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Prospective Case Series Evaluating the Efficacy of Radiofrequency Ablation With Stryker Venom Technology in the Treatment of Lumbar Facet Joint Pain

Emily A. Panteli, MCh[1], and Aaron K. Calodney, MD[2]

Background: Lumbar facet joint (FJ) arthropathy is a common source of low back pain (LBP). This study assesses the efficacy of radiofrequency ablation (RFA) using Stryker's MultiGen 2 RF Generator combined with the Venom 18G cannula and electrode system for treating FJ-mediated LBP.

Case Report: In this prospective, single-center case series, patients obtaining ≥ 80% improvement in pain after 2 medial branch blocks underwent RFA. Follow-ups were 1-, 3-, 6-, and 12-month post-RFA. Outcomes were the Visual Analog Scale (VAS), Oswestry Disability Index (ODI), Roland-Morris Disability Questionnaire (RMDQ), medications consumed, and adverse events (AEs). Nineteen patients were treated with RFA. Mean VAS, ODI, and RMDQ scores significantly decreased one-month postprocedure, and improvements were sustained to 12 months post-RFA. Patients' analgesic consumption remained stable. No procedure- or device-related AEs occurred.

Conclusions: This study highlights the effectiveness of RFA for treating FJ-mediated LBP. Significant improvements were observed rapidly and were sustained for the entire study.

Key words: Radiofrequency ablation, facet joint, chronic low back pain, medial branch block, MultiGen 2, Stryker, lumbar spine

BACKGROUND

Chronic low back pain (LBP) is defined as pain that persists for 12 weeks or longer, or as persistent pain after an initial treatment of acute LBP (1). LBP can be debilitating and is estimated to occur in > 80% of the population at some point in their lives (1). It can be caused by many reasons, including congenital conditions, degenerative disease, trauma, nerve and spinal cord conditions, and nonspinal etiologies. LBP can originate from several different joints in the spine, such as the lumbar facet joints (FJs), the intervertebral discs, the sacroiliac joint, and the coccyx (2).

Lumbar FJ arthropathy is a degenerative condition and a common source of LBP. It is estimated that lumbar FJs are the source of pain in 15% to 45% of patients with chronic LBP but are often misdiagnosed (3). Treatment often commences with conservative approaches, including analgesic medications and physical therapy. When conservative measures fail, steroid injections, nerve blocks, and radiofrequency ablation (RFA) can be useful (2). FJ blocks can be performed initially to test the hypothesis that FJs are the source of a patient's pain (4). Two medial branch nerves innervate each FJ. If pain is relieved postmedial branch block (MBB), a second block is performed to ensure a true positive result (4). In the setting of 2 positive lumbar MBBs, lumbar RFA

From: [1]Stryker Instruments, Portage, MI; [2]Precision Spine Care, Tyler, TX

Corresponding Author: Emily A. Panteli, MCh, E-mail: emily.panteli@stryker.com
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can be performed, which involves placing an insulated needle with fluoroscopic guidance near/at the target medial bundle branch nerve. A high-frequency current is applied, which produces thermal energy and destroys the target nerves, disrupting their ability to send pain signals (4). The current evidence supports RFA as an efficacious treatment for lumbar FJ pain (5-10).

The aim of this study is to assess the efficacy of thermal RF ablation using the Stryker MultiGen2 RF Generator (Stryker, Kalamazoo, MI) in combination with the Venom 18G cannula and electrode system (Stryker, Kalamazoo, MI) for treatment of FJ-mediated LBP in a real-world population. The study's specific objectives are:

1. To demonstrate improvement in LBP as measured by a Visual Analog Scale (VAS).
2. To show improvement in functional impairment and disability as measured through the Oswestry Disability Index (ODI) and the Roland-Morris Disability Questionnaire (RMDQ).
3. To demonstrate reduced consumption of pain medications.

