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The efficacy and safety of cooled-radiofrequency neurotomy in the treatment of chronic thoracic facet (zygapophyseal) joint pain

A retrospective study

Semih Gungor, MD[a,b,*], Burcu Candan, MD[c]

Abstract

Anatomic course of medial branches in the thoracic spine is significantly different. Cooled RFA (CRFA) is a newer technique that can create a larger spherical lesion with a potential to compensate for the anatomic variability of the medial branches in the thoracic spine. Our retrospective study aimed to investigate the efficacy and the adverse effects of the CRFA in the treatment of thoracic facet-related pain.

For this retrospective study, we evaluated 40 CRFA performed on 23 patients. The patients with diagnosis of thoracic facet joint-related pain underwent CRFA. Pain scores in numeric rating scale (NRS) were recorded at pretreatment and posttreatment 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.

Improvement of average pain level was 20.72% in the 1st follow-up (FU) (4–8 weeks), 53% in the 2nd FU (2–6 months), and 37.58% in the 3rd FU (6–12 months). Subgroup analysis was done based on age cutoff (age in years ≤ 50 versus >50), and pretreatment NRS (≤7 versus >7). Patients with age ≤50 and NRS score >7 experienced the best pain relief in the 2nd FU period (2–6 months). The patients with age > 50 and NRS pain level ≤7 showed steadily increased benefit both in the 2nd FU (2–6 months) and 3rd FU (6–12 months).

This is the first clinical study to evaluate the efficacy and adverse effects of CRFA in the thoracic spine for facet joint-related pain. Our results suggest that CRFA procedure is an effective treatment modality for thoracic facet-related pain. Our subgroup analysis demonstrated that the pain relief and duration varies with the age and the pretreatment pain levels.

Abbreviations: BMI = body mass index, CRFA = cooled radiofrequency neurotomy, FU = follow-up, NRS = numeric rating scale, RFA = radiofrequency neurotomy, TRFA = traditional heat radiofrequency neurotomy.

Keywords: cooled, facet, neurotomy, radiofrequency, spine, thoracic, zygapophyseal

1. Introduction

Chronic back pain is a significant cause of disability with increasing prevalence and with significant economic impact.[1,2] The etiology of back pain can be complex. Thus, its successful treatment is often highly challenging.

Thoracic spine-related pain is less frequently reported as compared with cervical and lumbosacral spine-related pain.[3] Thoracic facet (zygapophyseal) joints have been reported to be the primary source of pain in 48% cases.[4]

There is evidence that radiofrequency neurotomy (RFA) of medial branches provides symptomatic relief for chronic pain originating from facet joints in the cervical and lumbar spine.[5,6] However, there is very limited evidence for use of RFA in the thoracic spine.[7]

Traditional heat RF (TRFA) is commonly used for the treatment of cervical and lumbar facet joint-related pain. However, TRFA may have several limitations on thoracic facet joint-related pain: The anatomy of thoracic zygapophyseal joint and its innervation variability when compared with the lumbar region makes it difficult to benefit from TRFA.[8] Anatomically, the location and number of medial branches are significantly different than those of the lumbar spine.[9] The medial branches of the thoracic spine are more than 1 nerve per level, and are dispersed mainly in the superior and lateral aspect of the transverse processes. The relatively smaller sized lesions created by the TRFA usually necessitate multiple lesions to ablate all of the medial branches per vertebral level. Use of TRFA with

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multiple lesions increases the duration and the risk of the procedure while successful denervation of all medial branches may not be possible.[8] Therefore, a relatively newer radiofrequency system was developed known as water-cooled technology (CRFA). 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.[10] The larger spherical-shape lesion created by the CRFA may have a potential to compensate for the anatomic variability of the medial branches in the thoracic spine.[10] Therefore, CRFA may be advantageous in the treatment of thoracic facet joint-related pain.[11]

Zygapophyseal (facet) joint-originated thoracic spinal pain, and the potential use of RFA as a treatment option are not well studied. Thus, more conclusive evidence for efficacy of RFA in the thoracic spine is needed. Our retrospective study aims to investigate the efficacy and potential complications of the CRFA procedure in thoracic facet joint-mediated pain. To our knowledge, there is no published clinical study related to use of CRFA, specifically for the thoracic spine.

