



Cooled-radiofrequency neurotomy for the treatment of chronic lumbar facet (zygapophyseal) joint pain

A retrospective study

Burcu Candan, MD^a, Semih Gungor, MD^{b,c,*}

Abstract

Cooled-radiofrequency (CRFA) is a newer technique and may have some theoretical advantages over traditional radiofrequency ablation (TRFA). In this study, we aimed to investigate the efficacy and safety of CRFA for the treatment of lumbar facet joint-mediated pain. In this retrospective study, we evaluated 185 CRFA performed on 105 patients. All patients with axial lower back who received the preliminary diagnosis of lumbar facet joint-mediated pain and refractory to conservative therapy underwent diagnostic medial branch blocks. CRFA was recommended to those patients who responded favorably to two sets of diagnostic medial branch blocks. Pain scores in numeric rating scale (NRS) were recorded pre-treatment and post-treatment at different time-points. The primary outcome measure was to report descriptive NRS score and average % improvement from baseline at each time point. A significant pain relief was determined by a decrease of ≥50% of mean NRS. Secondary outcome measure was the time to repeat treatment with subsequent CRFA. Adverse events were also recorded.

Primary outcome measure determined as the improvement in NRS, for at least 50% or more, was achieved in both 1st (4–8 weeks) and 2nd (>2–6 months) follow-up (FU) with 60.5% and 53.6% reduction in NRS respectively. Our subgroup analysis comparing the younger (<50) and older (\geq 50) age groups showed superior pain relief with CRFA in the older (\geq 50) age group, both in the 1st (4–8 weeks) and 2nd (>2–6 months) FU time points (63.4% and 58.4% reduction in NRS, respectively). Cooled-radiofrequency ablation is an effective and safe procedure for the treatment of chronic lumbar facet joint related pain. The duration of pain relief was comparable to traditional radiofrequency ablation as reported in the literature.

Abbreviations: CRFA = Cooled radiofrequency neurotomy, FU = Follow up, NRS = Numeric rating scale, RFA = Radiofrequency neurotomy, TRFA = Traditional radiofrequency neurotomy.

Keywords: ablation, cooled, denervation, facet, joint, neurotomy, pain, radiofrequency, treatment, zygapophyseal

1. Introduction

Facet joints are well known source of axial lower back pain, and the prevalence of facet joint pain varies from 20% to 44%. [1,2]

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The data that support the findings of this study are available from a third party, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are available from the authors upon reasonable request and with permission of the third party.

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The clinical diagnosis of facet joint mediated pain is challenging due to inadequate sensitivity and specificity of clinical and radiological test. [3] Therefore, medial branch blocks are used for diagnostic purposes in refractory cases, and may provide prognostic value before proceeding with radiofrequency ablation. [3,4] The diagnostic blocks and radiofrequency treatments are validated in the facet joint mediated lumbar spinal pain. [3]

Majority of the studies in the literature are based on the traditional radiofrequency ablation (TRFA) procedure which was proved to be a safe, effective, and leading pain therapy used to create sensory dysfunction in appropriate nerves via thermal energy.^[3] Water-cooled radiofrequency (CRFA) is a newer technique, and may have some theoretical advantages over traditional radiofrequency (TRFA). This technology, similar to TRFA, is also based on the heat neurotomy (60°C in CRFA versus 70–80°C in TRFA). Water circulation (at room temperature) through an isolated channel around the electrode tip creates a continuous "cooling" of the needle tip; consequently, the procedure typically results in a larger spherical-shape ablative area, with a diameter twice as long and extending distally from the tip of the electrode. [5] Thus, CRFA may theoretically increase the success of radiofrequency ablation of the target nerves due to coverage of wider ablative area.

