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ORIGINAL RESEARCH

Outcomes of Cooled Radiofrequency Ablation of Lumbar Nerves as Treatment for Chronic Low Back Pain

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ABSTRACT

***Introduction*:** Worldwide, 23% of adults suffer from chronic lower back pain, which is defined as pain persisting for more than 3–6 months [Merskey in Can J Psychiatry 34:329–336, 1989]. The lifetime prevalence of back pain is as high as 84% in adults [Casiano VE, Sarwan G, Dydyk AM, et al. Back Pain. [Updated 2023 Dec 11]. In: Stat Pearls [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK538173/]. Conservative treatment options for chronic low back pain include as needed or scheduled analgesics, physical therapy, anticonvulsants, exercise, weight loss, muscle relaxants, and much more. With chronic pain that is refractory to the aforementioned treatments, more invasive procedures may be indicated. Cooled radiofrequency ablation (CRFA), a minimally invasive therapy, utilizes internally cooled radiofrequency probes to deliver targeted thermal energy that causes neurolysis, disrupting the transmission of pain stimuli along nociceptive pathways, thus resulting in pain relief [Walker in J Spinal Disord 13:205–217, 2000 June]. This study investigates whether patients receiving CRFA for relief of chronic low back pain caused by lumbar facet arthropathy experience a reduction in pain scores, the length of this reduction in pain scores, and the magnitude of this reduction in pain.

***Methods*:** This study was a retrospective analysis of data extracted from UW-Health Electronic Medical Health records (EMR), encompassing lumbar CRFA procedures performed from 2015 through April of 2024. Patient data was obtained, including diagnosis, preoperative pain score, postoperative pain score, duration of relief, patient age, sex, and BMI. A two-tailed paired *t* test was used to statistically analyze the preoperative and postoperative pain scores, in which a p value ≤ 0.05 was considered significant.

***Results*:** A total of 1450 lumbar CRFA procedures were reviewed, and 206 were excluded due to absent pre- or post-op pain scores. An additional eight procedures were excluded due to weekly lidocaine infusions in between their procedure and reporting of their post-op score. 1026 CRFA patients were included in the analysis, comprising 584 females and 442 males with an average age of 59.81 ± 13.40 and a BMI of 31.67 ± 7.13. The average pre-procedure

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visual analog scale (VAS) pain score was 6.44 (6.44 ± 1.67, $n = 1236$), and the average post-procedure VAS pain score was 3.21 (3.21 ± 2.45, $n = 1236$) this achieved statistical significance ($p < 0.0001$). Improvement of pain symptoms was reported in 85.92% ($n = 1062$), 14.08% ($n = 174$) reported complete pain remission, 7.61% ($n = 94$) reported no change, and 6.47% ($n = 80$) reported worsening symptoms. For effective procedures (those with any amount of pain relief, $n = 1062$) with an available postoperative pain score, the mean percentage improvement was 60.56 ± 27.21%. The average duration of improvement was 267.43 ± 393.18 days.

***Conclusions*:** This study supports the potential efficacy of CRFA as a minimally invasive treatment for chronic back pain secondary to lumbar facet arthropathy refractory to conventional treatment measures, demonstrating significant relief for a substantial length of time. Due to chronic pain's detrimental effect on one's quality of life, finding effective treatment options is essential, especially for those refractory to conventional treatments.

Keywords: Cooled radiofrequency ablation; Low back pain; Interventional pain management; Chronic pain management; Minimally invasive procedures; Long-term pain relief; Nerve ablation; Lumbar nerves

Key Summary Points

Why carry out this study?

Chronic pain is a significant health burden in the United States. The lifetime prevalence of back pain is as high as 84% in adults.

Conservative treatment options for chronic low back pain include as needed or scheduled analgesics, physical therapy, anticonvulsants, exercise, weight loss, muscle relaxants, and much more. However, many patients experience pain refractory to conservative measures and cooled radiofrequency ablation (CRFA) is indicated.

Why carry out this study?

This study investigates whether patients receiving CRFA for relief of chronic low back pain caused by lumbar facet arthropathy experience a reduction in pain scores, the length of this reduction in pain scores, and the magnitude of this reduction in pain.

What was learned from the study?

This study demonstrated that CRFA of lumbar nerves decreased pain symptoms in 85.92% of effective procedures on 1026 patients with minimal side effects reported.

Complete pain remission was reported in 14.08% of effective procedures on 1062 patients. Average duration of improvement was 267.43 ± 393.18 days for all 1236 procedures included in the study.

CRFA is a minimally invasive treatment for chronic lower back pain refractory to conventional treatment measures, demonstrating significant relief for a substantial time.