2. Material 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.

We retrospectively analyzed 40 consecutive percutaneous radiofrequency thoracic zygapophyseal neurotomy performed on 23 patients in our institution from January 2012 to April 2018. Seventeen patients who underwent the procedure at different levels on separate occasions were treated as separate individuals in the results.

We performed CRFA therapy in eligible patients with diagnosis of thoracic facet joint pain refractory to conservative therapy, after written informed consent was obtained from each patient. We evaluated the pain levels in Numeric Rating Scale (NRS), duration for requirement of repeat radiofrequency denervation at the same levels and adverse effects from the procedure.

Pretreatment and posttreatment NRS were recorded prior to 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.

2.1. Patient selection

All patients, who were complaining of upper or mid back pain refractory to conservative therapy for at least 6-months' duration fulfilling the inclusion criteria outlined below, were recommended diagnostic medial branch blocks. Those patients who consented for this therapy underwent dual diagnostic medial branch blocks. In eligible patients who responded to 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).

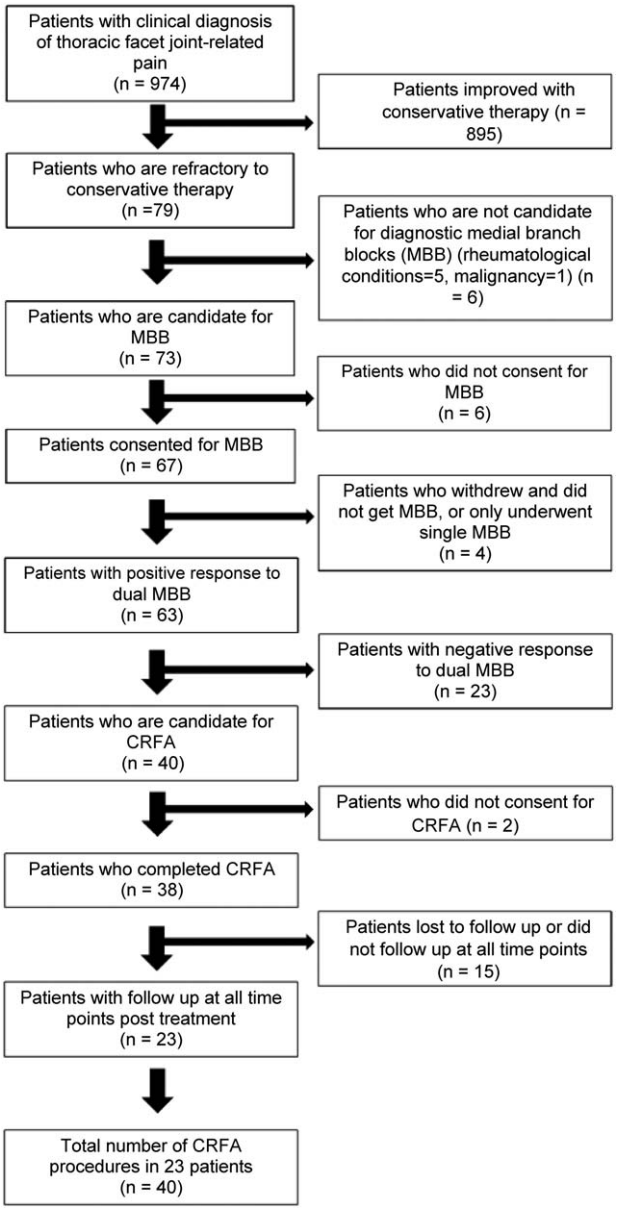

Figure 1. The patient selection flow diagram.

2.1.1. Inclusion criteria.

1. Age between 18 and 85 years.
2. ≥6-month history of nonspecific upper or mid-back pain.
3. 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 thoracic facet-related pain is made by the following criteria:
   a. Nonspecific upper or mid back pain-related thoracic spine.
   b. Absence of neurologic symptoms-related thoracic 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 thoracic facet joint-mediated pain such as: Reproduction of pain with palpation of the corresponding facet joints and extension maneuver of the thoracic 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 thoracic medial branch blocks with 0.5 mL of 2% lidocaine followed by 0.5% bupivacaine on 2 different sessions, were recommended CRFA procedure.

2.1.2. Exclusion criteria.

1. Disc herniation, stenosis, myelopathy, thoracic fracture, and suspected radiculitis or intercostal neuritis
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.

