of the true RF and by only 8% of the sham RF group; the positive GPE was reported by 67% of the true RF group at 9 months
 - o 16 of the 17 patients in the sham RF group elected to cross over after unblinding; 3 months later, 50% of them reported a positive GPE
- Most of the secondary outcome measures were also superior at 3 months in the true RF group

Authors' conclusions:

- RF neurotomy of the SI joint effectively reduces pain and disability for persistent SI joint pain
- The number needed to treat, based on the difference in GPE response rates, is approximately 3 in order to provide nearly complete relief in 3 months
- Not all patients were successfully treated
 - o Diagnostic blocks required only 75% and not 100% relief; some patients would not get full relief from RF neurotomy
 - o Diagnostic blocks did not use a placebo; some patients who had a placebo response to injection could enter the RF study
 - o Some patients had previously unidentified additional pain generators
 - o Some patients may have ventral innervation of the SI joint, but this is not likely to explain why they would not benefit from RF, since they should not have had a response to the diagnostic blocks
- The cooled RF probe is designed to prevent a high impedance between the tissue and electrode, compensating for the variations in location of the sacral lateral branches

Comments:

- Patient selection was very stringent; out of 304 potential cases, only 51 were randomized
 - o Some exclusion criteria are vague; an “irreversible psychological barrier to recovery” is undefined
- This means that the results can be applied with confidence only to patients who met the selection criteria; other applications of RF for SI joint pain are speculative
- Every effort was made to control bias in the performance and assessment of the RF effects; the risk of bias is low
- The text of the study provides extensive details about the placement of the probe and the performance of the test blocks, and these technical details may be important for the success of the procedure
- Even though the methods and reporting are of very high quality, there remains uncertainty about the effect size of RF for the SI joint due to the limited number of patients in the study

Assessment: High quality study which can support a statement that there is good evidence that RF neurotomy with a cooled probe may benefit patients with chronic SI joint pain who demonstrate at least a 75% pain response to repeated nerve blocks done under fluoroscopic guidance