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Research Article

A Novel Modality for Facet Joint Denervation: Cooled Radiofrequency Ablation for Lumbar Facet Syndrome. A Case Series

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Abstract

Background: While cooled radiofrequency ablation (C-RFA) appears to be a promising technology for joint denervation, outcomes of this technique for the treatment of lumbar facet syndrome have not been described. We report clinical outcomes in a case series of patients treated with C-RFA for lumbar facet syndrome.

Methods: Consecutive patients aged 18-60 years diagnosed with lumbar facet syndrome, confirmed by ≥75% symptom relief with at least one set of diagnostic medial branch nerve blocks, who underwent C-RFA between January 2007 and December 2013 in an urban academic pain center were included. The respective proportions of participants who reported ≥50% improvement in pain and in function were calculated. Change in median NRS score, daily morphine equivalent consumption (DME), and medication quantification scale III (MQS III) score were measured.

Results: Twelve patients underwent C-RFA; three were lost to follow-up. The median and 25%-75% interquartile range (IQR) for age was 44 years (35, 54). The median duration of follow-up was 34 months, IQR (21, 55). The percentage and 95% confidence interval (CI) of patients who reported ≥50% improvement in pain was 33% CI (12%, 64%) and in function was 78%, CI (41%, 96%). There was no significant change in DME or MSQ III score. Approximately 50% of patients sought additional healthcare by long-term follow-up. No complications were reported.

Conclusions: This case series suggests that C-RFA may improve function and to a lesser degree pain at long-term follow-up. A randomized, controlled trial is warranted.

Keywords: Zygapophyseal joint; Denervation; Low back pain

Abbreviations

CI: Confidence Interval; C-RFA: Cooled Radio Frequency Ablation; DME: Daily Morphine Equivalents; G: Gauge; Hz: Hertz; IQR: Interquartile Range; IVP: Intravenous Push; MBN: Medial Branch Nerve; MQSIII: Medication Quantification Scale III; NRS: Numerical Rating Scale; T-RFA: Conventional Thermal Radiofrequency Ablation

Introduction

Lumbar zygapophyseal or "facet" joint pain accounts for 15-30% of low back pain cases in the adult population [1-3]. When facet-mediated pain fails to improve with conservative treatment including non-steroidal anti-inflammatory drugs, physical therapy and postural re-education, interventional treatment may be indicated. Radiofrequency ablation (RFA) of the lumbar medial branch nerves provides significant improvement in pain, function and analgesic use for 6-12 months in individuals with facet-mediated low back pain [4-3-16]. RFA has also been shown to be a cost effective pain management modality [11].

The pain mediator in lumbar facet syndrome is the medial branch nerve of the dorsal ramus (MBN), which supplies the facet joints and multifidi muscles at each spinal segment. Thermal MBN lesioning interrupts these afferent nociceptive pathways by applying radiofrequency energy through an electrode placed at the target MBN. In contrast to conventional thermal radiofrequency ablation (T-RFA) wherein the target is heated to 80 degrees C for 90 seconds, cooled radiofrequency ablation (C-RFA) uses a constant flow of ambient water circulated through the electrode via a peristaltic pump to maintain a lower tissue temperature by creating a heat sink, but still allowing neurolysis to occur. By removing heat from tissues immediately adjacent to the electrode tip, a lower lesioning temperature is maintained, resulting in less tissue charring adjacent to the electrode and therefore less tissue impedance [17, 18]. The volume of tissue heated and the resultant thermal lesion size is substantially larger with C-RFA as compared to T-RFA [19]. C-RFA lesions are spherical and project several millimeters beyond the electrode tip as compared to T-RFA, thereby increasing the probability of successful denervation of the target MBN. The lesion characteristics in C-RFA also allow the electrode to be positioned at any angle to make contact

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with the target neural structure [20]. Together, these make the technique easier to perform.

C-RFA has been used to successfully treat cardiac arrhythmia [21-23] and solid tumors [24, 25]. More recently introduced for chronic pain indications, a number of studies have demonstrated improved pain and functional outcomes when C-RFA is used to treat chronic sacroiliac joint pain [26-29]. No published study has investigated C-RFA for the treatment of lumbar facet syndrome. In this case series, we describe the clinical outcomes of 12 patients with lumbar facet syndrome treated with C-RFA.