Application of proper technique for TRFA is described by Spinal Intervention Society Guidelines. [6] However, application of TRFA technique may be technically limited by the presence of anatomical variations in certain patient populations such as in

^a Department of Anesthesiology, Critical Care and Pain Management, Hospital for Special Surgery, New York, New York, ^b Department of Anesthesiology, Critical Care and Pain Management, Hospital for Special Surgery, New York, New York, ^c Department of Anesthesiology, Weill Cornell Medicine, New York, New York.

^{*} Correspondence: Semih Gungor, Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021 (e-mail: gungors@hss.edu).

patients with scoliotic deformity, severe degenerative changes, facet arthropathy, and bone spurs. [7] The placement of electrodes parallel to medial branches as described in the TRFA technique may not be technically straightforward or possible secondary to distorted anatomy in such patients. The technique for CRFA does not necessarily require placement of electrodes parallel to medial branches as the ablative area extends distally from the tip of the electrode. [5] Therefore, the placement of the CRFA electrodes perpendicular to medial branches, similarly to the placement of needles for application of diagnostic medial branch blocks described in the literature, [1] would theoretically suffice to ablate the targeted medial branches. Therefore, CRFA could potentially reduce the overall radiation exposure since having easier access to the nerves enables the use of shorter fluoroscopy times to obtain optimal imaging to help with the needle placement. [7] In spite of these anticipated advantages of large ablative area with CRFA. there is also a low level of certainty that larger lesions increase the chance of capturing nerves and increase the duration of pain relief.[3]

There is limited literature support for the use of CRFA as a treatment option for facet joint mediated pain. Our retrospective study aims to investigate the efficacy, duration of pain relief and safety of CRFA in the treatment of lumbar facet joint-mediated pain.

2. Materials and methods

This study was conducted at a single urban, academic pain medicine center specializing in the treatment of musculoskeletal disorders. This retrospective cohort study was approved by the Institutional Review Board (IRB#2018-0461). The requirement for written consent was waived by the IRB. Data was collected by retrospective chart review.

2.1. Participants

We analyzed 185 consecutive CRFA procedures performed for lumbar zygapophyseal neurotomy on 105 patients in our institution from January 2012 to April 2018. These 105 patients who underwent the procedure at different levels on separate occasions were treated as separate individuals in the results.

We performed CRFA procedure in eligible patients with diagnosis of lumbar facet joint pain refractory to conservative therapy for at least 6 months. Written informed consent was obtained from each patient for use of CRFA procedure. We recorded the pain levels in Numeric Rating Scale (NRS) at various time points and duration for requirement of repeat radio-frequency denervation procedure at the same level. The adverse events were also recorded.

Pre-treatment and post-treatment NRS were recorded at the following time points: Pre- procedure, at 4 to 8 weeks (early), >2 to 6 months (intermediate-term), and >6 to 12 months (long-term) time-points. Follow-up period was at least for 12 months for each patient.

Subgroup analysis was performed based on the age \leq 50 versus >50 years old.

2.2. Patient selection

All patients with history of non-radicular lower back pain refractory to conservative therapy for at least a duration of 6 months and fulfilling the inclusion criteria outlined below, were

recommended diagnostic medial branch blocks. Conservative therapy included activity modification, home exercise program, medication management and physical therapy. Those patients who consented for this therapy underwent dual diagnostic medial branch blocks. Those patients who responded to dual diagnostic medial blocks favorably (≥80% temporary pain relief), and consented for the procedure, CRFA procedure was performed. All patients who underwent CRFA with documented follow-up in all predetermined time-points were included in this study (Fig. 1).

2.2.1. Inclusion criteria.

- 1. Age between 18 and 85 years.
- 2. ≥6-month history of nonspecific lumbar pain.
- Refractory to conservative treatment including activity modification, home exercises, physical therapy, medication management.
- 4. Pretreatment pain levels of ≥ 5 in NRS.
- 5. Preliminary clinical diagnosis of lumbar facet-related pain is made by the following criteria:

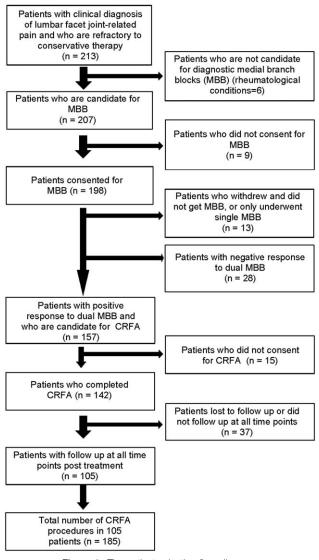


Figure 1. The patient selection flow diagram.