2.1.3. 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 ≥ 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 postprocedure. Secondary outcome measure was the time to repeat treatment with subsequent CRFA, thereby to measure the duration of the treatment. Adverse events were also recorded.

2.2. Medial branch blocks and CRFA procedure

All patients underwent the procedure awake without any sedation. Patients were positioned prone with a C-arm fluoroscopy with an anteroposterior view of the appropriate level of the spine. After local anesthetic is given for entry points, 22-gauge spinal needles were placed in the appropriate location described as thoracic medial branch blocks in Spinal Intervention Society Guidelines.[11] In those patients with positive response to dual local anesthetic blocks, CRFA procedure was performed. 17-gauge 75 mm 5.5 mm active tipped CRFA electrodes were placed in the appropriate location similar to described as thoracic medial branch blocks in Spinal Intervention Society Guidelines.[11] After appropriate testing for sensory and motor components, 1 mL of Lidocaine 1% was injected through each needle prior to the CRFA procedure. Radiofrequency denervation was carried out at 60°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.

A total of 40 CRFA procedures were performed in 23 patients (range 28–64 years old with mean age of 47.3). Of these 23 patients, 13 patients were female (with mean age of 49.7) and 10 were male (with mean age of 44.1). Average NRS at baseline was 7.4. Improvement of pain was 20.72% (NRS: 5.8) in the 1st follow-up (FU) (4–8 weeks). In the 2nd FU (2–6 months), there was 53% improvement of the pain scores (NRS: 3.4). In the 3rd FU (6–12 months duration), improvement of the pain scores was 37.58% (NRS: 4.6).

Pain reduction was 20.72% during the early period (4–8 weeks).

Primary outcome measure determined as the adequate reduction of pain scores (50% or more) was achieved only during the intermediate-term relief period (2–6 months) with 53.04% reduction in NRS pain scores. None of the patients required repeat radiofrequency neurotomy procedure during this period.

There was partial recurrence of pain starting after 6 months post-procedure; however, improvement in pain levels was still moderate (37.58% improvement from baseline).

Secondary outcome measure was: time to repeat treatment with subsequent CRFA, thereby to measure the duration of the treatment. Only 10% (4/40) of the patients required repeat radiofrequency procedure at 6–12 months period. Twenty-five percent (10/40) of the patients required repeat radiofrequency procedure 12 to 24 months period. Sixty-five percent (26/40) of

Table 1

Descriptive statistics of the baseline demographic and procedural characteristics.

Demographic information		Changes in NRS and (% relief)		Unilateral vs. bilateral procedure		Requirement for repeat CRFA procedure	
Female/male	56.5%/43.5%	Mean (NRS) (pretreatment)	7.4	Unilateral	34 (85%)	< 6 mo	0 (0%)
Patient count (n)	23	Follow-up #1 (4–8 wk)	5.8 (20.72%)	Bilateral	6 (15%)	6 mo–1 y	4 (10%)
Operation count (n)	40	Follow-up #2 (2–6 mo)	3.4 (53.04%)			1–2 y	10 (25%)
Mean age (y)	47.3	Follow-up #3 (6–12 mo)	4.6 (37.58%)			>2 y	26 (65%)
Mean age (female)	49.7						
Mean age (male)	44.1						

CRFA = cooled radiofrequency neurotomy, n = number, NRS = numeric rating scale.

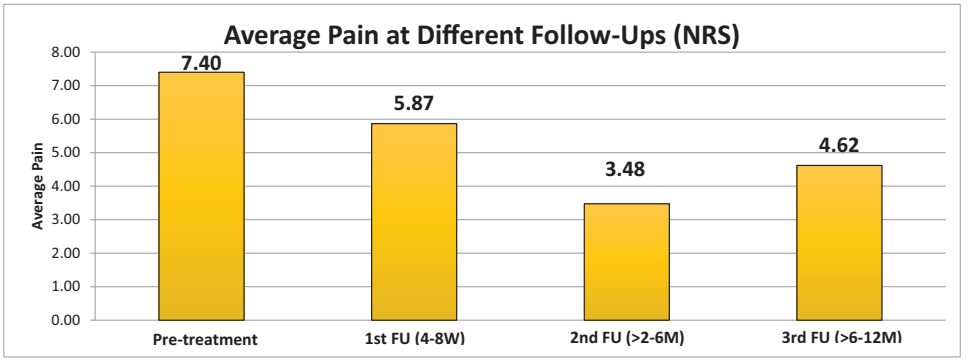

Figure 2. Comparison of average pain rating at different follow-ups.

the patients required repeat radiofrequency procedure 24 to 36 months period. Shortest pain relief requiring repeat radiofrequency procedure was 30 weeks and the longest pain relief requiring repeat radiofrequency procedure was 112 weeks (Figs. 2 and 3).