Methods

This is a longitudinal cohort study. The study protocol (STU00090028) was approved by the local Institutional Review Board and was conducted at a single-site interventional pain management practice in an urban tertiary academic medical center. Inclusion criteria were: age 18-60 years, lumbar facet syndrome corroborated by history, physical examination, imaging, and confirmation with >75% reduction in back pain following at least one set of diagnostic MBN blocks and C-RFA procedure between January 1, 2007 and December 31, 2013. Exclusion criteria were: radicular symptoms by history, nerve root tension signs, lower extremity strength or reflex asymmetry.

The medical records of participants were reviewed and demographic data (age, sex, and body mass index), duration of pain and anatomic levels of C-RFA, pre-C-RFA pain scores and pre C-RFA medication usage were recorded. After C-RFA, participants were contacted by telephone by a research assistant and follow-up outcome data (NRS pain score, duration of pain reduction, functional improvement, opioids and non-opioids medication use, and other healthcare utilization information) were collected using of a standardized questionnaire (Appendix A). If a patient could not be contacted by phone upon at least three attempts, on different days, at different times of the day, then the individual was considered "lost to follow up". Our primary outcome measure was the rate of ≥50% pain improvement at long-term follow up. We chose to use a categorical definition of "clinically significant" pain relief rather than the difference in group means because studies of low back pain interventions consistently show that there are "responders" and "non-responders," such that, when using group means, significant pain reduction in a subset of the study group can be masked [30-31].

Procedures

Based on history, physical examination and imaging studies, the treating physican selected the facet joints to be diagnostically blocked and performed MBN blocks to functionally anesthetize these joints. A needle was placed at each target location (described below) and following confirmation of appropriate needle placement with fluoroscopy, 0.5 cc of 0.5% bupivacaine or 2% lidocaine was injected. The maximum number of MBNs blocked for any diagnstic injection was limited to six.

At the time of the C-RFA procedure, patients were positioned prone on a fluoroscopy table and the lumbar region was prepped with chlorhexidine and draped in a standard sterile manner. Conscious sedation was used in some cases (midazolam 1-4 mg IVP and / or fentanyl 50-100 mcg IVP). After local anesthesia to the skin and subcutaneous tissues superficial to a planned target site, a 17 G C-RFA electrode (Lumbar Cool (R) Cooled Radiofrequency Kit, Kimberly-Clark, LLC, Roswell, GA) was positioned using fluoroscopic guidance at the medial, middle third of the transverse process at the anatomic transition to the pedicle for the L1-L4 medial branches and inferior to the concavity of the sacral ala for the L5 medial branch. Motor testing was performed at 2 Hz to confirm integrity of the corresponding exiting spinal nerve at each target. As the C-RFA electrode placement is anatomically different compared to a conventional lumbar T-RFA procedure, patients were not expected to experience concordant low back pain with sensory testing at 50 Hz. When appropriate C-RFA electrode positioning was confirmed, 1cc of 2% lidocaine was injected through the introducer needle for anesthesia during the ablation. C-RFA lesioning was performed at each target site at 60°C for 150 seconds. Following the ablation, 0.5- 1.0 cc of 0.5% bupivacaine was injected to provide post-procedure analgesia. No corticosteroids were used. Following the procedure, patients were observed for approximately 30 minutes and were then discharged. Patients were asked to follow up in 4-6 weeks after the C-RFA procedure was performed for clinical re-evaluation.

Data analysis

All collected data was entered into a password protected database. Opioids medication doses for each patient were converted to daily morphine equivalents (DME) at each follow up time point for direct comparison purposes. In addition, the Medication Quantification Scale (MQS) III score, a validated equation used to objectively quantify all medications used for pain management (including opioid and non-opioid medications), [32-33] was calculated for each patient at follow-up time points.

The number of individuals reporting ≥50% reduction in pain, the number of individuals reporting ≥50%improvement in function, the change in median DME and MSQIII score were calculated and analyzed, and post C-RFA healthcare utilization for pain management was evaluated.

Statistical analysis

All data were checked for distributional form using summary statistics and graphical displays. Data were not normally distributed, so medians and 25%-75% interquartile ranges were calculated for each continuous variable. Proportions and 95% confidence intervals were calculated for categorical variables. Statistical software was used to analyze the data (SPSS, Version 22; Chicago, IL).

Results

Twelve consecutive patients underwent C-RFA for the treatment of lumbar facet syndrome during the study time-frame. Three patients were lost to follow-up. Demographic, clinical, and procedural characteristics of the study population are shown in Table 1. The median and 25%-75% interquartile range (IQR) for age was 44 years (35, 54). Patients' duration of pain at presentation was categorized: <2 years in 3 (25%), 2-5 years in 3 (25%), >5 years in 6 (50%). The median baseline pre C-RFA NRS pain score was 6, IQR (5, 8).

