**Radiofrequency Neurotomy for Chronic Lumbar Zygapophysial Joint Pain and Long Term Follow-Up. A Blinded Randomized Controlled Trial Utilizing Water-Cooled Technology.**

Principal Investigator:

W. Jeremy Beckworth, MD

The Emory Spine Center

**Background**

The prevalence of chronic lumbar zygapophysial joint (Z-joint) pain in patients with chronic low back pain ranges from 15% in younger patients1 to as high as 40% in elderly patients.2 This is a relatively common problem and the only proven treatment for it is radiofrequency ablation, also known as medial branch neurotomy. Multiple studies, both descriptive studies and randomized trials, have shown medial branch neurotomy to give clinically significant pain relief, improved disability and reduced analgesic use.3,4,5,6,7,8  Other studies9,10,11 have not shown as favorable outcomes for lumbar medial branch neurotomy, but these studies used incorrect procedural technique and/or did not utilize controlled anesthetic medial branch blocks to diagnose the facet joints as the source of pain. Controlled anesthetic blocks are essential because the reported false positive rate of a single diagnostic block is 38%.12

Lumbar medial branch neurotomy with a standard radiofrequency (RF) electrodes produce lesioning circumferentially in a transverse direction around the sides of the electrode, but very little lesioning occurs distal to the electrode tip.13 Thus, it is essential that the electrode must lie parallel the nerve if the nerve is to be optimally coagulated. The need for the parallel approach has been reaffirmed in a radiographic cadaver study.14 Opposed to this parallel approach, a perpendicular trajectory to the medial branch nerve risks having the lesion miss the nerve altogether, or at best incorporating it with no more than a “spot” lesion since only very limited lesioning occurs distal to needle tip. This would theoretically result in limited duration of relief.15

The size of the needle is important as well. In prior studies, large 16 gauge electrodes could be relied upon to capture the target nerve nerves since the lesion produced was large.3 Smaller gauge electrodes, such as a 20 to 22 gauge, need to be placed exactly on the nerve for them to have any prospect of capturing the nerve. A displacement as little as 1mm could result in the lesion failing to encompass the target nerve.14

Water cooled RF utilizes water that cycles through the electrode tip and this results in a slower heat rise time and a larger lesion area. The lesion produced is spherical in nature around the electrode tip, including distal to the electrode tip. Otherwise, this is the same as standard RF which has been done for years. The advantage of this larger lesion area is that it ensures an adequate nerve lesion and theoretically could give longer lasting pain relief if more of the nerve is lesioned. Additionally, water cooled RF does not require a technically challenging parallel needle approach, rather it can be done perpendicular to the nerve since lesions occur distal to the electrode.

**Objective**

The purpose of this study is to assess the clinical efficacy of water cooled RF in a randomized controlled trial. Prior studies have suggested a standard RF can be expected to give up to 12 months of pain relief3. This study will evaluate if a larger lesion with water cooled RF gives longer lasting relief.

**Methods (Study Design, Population, Procedures, Safety, Statistical Analysis)**

Participants will be recruited from patients who present to a tertiary spine center in a university setting. Stringent inclusion criteria will be utilized. Patients must have had chronic low back pain for six months or longer and be between 18 and 80 years old. They have to exhibit clinical features consistent with possible lumbar Z-joint pain, such as pain and tenderness over not more than two lumbar segments bilaterally or three segments unilaterally. Confirmation of pain from the Z- joint will be from controlled anesthetic diagnostic medial branch nerve blocks, a known standard for diagnosis.15

Exclusion criteria will include prior low back surgery, pregnancy, compensable disability, work injury, ongoing litigation, or concurrent thoracic or cervical pain lasting longer than six weeks during the prior six months.

Further exclusion criteria will be based on clinical examination. This includes pain not originating from the lumbar spine, lower limb pain greater than low back pain and obvious inappropriate pain behavior during physical exam. Additionally, patients will be excluded if there are neurological deficits, upper motor neuron signs, gait abnormalities or evidence of significant spinal stenosis on advanced imaging studies. Patients with significant psychiatric comorbidities will be excluded as well.

Segmental levels to be blocked will be determined by location of maximal tenderness over suspected painful joints. Palpation will be done in exam room and under fluoroscopy to help locate potentially painful Z-joints. Controlled anesthetic medial branch nerve blocks will be performed according to contemporary validated methods.16,17 The first block will be with 0.5mL of preservative free 0.5% bupivicaine and if positive then at a later visit with 0.5mL of preservative free 2% lidocaine. Pain will be recorded 20 minutes after each injection and hourly for six hours on a pain diary form. To be considered a positive diagnostic block, the patient must have 80% or greater pain relief of low back pain for greater than one hour with lidociane and greater than two hours with bupivicaine.3

The water cooled RF will be done with an 18 gauge cooled RF probe with a 4mm active tip. The lesion is done at 70 degrees Celsius which creates a 10-12mm spherical lesion. Initially, the C-arm fluoroscopcy is oblique 30-40 degrees to the treatment side with the end plate squared off. Then, the RF electrode will be placed in a perpendicular fashion straight down to the medial branch nerve at junction of the superior articular process (SAP) and transverse process. This is similar to the technique for a diagnostic medial branch blocks.16,17 For lesioning of the L5 dorsal primary ramus (DPR), more of a straight AP to slightly oblique view will be utilized, again similar to a diagnostic block to the L5 DPR.16,17

For safety reasons multiple fluoroscopic views will be obtained. Lateral fluoroscopy will be obtained on all procedures to ensure that the electrode will be no further ventral than the anterior margin of the inferior articular process. This would limit the lesion from getting anterior to the SAP, which is the posterior edge of the neural foramen. There is an additional 8.1-15.5mm from the anterior edge of the SAP to the exiting ventral nerve root in the lumbar spine.22 This is an extra safety barrier from the ventral nerve root. This technique has been used previously without any notable complications.