- a. Nonspecific lower back pain.
- Absence of neurologic symptoms related to lumbar radiculopathy.
- c. As indicated; x-rays, computed tomography, or magnetic resonance imaging studies were performed to exclude the possibility of pathology that was amenable to primary therapy.
- d. Some of the examination findings suggestive, but not absolute requirement, for diagnosis of lumbar facet joint mediated pain such as: Reproduction of pain with palpation of the corresponding facet joints and extension maneuver of the lumbar spine.
- 6. The patients fulfilling the inclusion criteria outlined above were recommended diagnostic medial branch blocks.
- 7. The area of pain was marked on the skin prior to medial branch blocks, and the actual spinal levels of medial branch blocks were determined under fluoroscopic counting of the corresponding levels. In each patient, diagnostic local anesthetic blocks of the either 3 or 4 medial branches, corresponding to 2 or 3 facet joint levels respectively, were performed.
- 8. ≥80% temporary pain relief after dual diagnostic lumbar medial branch blocks with 0.5 mL of lidocaine 2% followed by 0.5 mL of bupivacaine 0.5% on 2 different sessions, were recommended CRFA procedure.

2.2.2. Exclusion criteria.

- Disc herniation, stenosis, myelopathy, lumbar fracture, and suspected radiculitis
- 2. Previous history of spinal surgery at the level of intervention
- 3. Systemic or local infection
- 4. Coagulation disorder
- 5. Allergy to iodinated contrast
- 6. Rheumatic disorders
- 7. Malignancy
- 8. Pregnancy
- 9. An uncontrolled medical or psychiatric condition
- **2.2.3.** Statistics. The primary outcome measure was to report descriptive NRS score and average % improvement from baseline at each time point. A significant pain relief was determined by a decrease of $\geq 50\%$ of mean NRS scores. Pain relief was also categorized as early relief at 4 to 8 weeks, intermediate-term relief at >2 to 6 months, and long-term relief >6 to 12 months post-procedure. Secondary outcome measure was the time to repeat treatment with subsequent CRFA, thereby to measure the duration of the treatment.

2.3. Medial branch blocks and CRFA procedure

All patients underwent the procedure awake without any sedation. Patients were positioned prone with a C-arm

fluoroscopy. The appropriate level of the spine is determined by anteroposterior view. Final needle entry points were determined in the in 25 degrees ipsilateral oblique and 10 degrees caudal tilt view. After local anesthetic is given for entry points, 22-gauge spinal needles were placed in the appropriate location described as lumbar medial branch blocks in Spinal Intervention Society Guidelines. [1] In those patients with positive response to dual local anesthetic blocks, CRFA procedure was performed. 17-gauge 4mm active tipped CRFA electrodes were used for the procedure. Appropriate length of needle was selected depending on the patients' body habitus (75 mm or 100 mm or 150 mm). The CRFA electrodes were also placed in the appropriate location similar to described as lumbar medial branch blocks procedure, [1] instead of traditional placement of electrodes described as in Spinal Intervention Society Guidelines. [6] After appropriate testing for sensory and motor components, 2 mL of Lidocaine 1% was injected through each needle prior to the CRFA procedure. Radiofrequency ablation (RFA) was carried out at 70°C for 150 seconds for each level (Halyard Health Cooled Radiofrequency [RF] System, Roswell, GA). No further medication was given at the procedure site postprocedure. All of the procedures were done by the same fellowship-trained and board-certified interventional pain specialist with 20 years of experience (SG).