METHODS

This prospective, single-center study enrolled patients with FJ-mediated LBP for ≥ 3 months duration, who have been identified from the Precision Spine Care clinic in Tyler, TX. All patients provided informed consent. Patient eligibility criteria were as follows:

Inclusion Criteria

- Aged 18-80 years.
- FJ-mediated LBP for ≥ 3 months.
- Clinical features consistent with lumbar FJ pain, such as pain/tenderness over no > 2 lumbar segments bilaterally or 3 segments unilaterally, radiological facet degeneration.
- VAS ≥ 5.
- ODI ≥ 30%.
- RMDQ ≥ 8.
- Willing and available to participate in follow-up.
- Health insurance that will cover costs of the RFA procedure and 2 MBB procedures.

Exclusion Criteria

- Prior lower back surgery at the treatment level.
- Prior treatment with RF neurotomy in lumbar region in the last 12 months.
- Significant concurrent thoracic or cervical pain.
- Pregnancy/intending to become pregnant within the next 12 months.
- Immunosuppression.
- Received a steroid injection in the lumbar FJs in the last 12 months.
- Pacemaker/other active electronic implant.
- Coagulopathies, malignancies, infections.
- Other causes of LBP (e.g., symptomatic disc herniation, spondylolisthesis, spinal stenosis, trauma).
- Major barriers that compromise the ability to provide written informed consent (e.g., nonEnglish-speaking, intellectual disability, psychological impairment).

Data points collected at baseline and at 1, 3, 6, and 12 months following RFA are as follows:

- Patient demographics: gender, age, race, duration of LBP, medical history.
- Medications consumed.
- VAS: a measure of pain intensity, consisting of a 10-cm line, with 2 endpoints representing 0 ("no pain") and 10 ("pain as bad as it could possibly be"). The patient is asked to rate their current level of pain by placing a mark on the line.
- ODI: a patient-completed questionnaire, which gives a score of level of function (disability) in activities of daily living (e.g., personal care, walking, lifting) in those rehabilitating from LBP. The ODI ranges from 0% to 100%, a higher score indicates a more severe disability.
- RMDQ: a standardized evaluation of LBP, which includes a list of statements. A patient agrees or disagrees with these statements (Yes/No). The final score, out of 24, represents the degree of disability due to LBP. A maximum score of 24 indicates the greatest degree of disability.

Adverse events (AEs) were also monitored for and collected throughout this study period.

All enrolled patients underwent a diagnostic MBB at a maximum of 3 nerves (2 segments) bilaterally or 4 nerves (3 segments) unilaterally. MBBs were carried out under fluoroscopic guidance using the technique and landmarks found in the International Pain and Spine Intervention Society (IPSIS) practice guidelines for spinal diagnostic and treatment procedures (11). A total of 0.5 mL of 0.5% bupivacaine was utilized for both injections. Those obtaining ≥ 80% relief of their index pain dur-

ing the diagnostic period (3 hours following injection) underwent a repeat diagnostic block at 2-3 weeks following the first block. Those obtaining ≥ 80% relief of index pain on both occasions were then scheduled for RFA within 30 days of the last diagnostic block.

RFA was conducted with the patient in the prone position under fluoroscopic guidance using the technique and landmarks found in the IPSIS practice guidelines for spinal diagnostic and treatment procedures (11). A parallel approach using an 18G Stryker Venom RF probe was utilized at the same levels injected during MBB testing, at a maximum of 3 nerves (2 segments bilaterally) or 4 nerves (3 segments unilaterally). Thermal lesioning was carried out between 80-90˚C for 90 seconds. Prior to lesioning, 1.0-1.5 mL of 0.5% bupivacaine was injected through the RF probe. Following the procedure, patients were given the opportunity to have a topical lidocaine patch placed over the injection area but were not given any additional analgesics other than that which they may have already been utilized prior to the procedure.

Patients were seen for a follow-up visit at 1, 3, 6, and 12 months after the procedure.