The median duration of long-term follow-up in this cohort was 34 months, IQR (21, 55). The clinical outcomes of C-RFA at this time point are shown in Table 2. The percentage of patients reporting ≥50% improvement in low back pain was 33% CI (12%, 64%). The

Table 1: Baseline demographic, clinical and procedural information (n=12).

	Median (IQR) or n (%)
Age (years)	44 (35, 54)
Sex Male Female	 6 (50%) 6 (50%)
BMI (Kg/m^2)	24 (21, 27)
Duration of pain at presentation <2 years 2-5 years >5 years	 3 (25%) 3 (25%) 6 (50%)
NRS pain score	6 (5, 8)
DME	5 (0, 55)
MQS III score	9.5 (4.8, 13.7)
Number of diagnostic MBB blocks 1 2	 6 (50%) 6 (50%)
Number of facet joint levels denervated 1 2 3	 5 (42%) 1 (8%) 6 (50%)
Bilateral procedures	4 (33%)
RFA procedure repeated Yes No	 7 (58%) 5 (42%)

BMI = Body Mass Index
Eq = Equivalents
IQR = Inter Quartile Range
MBB = Medial Branch Block
MQS III score = Medication Quantification Scale III score
NRS = Numerical Rating Scale
RFA = Radio Frequency Ablation

percentage of patients reporting ≥50% improvement in function was 78%, CI (41%, 96%). Median DME consumption and MSQ III scores did not change significantly. Additional healthcare was utilized by long-term follow-up that included: repeat spine imaging, 57% CI (25%, 84%), evaluation or consultation by another physician or surgeon, 43% CI (12%, 79%), and additional procedures to treat low back pain other than repeat C-RFA, 43% CI (12%, 79%).

Discussion

T-RFA is a widely accepted treatment for patients with lumbar facet syndrome refractory to conservative care. Here, we report the first description of clinical outcomes of C-RFA for the treatment of lumbar facet syndrome in a series of patients. Our data suggest that C-RFA may lead to significant long-term improvements in pain and to a greater extent, improvements in function. Clinically significant improvement in pain (≥50%) was observed in 33% of patients at a median follow-up of 3 years. Most of the literature related to T-RFA treatment of lumbar facet syndrome is limited to 1 year follow-up [4-16]. To the best of our knowledge, the longest follow-up interval reported is 3 years. Three studies have reported categorical pain outcome data indicating that 2% to 55% of patients experience a ≥50% pain reduction at 2 year follow-up after T-RFA [34-36]. This case series indicates superior pain reduction compared to one retrospective study (n=174, 2 year follow-up), [34] but somewhat less than a prospective (n=128, 2 year follow-up) [35] and a retrospective (n=42, 3 year follow-up) study, [36] though similar within the range of the 95% confidence interval. Large-scale comparative study is needed to determine whether T-RFA or C-RFA is superior or equivalent for

Table 2: Long-term Outcomes of Cooled Radiofrequency Ablation Procedure (n = 9).

	Median (IQR) or Percent [95% CI]
Duration between procedure and follow up (months)	34 (21, 55)
≥50% patient perceived functional improvement	78% [41%, 96%]
≥50% reduction in NRS pain score	33% [12%, 64%]
Change in DME	0 (-5, 0)
Change in MQS III score	0 (-7.4, 3.8)
Sought additional imaging	57% [25%, 84%]
Saw another physician to address low back pain	43% [12%, 79%]
Underwent another procedure to treat low back pain	43% [12%, 79%]

CI = Confidence Interval
DME = Daily Morphine Equivalents
Eq = Equivalents
IQR = Inter Quartile Range
MQS III score = Medication Quantification Scale III score
NRS = Numerical Rating Scale
RFA = Radio Frequency Ablation

pain reduction and function at long-term follow-up. To date, such a comparison is limited to outcomes of sacroiliac joint denervation with only a 6-month follow-up [26].

Interestingly, compared to pain, a far larger proportion of individuals (nearly 80%) reported ≥50% functional improvement at long-term follow-up. This finding is consistent with prior evidence that patient-reported pain and patient-reported function correlate weakly in patients with chronic low back pain [37-39]. Given the potential for this discrepancy, subjective pain should not be the sole outcome measure in long-term studies in this population [40-41]. In fact, it is functional improvement, not pain relief, which is the foundation of functional restoration programs for patients with chronic pain disorders. As 75% of patients in our cohort reported chronic pain for at least 2 years prior to the C-RFA procedure, the importance of their significant improvements in function cannot be overemphasized.