INTRODUCTION

Chronic pain is a significant health burden in the United States. It is defined by the International Association for the Study of Pain as pain persisting for longer than three months or that recurs [1]. Chronic pain is an economic burden associated with substantial healthcare costs and lost productivity [2]. Chronic low back pain is particularly burdensome and very common, with a lifetime prevalence of 84% [3]. Low back pain is often a multifactorial condition but frequently arises from lumbar vertebrae, facet joints, spinal nerve roots, or intervertebral discs [4]. Some of the most common reasons patients report to pain clinics with a primary complaint of low back pain include lumbar spondylosis, lumbar facet arthropathy, and lumbar facet dysfunction [5]. Furthermore, elevated BMI has been shown to be a possible risk factor for chronic low back pain [6].

Current therapies for low back pain secondary to lumbar facet dysfunction include exercise, physical therapy, weight loss, muscle relaxants, and other pharmacotherapies. Despite the vast array of non-invasive therapies for the treatment of low back pain, these modalities often do not provide significant, lasting relief for patients. More invasive therapies, such as steroid joint injections and electrotherapy, have been shown to provide some temporary relief [7].

Radiofrequency ablation (RFA) is a minimally invasive intervention that employs high-frequency current to thermally ablate nociceptive nerve tissue. During the RFA procedure, an electrode is positioned adjacent to the target nerve, allowing radiofrequency waves to generate localized thermal energy, thereby inducing neurolysis of the nerve fibers responsible for transmitting pain signals [8, 9]. This technique typically utilizes fluoroscopy to guide electrode placement [10]. Cooled radiofrequency ablation (CRFA) is a specialized form of RFA wherein the electrode tip is intermittently cooled. This process facilitates the creation of more extensive ablation lesions, mitigates tissue charring, and minimizes blood coagulation [11].

Previous studies have demonstrated the efficacy of radiofrequency ablation (RFA) in alleviating pain when more conservative treatment modalities have been unsuccessful [8, 12, 13]. RFA of peripheral nerves has relatively few contraindications. Absolute contraindications include infection at the site and patient refusal. Other considerations involve the patient's anticoagulation status if anticoagulation therapy cannot be paused and surgically complex congenital anatomical variations [14].

While RFA of lumbar nerves demonstrates potential as an effective intervention for chronic lower back pain, a comprehensive evaluation of its efficacy is essential to characterize its clinical role further. This retrospective analysis aims to evaluate the therapeutic efficacy of RFA targeting various lumbar nerves as an alternative treatment modality for patients with chronic lower back pain refractory to conservative measures.

METHODS

This was a retrospective study where we reviewed charts of individuals who received CRFA of the lumbar nerves as a treatment for chronic low back pain from 2015–2024. Patient data, including diagnosis, preoperative pain score, postoperative pain score, duration of relief, subjective reports of pain improvement, age, sex, and BMI, was collected and organized using Microsoft Excel spreadsheets. Data was then coded and transferred to SPSS (version 26) for statistical analysis. A two-tailed paired *t* test was used to statistically analyze the preoperative and postoperative pain scores, with a p value of ≤ 0.05 considered significant.

The visual analog scale (VAS), a widely adopted method for quantifying pain intensity and changes, was used to assess preoperative and postoperative pain scores [15]. For charts that included both preoperative and postoperative VAS pain scores but lacked a reported percentage of pain improvement, the percentage improvement was calculated using the pre- and post-ablation scores (e.g., a pre-ablation VAS pain score of 10/10 and a post-ablation score of 5/10 indicated a 50% improvement). In cases where charts provided a preoperative pain score and subjective improvement but not a postoperative pain score, the postoperative pain score was derived from the given data (e.g., a preoperative pain score of 10/10 with a 25% improvement indicated a postoperative pain score of 7.5/10).

Only procedures documenting symptom improvement were included to analyze the duration of pain relief. The reviewed charts showed either a postoperative VAS pain score lower than the preoperative score or symptom improvement greater than zero. Additionally, any adverse events related to the procedure were recorded.

Before being selected for ablation, patients were seen in the outpatient clinic setting and verified to have lower back pain over the lumbar facet joints. Additionally, patients were required to undergo two diagnostic medial branch blocks. To be eligible to proceed to radiofrequency ablation, patients had to have greater than 50% improvement in their pain from each diagnostic

block. Diagnostic blocks were performed under fluoroscopic guidance using local anesthetics such as bupivacaine 0.25% or lidocaine 1%. Furthermore, patients had to have failed previous treatment modalities, including physical therapy, muscle relaxants, steroid injections, and more. All these steps needed to be cleared to be selected for ablation.

Consent and IRB

The University of Wisconsin Institutional Review Board reviewed and exempted this study since it was a retrospective analysis utilizing UW-Health Electronic Medical Records (EMR).