3. Results

Descriptive statistics of the baseline demographic and procedural characteristics are shown in Table 1.

The data were obtained from the pre-procedural and post-procedural follow-up visits of total 185 lumbar CRFA procedures. The data obtained are summarized in Table 2. The mean NRS scores were recorded. We also performed subgroup analysis of the data based on the age in years \leq 50 versus >50.

A total of 185 CRFA procedures were performed in 105 patients (Age range 22–86 years old, with mean age of 54.03). Of these 185 CRFA procedures, 60% patients were female (with a mean age of 54.01) and 40% were male (with a mean age of 54.06). Average NRS at baseline was 7.6 for all age groups. Improvement of pain was 60.5% (mean NRS: 3.0) in the 1st follow-up (FU) (4–8 weeks). In the 2nd FU (>2–6 months), there was 53.6% improvement of the pain scores (mean NRS: 3.5). In the 3rd FU (>6–12 months), improvement of the pain scores was 29.1% (mean NRS: 5.2) (Table 3).

Primary outcome measure determined as the adequate reduction of pain scores (50% or more) was achieved in both 1st FU (4–8 weeks) and the 2nd FU (>2–6 months) with 60.5% and 53.6% reduction in NRS pain scores respectively.

For the third follow-up (>6–12 months), there was a partial recurrence of pain with a residual reduction of the NRS 29.1% less than the baseline. During this period, 18 patients required repeat radiofrequency neurotomy procedure.

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Descriptive statistics of the baseline demographic and procedural characteristics.

	Mean age	Counts of procedure	Percentage of procedure	Unilateral	vs bilateral _l	orocedure	Pain duration	Percentage of procedure
Female	54.01	111	60%	Unilateral	167	(90.3%)	6m-2y	23.2
Male All	54.06 54.03	74 185	40%	Bilateral	18	(9.7%)	>2y	76.8
All	34.03	100						

Table 2

The counts and percentages of patients at	the different follow-ups (pre-treatment NRS)). FU-1 NRS1. FU-2 NRS2. FU-3 NRS3).

Age	NRS0	NRS1	NRS2	NRS3
≤ 50	66	64	45	28
>50y	119	116	87	55
TOTAL #	185	180	132	83
Percentage of patients (%)	100	97.2	71.3	44.8

Table 3

Changes in mean NRS and pain relief (%) in all patients at followups.

	Mean NRS	Pain relief (%)
Pre-treatment	7.6	
FU #1 (4-8 wks)	3.0	60.5
FU #2 (>2-6 m)	3.5	53.6
FU #3 (>6-12 m)	5.2	29.1

Secondary outcome measure was the time to repeat treatment with subsequent CRFA, thereby to measure the duration of the treatment. There were totally 37 repeated CRFA in 185 procedures. There were no complications reported in 185 procedures. Among our results;

- The most frequent requirement for repeated CRFA procedure period was between >6 to 12 months in all age groups with a total number of 18 repeated CRFA procedures.
- Shortest pain relief requiring repeated CRFA was 24 weeks and the longest pain relief requiring repeated CRFA was 228 weeks.

When we performed subgroup analysis of the data based on the age and pain score of the patient in different age categories (age in years \leq 50 versus >50), the following were our findings:

- a. Average baseline (pre-procedure) pain was similar for both age groups (NRS0: 7.6).
- b. Pain relief was superior in >50 age group in the 1st FU (4-8 weeks) and 2nd FU (>2-6 months), with 63.4% (NRS1: 2.8) and 58.4% (NRS2: 3.1) reduction in pain. However, the