A *P* value ≤ 0.05 was interpreted as a statistically significant change (i.e., improvement) in the outcome measures, relative to baseline. Additionally, for each outcome measure, the proportion of patients reporting a meaningful improvement in pain was calculated. This was defined as a reduction in score, relative to baseline, as follows:

- VAS score > 2.
- ODI score > 10%.
- RMDQ score > 20%.

Additionally, each patient's medication list was reviewed at each follow-up to detect any changes in pain medication usage.

RESULTS

Twenty-three patients were initially screened, 3 of whom failed screening. Hence, 20 (9 men, 11 women, mean age 63.1 years) were enrolled. Duration of LBP ranged between 2.77-627.57 months (mean 155.83 months, median 52.77 months). Patient demographics are summarized in Table 1, and procedural data for the MBB and RFA procedures can be found in Table 2.

All 20 enrolled patients underwent both MBB procedures. After the first MBB, 7 patients reported an 80% improvement in LBP, 5 reported a 90% improvement, and 8 reported a 100% improvement. After the second

Table 1. Patient demographics.

Demographic	# of Patients
Gender Distribution n (%)	Men: 9 (45%) Women: 11 (55%)
Age (y) Mean +/- SD, Range	63.1 +/- 9.5, 43-77
Race n (%)	Caucasian: 19 (95%) Black or African American: 1 (5%)
Duration of LBP (mo) Mean, Median, Range	155.83, 52.77, 2.77-627.57
Medical History n (%)	Musculoskeletal conditions: 73 (31.2%) Neurological conditions: 10 (4.3%)

Abbreviation: LBP, low back pain.

Table 2. MBB & RFA procedural data.

MBB		
	MBB 1	**MBB 2**
# Patients Treated (n)	20	20
# Nerves Treated – total (n)	62	60
# Nerves Treated per Patient		
3 (n, %)	18 (90%)	20 (100%)
4 (n, %)	2 (10%)	0
# Nerves Treated Bilaterally (n, %)	53 (85.5%)	51 (85%)
Pain Relief Achieved Post-MBB (n)		
< 80%	0	1*
80%	7	7
90%	5	2
100%	8	10
RFA		
	Procedure 1	**Procedure 2**
# Patients Treated (n)	19	13
# Nerves Treated (total)	57	39
# Nerves Treated per Patient		
2 (n, %)	0	1 (7.7%)
3 (n, %)	19 (100%)	11 (84.6%)
4 (n, %)	0	1 (7.7%)
# Nerves Treated Unilaterally (n, %)	54 (95%)	39 (100%)
# Nerves Treated Bilaterally (n, %)	3 (5%)	0
# Lesions per Treated Nerve		
1 (n, %)	3 (5%)	0
2 (n, %)	54 (95%)	35 (89.7%)
3 (n, %)	0	0
4 (n, %)	0	4 (10.3%)

MBB, 7 patients reported an 80% improvement in LBP, 2 reported a 90% improvement, and 10 reported a 100% improvement. One patient reported an improvement in LBP below the threshold of 80%, thus this patient did not undergo RFA (Table 2).

Nineteen patients (57 nerves) underwent RFA, and of these 13 (39 nerves) underwent a second RFA procedure. All procedures were performed on an outpatient basis. Treated levels ranged from L3-S3, and number of lesions per nerve ranged from 1-4. Mean lesion temperature was 85.26 °C in procedure 1 and 85.9 °C in procedure 2. Mean lesion duration was 101.05 seconds in procedure 1 and 102.31 seconds in procedure 2 (Table 2).

Sixteen patients completed one-month follow-up, 17 completed follow-up at 3 months, 14 completed at 6 months, and 14 completed at 12 months.

Outcome Measures

For VAS, the mean baseline score of 7.05 significantly decreased to 3.5 at one month (P = 0.0016), 2.71 at 3 months (P = 0.0001), 2.79 at 6 months (P = 0.0005), and 2.93 at 12 months (P = 0.002) (Fig. 1). This represents a significant reduction in pain postprocedure.