Radiofrequency Procedure

Patients were sterilely prepped and draped in the usual fashion in the prone position. Patients undergo continuous monitoring of EKG, pulse oximetry, and blood pressure monitoring. Intravenous sedation was used on most patients unless they requested no sedation.

Fluoroscopic guidance was used to identify the anatomical location of the target medical branches. The skin was anesthetized using a local anesthetic, mostly lidocaine 1%. Then, a 100-mm, 17-gauge CRFA needle with a 10-mm action tip was placed at each target medial branch. After confirming the location of each needle, a CRFA probe was placed through each needle to perform testing and procedure.

Motor testing was done at each needle to confirm the lack of stimulation of close-by nerve roots, and then more local anesthetic was given through the needle before starting the CRFA procedure. Impedance was measured and ranged from 180 to 406 Ohms. A single radiofrequency lesion was performed at each level bilaterally at a temperature of 80 °C tissue temperature for 2 min and 30 s.

Follow-up

Following the procedure, patients returned for follow-up appointments to discuss outcomes, side effects, and evaluation via physical exam. Postoperative pain scores were collected via the visual analog scale at follow-up appointments.

RESULTS

A total of 1450 CRFA procedures were reviewed, and 206 were excluded due to absent pre- or post-op pain scores. An additional eight procedures were excluded due to weekly lidocaine infusions in between their procedure and reporting of their post-op score; 1026 CRFA patients were included in the analysis, comprising 584 females and 442 males with an average age of 59.81 ± 13.40 and a BMI of 31.67 ± 7.13 (Table 1).

Of the 197 totaling 214 procedures that were excluded due to absent pre- or post-op pain scores and lidocaine infusions, nine reported qualitative improvement in their pain. Still, they did not have a post-RFA VAS pain score or a postoperative percent improvement in their chart.

The average pre-procedure VAS pain score was 6.44 (6.44 ± 1.67, $n = 1236$), and the average post-procedure VAS pain score was 3.21 (3.21 ± 2.45, $n = 1236$) (Table 2). The difference between pre- and post-RFA was statistically significant with a $p < 0.0001$. Improvement of pain symptoms was reported in 85.92% ($n = 1062$), 14.08% ($n = 174$) reported complete pain remission, 7.61% ($n = 94$) reported no change, and 6.47% ($n = 80$) reported worsening symptoms. The mean percent improvement was 50.01 ± 36.41% for all procedures ($n = 1236$) for which a postoperative pain score was available. For effective procedures (those with any amount of pain relief, $n = 1062$) with an available postoperative

Table 1 Patients' demographics

Total # c-RFA (n)	1450
Total # patients (n)	1026
Sex (F/M)	584/442
Age (years), mean ± SD	59.81 ± 13.40
BMI (kg/m^2), mean ± SD	31.67 ± 7.13

BMI body mass index, *c-RFA* cooled radiofrequency ablation

Table 2 Changes in VAS pain scores and duration of improvement following procedure

Average VAS pain score pre-procedure ($n = 1236$)	6.44 ± 1.67
Average VAS pain score post-procedure ($n = 1236$)	3.21 ± 2.45
Average VAS % improvement ($n = 1236$)	50.01 ± 36.41
Average VAS % improvement in effective RFAs ($n = 1062$)	60.56 ± 27.21
Mean duration of improvement ($n = 1236$), days	267.43 ± 393.18

Table 3 Reported adverse events

Adverse event	Number
Worsened pain following procedure/soreness at the site of needles	26
Numbness	6
Hypotension	5
Skin rash	3
Procedure was painful	2

pain score, the mean percentage improvement was 60.56 ± 27.21%. The average duration of improvement was 267.43 ± 393.18 days (Table 2). A total of 157 patients were not included in this study due to a lack of improvement following CRFA. The difference in the procedure number and the patient number has to do with 304 patients having more than one procedure done, which explains why there is not a 1:1 ratio between patients and procedures.

Forty-two of the procedures reviewed reported adverse events following their procedure. The most common complaint was pain during the procedure or immediately afterward. As shown in Table 3, 26 procedures experienced worsening lower back pain or new pain in the groin or thigh area. Six reports of numbness or loss of sensation, usually around the lower back; five patients had hypotension, four of which were responsive to medications and fluids. One of the patients did not respond well to this treatment and was transported to the ER, where they were stabilized and released; two patients stated the procedure was painful or difficult to endure; three patients reported a skin rash around the incision site following the procedure. All reported side effects were self-limited, outside of the one instance mentioned above, and resolved independently without needing interventions.

DISCUSSION

Our study's outcomes demonstrate that CRFA, targeting the medial branches of the lumbar spine, significantly decreases pain in patients with chronic back pain refractory to other modalities for a significant period. The difference in pre- and post-op pain scores reached statistical significance ($p < 0.0001$), highlighting our results' magnitude.