- recurrence of pain was similar and moderate for both groups in the 3rd FU (>6–12 months) (Fig. 2 and Fig. 3).
- c. There were total of 37 repeated procedures in both groups (37/185, 20%) (Table 4). 12/37 (32.4%) were in the ≤50 group and 25/37 (67.5%) were in the >50 group. In the ≤50 group, 10/12 repeated procedures were performed in the first 12 months. In the >50 group 13/25 repeated procedures were performed in the first 12 months.
- d. Average baseline (pre-procedure) pain was similar for both age groups (NRS0: 7.6)
- e. Only 5 patients needed repeated CRFA between 6 and 7 months. Most frequent requirement for repeated CRFA procedure period was between 7 and 12 months in both groups with total of 18 repeated CRFA procedures performed.
- f. Shortest pain relief requiring repeated CRFA was 6 months for both age groups, and the longest pain relief requiring repeated CRFA was 57 months for ≤50 age group and 52 months for >50 age group. The number of repeated CRFA, during the 12 to 24 months' period was 7, and during the 24 to 36 months' period was 5 in both age groups.
- g. When all time periods were evaluated, repeated procedures were more frequently required in >50 age group.

When subgroup analyses were performed depending on the age cut-off (age in years \leq 50 versus >50), and percentage of patients available for follow ups, the following were our findings:

a. Table 2 shows the number and percentages of patients during the different follow-up time points. The number of patients presented for follow up were 97.2%, 71.3%, and 44.8% for 1st, 2nd, and 3rd FU respectively.

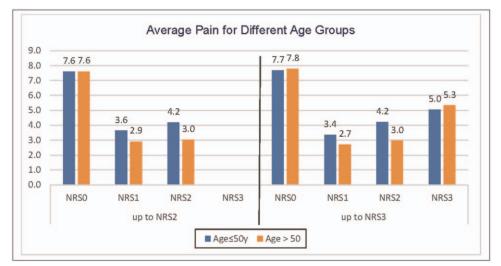


Figure 2. The average pain (NRS) at baseline and post-procedural follow-ups according to age groups.

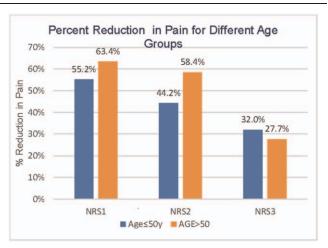


Figure 3. The percentage of pain reduction at post-procedural follow-ups according to age of the patients.

Table 4 Requirement for repeated CRFA procedure.

	All	≤ 50 y	> 50 y
<6 m	5	1	4
>6 m to 1 y	18	9	9
>1 y to 2 y	7	1	6
>2 y	7	1	6
Total	37	12 (32.4%)	25 (67.5%)

- b. Figure 4 shows the average pain of the 71.3% patients that presented in all NRS0, NRS1, and NRS2 (on the left) and the average pain of the 39.4% patients that presented in all NRS0, NRS1, NRS2, and NRS3 (on the right).
- c. According to our results, average pain in follow-ups (up to NRS2 vs up to NRS3) did not show any significant difference in NRS0 (pre-treatment NRS), NRS1, and NRS2 (Table 4);

- (1) Primary outcome (the adequate reduction of pain scores (≥50%) was achieved in both first and second follow-up periods with 60.5% and 53.6% reduction in NRS pain scores, respectively.
- (2) There was a partial recurrence of pain with the improvement in pain levels 29.1% when compared to baseline NRS in the third follow-up (>6–12 months). NRS3 graph possibly includes patients with recurrence of pain and thus presented for follow up at the NRS3 time point. There was no significant difference in pain levels between two different age groups during NRS3 (5 versus 5.3).

4. Discussion

Traditional heat RF (TRFA) is commonly used for the treatment of lumbar facet joint-related pain. According to recently published "Facet Joint Interventions Guidelines"; the recommendation for lumbar diagnostic facet joint nerve blocks is moderate to strong with the level of evidence is I to II, and the recommendation for therapeutic lumbar radiofrequency ablation is moderate with the level of evidence is II. [8] There are theoretical advantages of CRFA as compared to TRFA. The major difference between the TRFA and CRFA is the size of the lesion created by the released thermal energy. [5] Water-cooled RF (CRFA) is not well studied in the treatment of lumbar facet joint-mediated pain. There is one randomized controlled trial comparing TRFA versus CRFA that did not show any significant difference in terms of efficacy and duration of the pain relief. [9]

We retrospectively evaluated the efficacy and potential complications of CRFA for the treatment of chronic lumbar facet joint-mediated pain.

