International Spine Intervention Society – 2015
23rd Annual Scientific Meeting Research Abstracts

Technical Efficacy of a Direction Specific Radiofrequency Device in the Performance of Lumbar Medial Branch Neurotomies – An MRI and EMG Confirmation Study (Interim Analysis)

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Background/Objectives: Lesion position and geometry are cardinal in maximizing safety and efficacy when performing lumbar medial branch radiofrequency ablation (LMBRFA). Technical efficacy of a multitined expandable electrode (MEE), with perpendicular approach, was demonstrated using a novel LMRI validation protocol and corroborated with paraspinous EMG (PEMG) findings in this IRB approved study.

Methods: Patients (n=6 MRI, n=5 EMG) chosen for LMBRFA underwent pre and post LMRI and PEMG[1]. Post-ablation LMRI using a previously described[2] protocol was obtained 7 days following RFA and used to quantify lesion size and provide lesion topography and anatomic relationship information. Post-LMBRFA EMG was obtained at 3-6 weeks. Monitoring of possible complications was carried out.

Results: Lesions were achieved, incorporating the target MB/SAP wall, in all cases*. Mean lesion volume was 601.7 mm³ (n=40, 95% CI: 522.6, 680.8). No bony edema or complications were noted. EMG evidence of target medial branch ablation was achieved in 88%* (n=34, 95% CI: 77-99) of targets which compares favorably with EMG % ablation of Dreyfuss, et al [3] of 90.5%. *One subject underwent repeat procedure, adding one additional MRI/EMG positive ablation site – included in these results. There were no complications.

Comments: Post-MBRAF LMRI, supported by PEMG, was used to demonstrate technical efficacy and safety of a multi-tined expandable RF electrode, using a new technique (perpendicular approach) that simplifies this ablative procedure for this common target. This validation method is an extension of all ex-vivo RF work done to date, and may be used for future research, as well as being a useful tool for educational purposes.


Comparison of Lumbar Facet Radiofrequency Neurotomy Using a Conventional Monopolar versus Multitined Electrode

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Background: strategies to expand radiofrequency (RF) lesion size to accommodate medial branch nerve location variability include multiple lesions using a conventional monopolar electrode and the use of a multitined (Nimbus) electrode.

Objective: to compare the effect of electrode type (conventional monopolar versus multitined) on relief of pain and disability, procedure time and fluoroscopy exposure.

Methods: 25 consecutive patients underwent lumbar facet RF using a single multitined thermal lesion per medial branch nerve. Each had previously undergone successful lumbar facet RF using 2 conventional monopolar lesions over the same medial branch nerves. Prospectively gathered Pain Disability Questionnaire (PDQ) scores were recorded prior to and at 2 months post RF for both groups and at 6 months post RF for the multitined electrode group. RF procedure duration and fluoroscopy times were also recorded. Data were analyzed using Analysis of Variance. Results: PDQ scores dropped significantly and comparably at 2 months post RF in both the monopolar and multitined electrode groups (pre-post mean(sd) scores - monopolar 28.8(5.5):11.6(6.1); multitined 28.6(5.6):11.0(6.7)). The 6 month post RF PDQ score remained significantly improved in the multitined group (14.9(7.5)). Pain scores also dropped significantly and comparably in both groups (pre-post mean(sd) scores - monopolar 6.4(1.8):2.6(1.4); multitined 6.3(1.6):2.3(1.4)). The 6
month post RF pain score remained significantly improved in the multituded group (3.3±2.1). At 2 months post RF, 76% and 72% of the monopolar and multituded groups respectively had experienced 50% or more pain relief. Procedure time was significantly shorter with the multituded electrode [in minutes - monopolar 45.1(5.2); multituded 25.5(8.2)]. Fluoroscopy exposure was comparable [in seconds - monopolar 117.3(49.8); multituded 98.4(34.4)]. Conclusions: pain and disability relief from lumbar facet radiofrequency neurotomy are significant and comparable whether using a conventional monopolar or multituded electrode. The procedure is significantly quicker when using the multituded electrode. Fluoroscopy exposure is comparable.

**Quadrupolar Strip Lesion Technique of Sacroiliac Joint Radiofrequency Neurotomy**

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Background: prior to 2012, sacroiliac joint radiofrequency neurotomy (SIJRF) was performed by the author using a bipolar leapfrog technique around the lateral border of the S1 through S3 dorsal sacral foramina. A technique creating linear quadrupolar strip lesions lateral to the S1 through S3 foramina was adopted in 2012. Objective: describe the effectiveness and reproductivity of quadrupolar SIJRF, factors that predict its effectiveness and compare the quadrupolar to the bipolar technique. Methods: records of all patients who had undergone quadrupolar SIJRF in 2012 through 2014 were reviewed (n=88). 28 were excluded because of incomplete data. All 60 study subjects experienced >50% relief following a single lateral branch block (Lbb). Prior to and at 2 months post-RF, patients completed a Pain Disability Quality-of-Life Questionnaire (PDQQ). If they came back for repeat SIJRF (n=15), they estimated the percentage and duration of pain relief from the prior procedure. Analysis of variance and multiple linear regression analyses were used. Results: mean(sd) PDQQ scores dropped significantly post quadrupolar SIJRF [prepost 46.3±7.8; 23.6±14.4; F=135.2]. Numerical rating pain scores (0-10) also dropped [prepost 6.8±1.8; 3±1.2; F=139.2]. On average, patients undergoing repeat quadrupolar SIJRF reported 80.1±16.8% improvement lasting 11±4.6 months. Percentage relief following Lbb and regular exercise positively and age negatively correlated with improvements in PDQQ scores (R²=0.34). Pain relief 2 month post bipolar and quadrupolar SIJRF was comparable (≥50% relief: bipolar=67%; quadrupolar=65%). Quadrupolar technique was significantly shorter [in minutes - bipolar=53±22.3; quadrupolar=30±7.9; F=46.2] and used less fluoroscopy [in seconds - bipolar=117±3(69.6); quadrupolar=76.7±18.4; F=18.6]. Pain relief with repeat quadrupolar SIJRF was comparable. Conclusions: quadrupolar SIJRF significantly reduces pain and disability for ~11 months and can be successfully repeated. Its effect is comparable to the bipolar technique but the procedure is shorter and uses less fluoroscopy. Young age, regular exercise and greater relief with Lbb are associated with positive outcomes.

**Introducing the Concept of Remission from Chronic Pain: Application in Spinal Cord Stimulation Clinical Trial Results and Its Correlation to Functional Outcomes**

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Background and Objectives: “Remission” refers to the absence of clinically significant signs and symptoms of an incurable disease. Although remission is utilized in specialties such as psychiatry and oncology, it has not been applied to interventional pain management. We introduce the concept of remission from chronic pain and apply it to the SENZA-RCT data. Methods: We defined remission as a sustained VAS pain score of ≤2.5 out of 10.0. This was based on pain scores of ≥4.0 warranting pharmaceutical intervention and patients seek treatment when their pain level is >2.5. Furthermore, a score of ≤2.5 results in minimal impact on the patient activities of daily living (ADLs) and quality of life (QOL). This definition was applied to the SENZA-RCT study, a prospective multicenter randomized controlled pivotal