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

1. Pain relief was faster and better in $\leq$ 50 age group in the 1st (4–8 weeks) and 2nd (2–6 months) follow-up (FU), but the recurrence was also faster in the 3rd FU (6–12 months) as compared with >50 age group.
2. >50 age group had slower but more steady reduction in NRS scores sustained into 3rd FU period with further pain relief. This group (>50) had the best pain relief in the 3rd FU period, and did not require any repeat RF procedure before 12 months.
3. All of the repeat procedures (4/40) were in the $\leq$ 50 group in the 3rd FU (6–12 months) period.

Further subgroup analysis was performed including both the age cutoff (age in years $\leq$ 50 versus >50) as well as baseline NRS scores ($\leq$7 versus >7). The following were our findings:

1. Those patients with age $\leq$50 and NRS score>7 experienced the best pain relief in the 2nd FU period (2–6 months), and still continued to have moderate (37.58% improvement from baseline) benefit from the procedure in the 3rd FU period (6–12 months).
2. Although the patients with age > 50 and NRS pain level $\leq$7 showed the least benefit in the first follow-up (4–8 weeks), they showed a steadily increased benefit both in the 2nd FU (2–6 months) and 3rd FU (6–12 months), showing the most benefit in the 3rd FU (6–12 months).
3. Based on this data we can conclude that those patients with younger age and more severe pain scores (age $\leq$50 and NRS >7) would benefit from procedure best at the intermediate-term (2–6 month) period. Elderly patients with less severe pain scores (age > 50 and NRS pain level $\leq$7) will have a sustained pain relief lasting at least up to 12 months and better pain relief in the long-term (6–12 month) period (Figs. 4 and 5).

Adverse events were also recorded. There was a single case with a complication. This patient developed a 3rd degree skin burn area at 1 level (1/40, 2.5%). Otherwise, there were no other adverse events.

Lower thoracic levels T10, T11, and T12 levels were the most frequently applied levels, each with at least 10 procedures. The percentage of bilateral medial branch radiofrequency procedures was 15% (6 procedures). The remainder of the procedures were unilateral (Fig. 6).

4. Discussion

To our knowledge, this is the first clinical study to evaluate the efficacy and adverse effects of CRFA for the treatment of facet joint-related pain in the thoracic spine.

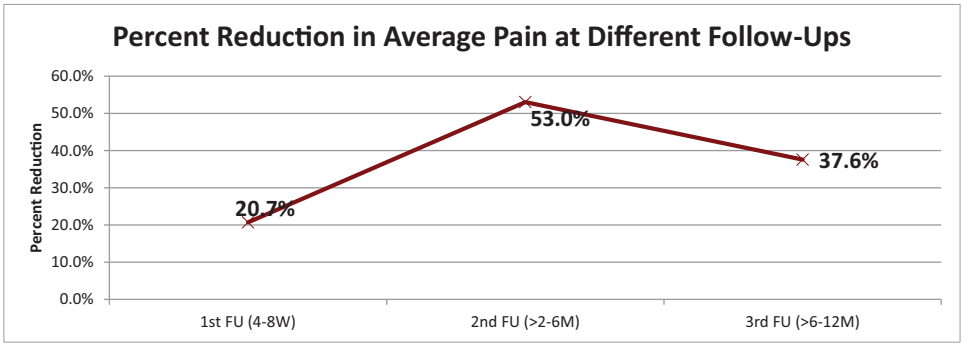

Figure 3. Percent reduction of average pain at different follow-ups.