4.1. Studies reported that radiofrequency facet joint denervation appears not to be more effective than sham treatment

van Wijk et al designed a multicenter, randomized, double-blind, sham treatment-controlled trial to determine the efficacy of

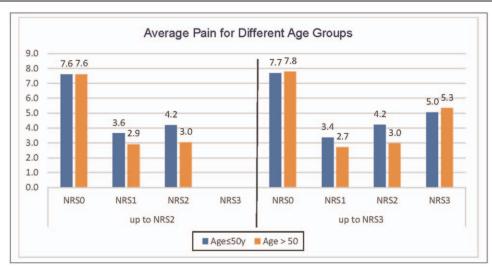


Figure 4. The average pain (NRS) at baseline and post-procedural follow-ups. Graphic (left) shows the average difference in the NRS for all the patients who were available at NRS0, NRS1 and NRS2. Graphic (right) shows the average difference in the NRS for all the patients who were available in all NRS0, NRS1, NRS2, and NRS3

radiofrequency facet joint denervation. Totally 81 patients were randomized to undergo radiofrequency facet joint denervation or sham treatment. At the third month follow-up, the combined outcome measure and VAS showed no difference between radiofrequency and sham. In both groups, significant VAS improvement occurred. [10]

4.2. Studies reported that radiofrequency facet denervation treatment for chronic low back pain can be used in carefully selected patients

In carefully selected patients with strict application of diagnostic medial branch blocks, RFA technique resulted in greater success both in pain and physical function for at least 6 to 24 months. [4,11] Nath et al demonstrated that radiofrequency facet denervation is not a placebo and could be successfully used in the treatment of carefully selected patients with chronic low back pain. [12] Similarly, van Kleef et al reported that radiofrequency lumbar zygapophysial joint denervation results in a significant alleviation of pain and functional disability in a select group of patients with chronic low back pain, both on a short-term and a long-term basis. [13] Dreyfuss et al reported that lumbar medial branch neurotomy is an effective means of reducing pain in patients carefully selected on the basis of controlled diagnostic blocks. [14] Dreyfuss applied lumbar facet RFA to 15 patients with chronic low back pain whose pain was relieved by controlled, diagnostic medial branch blocks of the lumbar zygapophysial joints. Some 60% of the patients obtained at least 90% relief of pain at 12 months, and 87% obtained at least 60% relief.

In our study, total of 185 CRFA procedures were performed in 105 patients (with average pretreatment NRS=7.6) and evaluated their short and long-term pain outcomes (NRS). Our patients were carefully selected after ≥80% temporary pain relief with dual diagnostic lumbar medial branch blocks after which CRFA procedure was recommended. Our primary outcome (adequate reduction of pain scores 50% or more) was achieved in both first and second follow-up time points with 60.5% and 53.6% reduction in NRS pain scores respectively. For the third follow-up (7–12 months), there was a partial recurrence of pain with the improvement in pain levels 29.1% when compared to baseline NRS. Our results were similar to the other studies in the literature with the superior pain relief achieved within the first 6 months.

Among these 185 CRFA procedures, there were 37 repeated CRFA procedures (37/185, 20%). The most frequently repeated CRFA procedure was between 6 and 12 months' period with a total of 18 repeated CRFA procedures due to recurrence of pain.

Our results were similar other studies that demonstrated positive results above. Therefore, we can suggest that CRFA provides effective for pain relief for at least 6-months duration in carefully selected patients.