In general, outcome studies of T-RFA consistently show short-term functional improvement in patients treated for lumbar facet syndrome, [5-7, 9, 10, 12, 14, 16, 36] but little has been published on the durability of functional outcomes following T-RFA. Literature review reveals only one retrospective study that assessed functional outcomes beyond 12 months. Using 1 set of diagnostic MBN blocks, North et al. observed functional improvement in 30% of patients at 3 year (standard deviation 2 years) follow-up after T-RFA for treatment of lumbar facet syndrome [36]. Although functional improvement was observed in a significantly larger proportion of patients treated with C-RFA in our case series at a similar follow-up, prospective comparative studies will be needed to confirm the functional benefit of C-RFA as compared to T-RFA.

Of note, the C-RFA procedure was repeated in 6 of 9 patients who were reached at long-term follow-up, increasing the likelihood of a prolonged treatment effect [8, 34, 42-46]. Of the three individuals who underwent a single C-RFA procedure, two experienced 32 and 35 months of meaningful benefit, with 50% and 83% improvement in function. These outcomes after single-lesioning are superior

compared to what has been reported in the T-RFA literature [5, 6, 9-11]. Although this sample size is small, our findings are consistent with studies of chemical neurolysis. Like C-RFA, alcohol neurolysis can cause more wide spread and complete denervation than T-RFA, but in a volume dependent manner that may sacrifice safety. In a comparative study of alcohol neurolysis and conventional RFA, patients who underwent alcohol neurolysis demonstrated nearly twice the duration of pain relief and more than 20% improvement in functionality as measured by the Oswestry Disability Index [14]. Similarly, C-RFA may provide prolonged duration and quality of pain relief and functional improvement compared to conventional RFA, but warrants further study to prove this hypothesis.

We found no relationship between pain relief and DME or MQS III score, although the median DME was 5 (the equivalent of one tablet of 5mg/325mg hydrocodone/acetaminophen). This low DME leaves little room for further improvement. Prior authors have described this as the "healthy person effect" [47]. We may have seen more dramatic improvements if our cohort had higher baseline DME or MQS scores prior to C-RFA. Prior studies of T-RFA have demonstrated highly variable reductions in analgesic use, ranging from 0-80% so we are not surprised by this finding [5, 6, 11, 15, 34]. Opioid prescribing habits are highly correlated with physician preference or other immeasurable patient or cultural factors.

Finally, this case series provides preliminary data regarding long-term healthcare utilization for pain management after C-RFA is performed for chronic lumbar facet syndrome, an important issue in our era of cost-effective medicine and quality of care. Approximately half of patients in our cohort avoided additional imaging studies or further treatments for low back pain over the median 3-year follow-up period. In comparison to the general low back pain literature, this rate appears favorable. In patients with new or recurrent acute low back pain, 50% seek medical care [48-50]. Of patients with chronic low back pain, multiple office visits and repeat imaging are respectively sought in 60% and 30% of patients annually [51]. Few studies of RFA have investigated this aspect of care. In a study of healthcare utilization and costs of pain care following RFA for lumbar facet syndrome, costs (the sum of physician office visits, chiropractic treatments, physical therapy treatments and treatments from other allied health practitioners) were decreased for up to nine months following the procedure compared for an analogous time-period prior to the RFA procedure [11]. While we did not perform a cost-effectiveness analysis, the present case series provides preliminary data with regard to expected healthcare utilization after C-RFA. Future studies should evaluate the direct and indirect costs of C-RFA and compare not only treatment efficacy but also healthcare utilization costs following this procedure.

Study Limitations

We used a percentage-based self-reported functional outcome measure in order to simplify the patient interview to decrease survey burden on participants. Pre-procedure and follow-up ODI or Roland-Morris Disability assessments would provide more valuable functional outcomes data in future studies [52]. While classification bias is possible, we believe the likelihood in this study is small, as all of the patients who underwent C-RFA for lumbar facet syndrome reported at least 75% reduction of pain with at least one set of low volume diagnostic medial branch nerve blocks.

Conclusions

This case series supports C-RFA as an effective means of improving self-reported function and to a lesser degree, pain at long-term follow-up. The importance of defining the durability of treatment effect associated with RFA for lumbar facet syndrome is vital given the progressive nature of the condition and the lack of low risk, high value surgical options. While the present data addresses this knowledge gap, randomized, controlled studies of C-RFA and direct comparisons to conventional RFA for lumbar facet syndrome are needed.

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