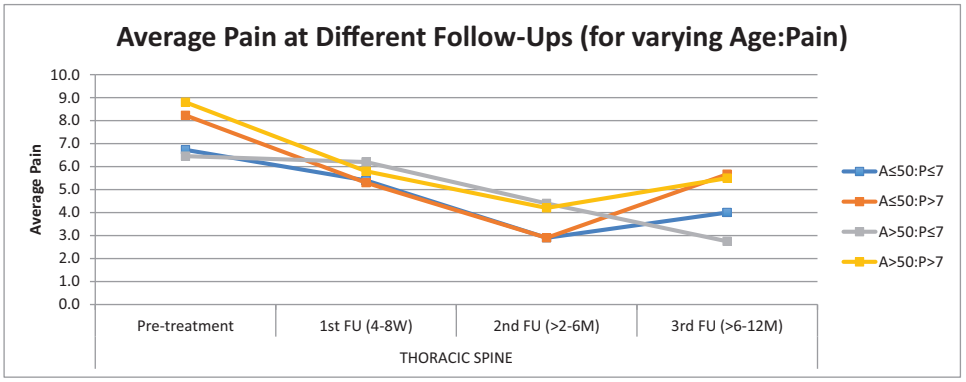

Figure 4. Average pain intensity at different follow-ups (for varying age: pain).

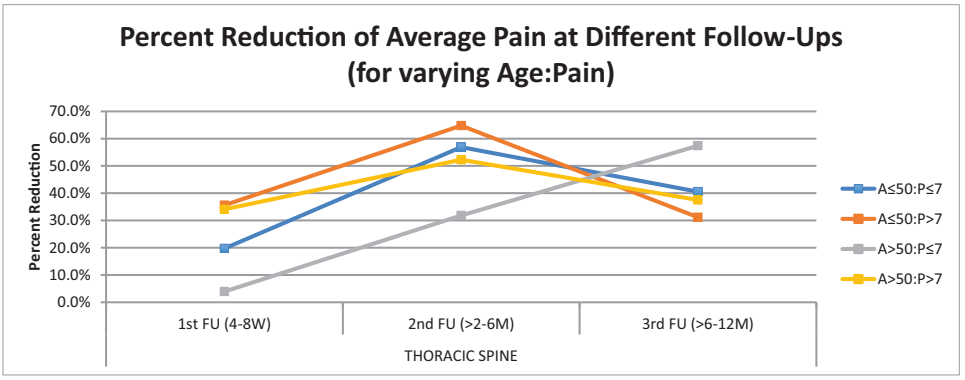

Figure 5. Percent reduction of average pain at different follow-ups (for varying age: pain).

There was one randomized prospective comparative study investigating the effectiveness of TRFA versus CRFA in ablation of the medial branch nerves for the treatment of facet joint pain in the lumbar spine.[12] In this study, investigators were not able to demonstrate any meaningful difference in treatment outcomes between CRFA as compared with TRFA.

In our study, for all CRFA procedures performed (n = 40), pain reduction was the least in the 1st FU (4–8 weeks), only demonstrating a brief pain reduction of 20.72% in this early period. This may be attributable to more intense perineural inflammatory reaction in the surrounding tissues secondary to the larger size heat lesion created by the CRFA,[10] which in turn, may lead to a longer duration of recovery from the intense inflammatory reaction created in the surrounding tissues. Thus, this may be one of the mechanisms by which the expected pain relief in 4–8 weeks postprocedure was less than expected after the CRFA as compared with our experience with TRFA in cervical and lumbar spine.

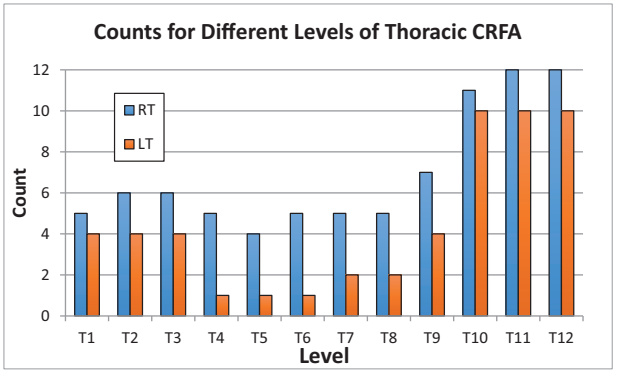

Figure 6. Number procedures at different thoracic levels.

In our study, recurrence rate of pain was faster in the younger group with more severe pain (age ≤50 and NRS score >7). Yet, this younger group with severe pain still reported moderate pain relief in the 3rd FU period (37.58% improvement from baseline), only 10% of the patients (4/40) requiring repeat CRFA in this period.