4.3. Studies comparing water-cooled radiofrequency vs traditional heat radiofrequency

There is only one randomized prospective comparative study comparing the TRFA versus CRFA in the lumbar spine. In this study, McCormick et al targeted to evaluate 6-month outcomes of pain and improvement of physical function in 43 low back pain patients who underwent randomized trial of TRFA versus CRFA.^[9] The primary outcome was the proportion of

"responders" (>50% NRS reduction) at 6-months. Therefore, the aim of the study was to determine whether the results of CRFA or TRFA were superior in treatment outcomes for individuals with lumbar facet joint pain. According to outcomes of this study, no significant differences were observed between the two RFA modalities. A greater proportion of participants reported a clinically significant improvement in physical function at 6-month follow-up in the CRFA group, but this difference was not statistically significant. When comparing procedure time for two RFA modalities, it was shorter in the CRFA group, but similarly, this difference also was not statistically significant. In this study, McCormick et al reported that with using a single diagnostic block with a threshold of >75% pain reduction, CRFA resulted in a treatment success rate >50% when defined by pain reduction, and greater that 60% when defined by improvement in physical function, at 6-month follow-up. The authors did not report any serious adverse events in both RFA treatment group. This study was the first trial that compared the clinical outcomes for the two RFA modalities for the treatment of lumbar facet joint-mediated pain. This study had the limitations of including relatively low number of patients and short followup of outcome for only 6 months.

In our study, our results also demonstrated better pain relief in first 6 months when compared to long-term period.

In addition, according to our results, we performed subgroup analysis of the data based on the patients' age (age in years \leq 50 versus >50). In the pretreatment period, average pain was same for all ages (NRS0:7.6). For the short-term period, pain relief was better in >50 age group. The percent reduction for this age group was 63.4% (NRS1: 2.8) and 58.4% (NRS2: 3.1) in the 1st and 2nd follow-up (FU), respectively. However, the recurrence of pain was similar and moderate for both groups in the 3rd FU, >50 age group's pain recurrence was faster than the younger group. \leq 50 0 age group had slower but more steady reduction in NRS scores sustained into 3rd FU period with further pain relief. This group (\leq 50) had the better pain relief in the 3rd FU period with the 32.0% (NRS3:5.0) comparing 27.7% (NRS3:5.3) pain relief in >50 group. Our subgroup analysis demonstrated that the pain relief and pain recurrence were similar in all age groups.

In a recent systematic review and meta-analysis conducted by Shie et al comparing the efficacy of different radiofrequency techniques for treating lumbar facet joint, cooled radiofrequency was found to be more effective than thermal radiofrequency at 6 months. This was different than our findings it that there was no significant difference found in our study at 6 months between these two radiofrequency techniques. No serious complications were reported after receiving all types of radiofrequency techniques similar to our findings. [15]

Limitations of this study were: This was a single center study. This study was designed as a retrospective and data-based research with the aim of investigating the efficacy and safety of CRFA of medial branches. Data were affected by patients lost to follow up.

5. Conclusion

Our results suggest that CRFA is a safe and effective treatment modality to achieve targeted pain relief in all age groups lasting at least 6 months for the treatment of lumbar facet-mediated pain. The duration of pain relief with CRFA was comparable to, but not significantly longer than, the duration of pain relief achieved with TRFA as reported in the literature for the treatment of chronic lumbar facet joint related pain.

Author contributions

Conceptualization: Semih Gungor.

Data curation: Burcu Candan, Semih Gungor. Formal analysis: Burcu Candan, Semih Gungor. Investigation: Burcu Candan, Semih Gungor.

Methodology: Semih Gungor.

Project administration: Semih Gungor.

Resources: Semih Gungor.

Software: Burcu Candan, Semih Gungor.

Supervision: Semih Gungor.

Validation: Burcu Candan, Semih Gungor. Visualization: Burcu Candan, Semih Gungor.

Writing – original draft: Burcu Candan, Semih Gungor. Writing – review & editing: Burcu Candan, Semih Gungor.

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