For ODI, the mean baseline score of 50.9 also significantly decreased to 28.31 at one month (P =0.0007), 26.35 at 3 months (P = 0.0002), 24.71 at 6 months (P = 0.0001), and 21.64 at 12 months (P = 0.0001) (Fig. 2). This signifies a significant improvement in disability and function post-RFA.

Table 2 cont. MBB & RFA procedural data.

Treated Levels		
L3 (n, %)	19 (100%)	11 (84.6%)
L4 (n, %)	19 (100%)	12 (92%)
L5 (n, %)	19 (100%)	13 (100%)
S1 (n, %)	0	1 (7.7%)
S2 (n, %)	0	1 (7.7%)
S3 (n, %)	0	1 (7.7%)
Mean Lesion Temperature (Celsius)	85.26	85.9
Mean Lesion Duration (s)	101.05	102.31
Mean Treatment Time (min)	33.4	27.4
Setting	Outpatient (100%)	Outpatient (100%)

* This patient did not achieve ≥ 80% pain reduction after MBB 2, thus was not treated with RFA.
Abbreviations: MBB, medial branch block; RFA, radiofrequency ablation.

For RMDQ, the mean baseline score of 15.15 significantly decreased to 6.63 at one month (P = 0.0012), 6.18 at 3 months (P = 0.0004), 6.21 at 6 months (P = 0.0006), and 5.36 at 12 months (P = 0.0007) (Fig. 3). Similarly to ODI, this suggests a significant improvement in disability and function postprocedure.

Table 3 shows the number of patients who experienced clinically meaningful improvements. For VAS, 63% experienced a meaningful improvement at one month, 76% at 3 months, 71% at 6 months, and 57% at 12 months. For ODI, 81% of patients experienced a meaningful improvement at one month, 94% at 3 months, 93% at 6 months, and 93% at 12 months. For RMDQ, 75% of patients experienced a meaningful

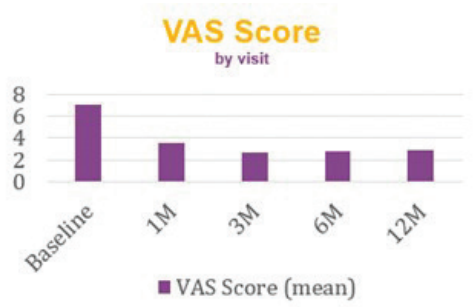

Fig. 1. Mean VAS score by visit.

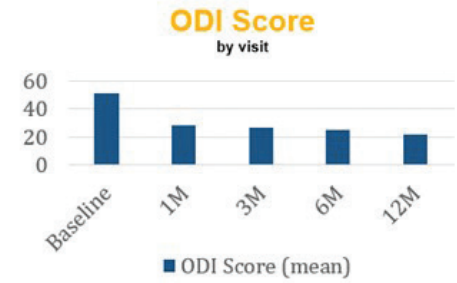

Fig. 2. Mean ODI score by visit.

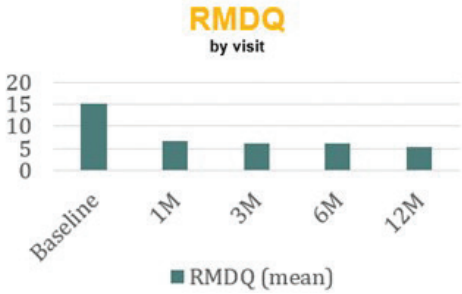

Fig. 3. Mean RMDQ score by visit.

Table 3. Patients with meaningful improvements in VAS, ODI, and RMDQ.

Outcome	1M	3M	6M	12M
Reduction in VAS > 2 points (n, %)	10 (63%)	13 (76%)	10 (71%)	8 (57%)
Reduction in ODI > 10% (n, %)	13 (81%)	16 (94%)	13 (93%)	13 (93%)
Reduction in RMDQ > 20% (n, %)	12 (75%)	13 (76%)	10 (71%)	11 (79%)

Abbreviations: VAS, Visual Analog Scale; ODI, Oswestry Disability Index; RMDQ, Roland-Morris Disability Questionnaire.

improvement at one month, 76% at 3 months, 71% at 6 months, and 79% at 12 months.