With 1236 CRFA procedures included in our study, our results make a meaningful contribution to the existing literature on cooled radiofrequency ablation as a treatment for chronic low back pain. A systematic review of 23 RCTs with a sample size of 105 demonstrated efficacy in this location, similar to our results. They also showed a decrease of 60.5% in scores [16]. This is similar to our findings of a 60.56% reduction in lumbar back pain in patients with a successful CRFA ($n = 1062$). However, our study further elaborated upon the existing literature, as 14.08% ($n = 174$) of patients reported a complete remission of their pain. Our study includes the largest cohort ever published on the efficacy of RFA of lumbar medial branches for treating low back pain.

Adverse effects were reported in 42 cases of 1450 procedures. The most common complaint was pain during the procedure or immediately afterward. Pain after this kind of procedure can happen similar to any minimally invasive procedure, but we reported it as an adverse event to provide comprehensive outcomes related to the

procedure. For those who experienced adverse effects, all were self-limiting and resolved shortly after the procedure. Procedures, even those that are minimally invasive, like CRFA, have an inherent risk associated with them; however, as our results showed, this risk is minimal. Existing literature corroborates this claim. A retrospective analysis showed that the complications of radiofrequency denervation of the lumbar facets are associated with an overall 1.0% incidence of minor complications per lesion site [17].

Our reported adverse events were consistent with those found in previous studies of CRFA, demonstrating minimal harm associated with the procedure. For instance, a study on CRFA of the genicular nerve reported adverse events in 54 of 406 procedures, all of which resolved within 6 months [18]. Similarly, a study on CRFA of cervical nerves observed adverse events in 74 of 450 procedures, with all cases resolving spontaneously shortly after the procedure [19]. These findings, alongside ours, collectively highlight the minimal risk and harm associated with CRFA, reinforcing its safety as a minimally invasive treatment option.

Our study found that CRFA demonstrated efficacy similar to traditional thermal RFA in the literature. Recent studies on lumbar thermal RFA ($n=15$, $n=40$) showed an average VAS decrease between preoperative and postoperative of 3.1 and 2.12, respectively [20, 21]. These results align closely with our study, which observed an average VAS reduction of 3.21, further reinforcing the comparable effectiveness of CRFA and thermal RFA in pain management.

Some limitations of our study resulted from the difficulties inherent to retrospective analysis. The most notable are inconsistent patient follow-up dates or missing appointments after the CRFA procedure. As our study covered 2015–2024, our data clearly showed that many patients were lost to follow-up during the COVID-19 pandemic. Additionally, we hypothesize that many patients were reluctant to attend follow-up appointments if they had remission of their pain altogether. However, the many patients included in this analysis provide credible outcomes. Another limitation of this study is the lack of radiographic follow-up to monitor spinal stability. This study did not focus on spinal stability, but rather the efficacy of using CRFA, thus further studies should explore radiographic follow-up to monitor for spinal stability following CRFA.

Patients experiencing chronic pain can be medically complex, and subsequent procedures and pain relief sought for other conditions can complicate quantifying relief purely from CRFA and separating it from different modalities. However, we mitigated this by excluding patients who had other invasive procedures done at the same site, including lidocaine injections or surgery, as mentioned above. Similarly, to qualify for RFA, patients needed to have failed conservative management; thus, quantifying each patient's pain medication regimen became unnecessary. Additionally, all patients in this study received care from the same health system, allowing for accurate record-keeping and data retrieval.

We mitigated bias in our study by having a separate physician perform the procedure compared to the provider who saw the patient and recorded their post-op pain score at follow-up visits. Additionally, our data collection was conducted by students who do not work with any of the clinic staff, further eliminating bias in pain score outcomes and data analysis.

CONCLUSIONS

This study suggests the efficacy of CRFA as a minimally invasive treatment for chronic lower back pain secondary to lumbar facet arthropathy refractory to conventional treatment measures, demonstrating significant relief for a substantial time. Due to chronic pain's detrimental effect on one's quality of life, finding effective treatment options is essential, especially for those refractory to conventional treatments.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Alaa Abd-Elsayed is a consultant of Avanos and an Editor-in-Chief/Editorial Board member of Pain and Therapy Journal. Alaa Abd-Elsayed was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions. Trevor N. Johnson, Kylie K. Ruprecht, Tristan R. Argall, Lukas J. Henjum, and Kenneth J. Fiala have nothing to disclose. Kenneth J. Fiala, MD, is now currently in Anesthesiology residency at the University of Michigan following graduation from the University of Wisconsin School of Medicine and Public Health.

Ethical Approval. The University of Wisconsin Institutional Review Board reviewed and exempted this study since it was a retrospective analysis utilizing UW-Health Electronic Medical Records (EMR).

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