There is evidence that TRFA of medial branches provide symptomatic relief for chronic pain originating from facet joints in the cervical and lumbar spine.[5,6] There is only single study comparing the TRFA versus CRFA in the lumbar spine.[12] However, available evidence for thoracic spine TRFA is very limited in the medical literature.[7] There are limited cadaveric studies and case reports regarding the CRFA, but to our knowledge, this is the first clinical study to evaluate the efficacy and adverse effects of CRFA for the facet joint-related pain in the thoracic spine. One study published by Stolker et al,[13] related to application of TRFA for facet joint-related pain in the thoracic

spine, reported significant improvement of pain during 18–54 months follow-up. Stolker et al applied 51 TRFA on 40 patients with thoracic facet joint-related pain; 83% patients had 50% to 75% reduction in pain levels 2 months after the interventions, and at the end of the study 83% of patients reported good to excellent results, defined as greater than 50% pain reduction during 18 to 54 months follow-up. In this study by Stolker et al the results were superior to our results. In another prospective observational study, Tzaan and Tasker published the results of 118 thoracic TRFA procedures in 90 consecutive patients, 41% of those reported more than 50% reduction in pain at the 6-month follow-up. The results of the study done by Tzaan and Tasker [14] were comparable to our results.

In our study, lower thoracic levels (T10, T11, T12) were the most frequently applied levels, each with at least 10 procedures.

Water-cooled RF (CRFA) has been suggested as a potentially more effective treatment alternative for thoracic facet-mediated pain, and has been shown to provide several advantages over TRFA, including the ability to create larger lesions, providing easier access to the nerves, and shorter fluoroscopy times.[8] We preferred CRFA in all our patients due to its potential theoretical advantages over TRFA. However, there have been no comparison studies published between these 2 techniques, specifically for the thoracic spine.

Secondary outcome measure was the time to repeat treatment with subsequent CRFA, thereby to measure the duration of the treatment. Only 10% (4/40) of the patients required repeat radiofrequency procedure at 6 to 12 months period. Twenty-five percent (10/40) of the patients required repeat radiofrequency procedure 12 to 24 months period. Sixty-five percent (26/40) of the patients required repeat radiofrequency procedure 24 to 36 months period. Shortest pain relief requiring repeat radiofrequency procedure was 30 weeks and the longest pain relief requiring repeat radiofrequency procedure was 112 weeks (Figs. 2 and 3).

The other aim of our study was to report any adverse events, if any. There was a single case with presentation of 2nd degree skin burn as a complication (1/40, 2.5%). This was the skin burn at 1 level in a patient with low body mass index (BMI) of 15. This complication was conservatively managed by skin care and the lesion healed completely with minor skin scar formation. Similarly, there was another single case report in the literature with the development of 3rd degree skin burn as a complication.[15] We believe that the CRFA procedure should be avoided in those patients with low BMI and/or inadequate subcutaneous tissue at the level of procedures due to the fact that the formation of larger and spherical lesion in CRFA may extend to skin level as shown in these complications. Instead, TRFA may be considered in such high-risk patients as the lesion created by TRFA is smaller in size. In other studies, published in regards to application of TRFA in thoracic spine, there were no complications reported.[13,14] There were no other adverse effects or complications observed in our study.

5. Conclusion

This is the first clinical study to evaluate the efficacy and adverse effects of CRFA in the thoracic spine for facet joint-related pain. Our results suggest that CRFA of thoracic facet joints is an effective treatment modality. Our subgroup analysis demonstrated that the pain relief and duration varies with the age and the pretreatment pain levels. Our results suggest that younger patients (age ≤ 50) with more severe baseline pain (NRS >7) will report more effective pain relief in the intermediate-term (2–6 months), while older patients (age >50) with less severe (NRS ≤ 7) baseline pain levels will report significant pain relief both in intermediate-term (2–6 months) and long-term (6–12 months). Further prospective comparative studies are required to evaluate the efficacy and adverse effects of different RFA modalities in the management of facet joint-related pain in the thoracic spine.

Author contributions

Dr. Gungor designed and conducted the study, including patient recruitment, data collection, and Drs. Gungor and Candan performed the data analysis. Drs. Gungor and Candan prepared the manuscript. All authors approved the final manuscript. Drs. Gungor and Candan had complete access to the study.

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