Of patients with positive controlled blocks, 15 will be randomized to receive water cooled RF and 15 will receive intra-articular Z-joint injections. The numbers of patients to enroll are based on a prior RF study.7 Both of these procedures are commonly used in clinical practice for treatment of Z-joint pain. Patients will be followed up at 1, 3, 6 and 12, 24 and 36 months after treatment procedure for data collection with a physician who is blinded to treatment. Outcomes measures will be visual analog score (VAS) covering current pain and weekly average18, SF-36 general health questionnaire,19,20 andOswestry Disability Index.21.

Patients in the Z-joint injection group who fail to have improvement and want further treatment will have the opportunity to receive a RFA after three months. These patients who switch will be considered a treatment failure.

A simple means test comparing treatment groups at each interval will be used. Additionally, a Friedman, 2-way analysis of variance will be used to determine differences and changes between baseline and all follow-ups. A categorical dependent variable regression, also known as an order probic regression, will be used to account for other cofounding factors such as age, sex, weight and other medical comorbidities. Ideally, cofounding factors will be negligible in a truly randomized trial. A statistician that works for the Emory Orthopedic and Spine Center will be assisting in data anaylsis.

The primary endpoint of this study will be efficacy of water-cooled RF and length of improvement. This will be compared to published data on length of improvement with standard RF. Additionally, this study will determine if there is a statistically significant difference in efficacy between water-cooled RF and facet joint injections.

**References**

1. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints: Isthe lumbar facet syndrome a clinical entity? Spine 1994;19:1132–7.
2. Schwarzer AC, Wang S, Bogduk N, McNaught PJ, Laurent R. Prevalence and clinical features of lumbar zygapophysial joint pain: A study in an Australian population with chronic low back pain. Ann Rheum Dis 1995;54:100–6.
3. Dreyfuss P, Halbrook B, Pauza K, et al. Efficacy and validity of radiofrequency neurotomy for chronic lumbar zygapophysial joint pain. Spine 2000;25: 1270–7.
4. Gofeld M, Jitendra J, Faclier G. Radiofrequency denervation of the lumbar zygapophysial joints: 10-year prospective audit. Pain Physician 2007;10: 291–300.
5. Burnham RS, Hollistski S, Dimnu I. A prospective outcome study on the effects of facet joint radiofrequency denervation on pain, analgiesc intake, disability, satisfaction, cost, and employment. Arch Phys Med Rehabil 2009;90:201–5.
6. van Kleef M, Barendse GA, Kessels A, et al. Randomized trial of radiofrequency lumbar facet denervation for chronic low back pain. Spine 1999;24: 1937–42.
7. Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain. A randomized double-blind trial. Spine 2008;33:1291–7.
8. Tekin I, Mirzai H, Ok G, Erbuyun K, Vatansever D. A comparison of convetnional and pulsed radiofrequency denervation in the treatment of chornic facet joint pain. Clin J Pain 2007;23: 524–9.
9. Gallagher J, Petriccione di Valdo PL, Wedley JR, et al. Radiofrequency facet joint denervation in the treatment of low back pain: A prospective controlled double-blind study to assess its efficacy. Pain Clin 1994;7:193–8.
10. Leclaire R, Fortin L, Lamber R, et al. Radiofrequency facet joint denervation in the treatment of low back pain: A placebo controlled clinical trial to assess efficacy. Spine 2001;26:1411–17.
11. van Wijk RMA, Geurts JWM, Wynne HJ, et al. Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain. A randomized, double-blind sham lesion-controlled trial. Clin J Pain 2004;21:335–44.
12. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The false-positive rate of uncontrolled diagnostic blocks of the lumbar zygapophysial joints. Pain 1994;58:195–200.
13. Bogduk N, Macintosh J, Marsland A.Technical limitations to the efficacy of radiofrequency neurotomy for spinal pain. Neurosurgery 1987;20:529–35.
14. Lau P, Mercer S, Govind J, Bogduk N. The surgical anatomy of lumbar medial branch neurotomy (facet denervation). Pain Med 2004;5:289–98.
15. Bogduk N, Dreyfuss P, Govind J. A narrative review of lumbar medial branch neurotomy for the treatment of back pain. Pain Medicine 2009;10:1035-1045.
16. Dreyfuss P, Schwarzer AC, Lau P, Bogduk N. Specificity of lumbar medial branch and L5 dorsal ramus blocks: A computed tomographic study. Spine 1997; 22:895–902.
17. Kaplan M, Dreyfuss P, Halbrook B, Bogduk N. The ability of lumbar medial branch blocks to anesthetize the zygapophysial joint. Spine 1998;23:1847–52.
18. Huskisson EC. Visual analogue scales. In: Melzack R, ed. Pain Measurement and Assessment. New York: Raven Press, 1983:33–7.
19. McHorney CA, Ware JE, Raczek AE. The MOS 36-item short-form health survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Med Care 1993;31:247–63.
20. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. Med Care 1992;30:473–83.
21. Fairbank JC, Peynsent PB. The Oswestry Disability Index. Spine 2000 Nov 15;25(22):2940-52.
22. Min et al. *J Spinal Disord Tech.* 2005. 18(2):132-135.