Table 4 summarizes the status of each patient's analgesic consumption post-RFA. Most patients remained stable on their medications. Any changes in medications were not statistically significant. Three patients' medications could not be assessed as they were lost to follow-up (i.e., did not attend any visits at 1, 3, 6, or 12 months).

During the study, 14 AEs were reported, of which 2 were classified as serious (both were related to SARS-CoV-2 infection). No procedure- or device-related AEs were reported, and no device deficiencies were identified.

Table 4. Post-RFA changes to analgesic medications.

	1M	3M	6M	12M
Paracetamol, ASA & NSAIDs (n, %)				
→	16 (100%)	16 (94.1%)	14 (100%)	14 (100%)
↑	0	0	0	0
↓	0	1 (5.9%)	0	0
P value	1	1	1	1
Codeine-Containing Medication (n, %)				
→	16 (100%)	17 (100%)	14 (100%)	14 (100%)
↑	0	0	0	0
↓	0	0	0	0
P value	1	1	1	1
Central Working Agents (n, %)				
→	15 (94%)	16 (94%)	13 (93%)	13 (93%)
↑	1 (6%)	1 (6%)	1 (7%)	1 (7%)
↓	0	0	0	0
P value	1	1	1	1
Morphine (or equivalent) (n, %)				
→	16 (100%)	17 (100%)	14 (100%)	14 (100%)
↑	0	0	0	0
↓	0	0	0	0
P value	1	1	1	1

→ No change; ↑ Increase; ↓ Decrease
Abbreviations: RFA, radiofrequency ablation; ASA, acetylsalicylic acid; NSAIDs, nonsteroidal anti-inflammatory drugs.

DISCUSSION

Lumbar FJ arthropathy is a degenerative syndrome that typically occurs secondary to age, obesity, poor body mechanics, repetitive overuse, and microtrauma. FJ-mediated pain occurs secondary to these degenerative changes, as there is rich innervation of the joint (12).

The prevalence of lumbar FJ-mediated pain widely varies in the literature, from < 5% to > 90% of patients reporting chronic LBP (12). Studies (3,13) following criteria established by the International Association for the Study of Pain, involving controlled MBBs, have implicated lumbar FJs as the source in 15% to 45% of patients with LBP.

The global burden of pain-related disease is significant. Fatoye et al (14) reported that LBP is the leading cause of disability and work absenteeism globally and poses a significant clinical and economic burden. To reduce the clinical and economic burden associated with LBP, it is important that effective management strategies are implemented.

The findings of our study, which show significant improvements post-RFA in pain, disability, and functioning support the existing clinical literature for the use of RFA in chronic LBP that is refractory to conservative measures. The last updated guidelines of the American Society of Interventional Pain Physicians recommend lumbar RFA with a level of evidence II and a moderate strength of recommendation (15). However, the identification of patients who will benefit most is critical. Therefore, MBBs should be undertaken as a prognostic screening tool before planning RFA. Since the medial branch innervates other possible pain-generating structures, including the paraspinal muscle and the sacroiliac joint, there can be a high false-positive rate (13). Therefore, a double MBB was performed for each patient in this study.

Limitations of this study include its monocentric nature and small sample size. Additionally, loss to follow-up is a limitation of this study; 14 of the 19 patients who

received RFA completed the follow-up to 12 months. The US-only sample may limit generalizability to other geographies.

CONCLUSIONS

This prospective case series highlights the safety and effectiveness of lumbar RFA for the treatment of lumbar FJ-mediated LBP in a real-world population. Significant improvements in pain and functional impairment were observed rapidly (with one month) posttreatment and were sustained for the entire study period (12 months).

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