

Retrospective Review

Long-Term Retrospective Assessment of Clinical Efficacy of Radiofrequency Ablation of the Knee Using a Cooled Radiofrequency System

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Background: Cooled radiofrequency ablation (CRFA) in a randomized, prospective study demonstrated significantly greater improvements in pain, functional, and global outcome measures.

Objectives: This large, real-life, retrospective study evaluated the long-term effectiveness of CRFA in the general chronic knee pain population.

Study Design: Retrospective electronic chart review.

Setting: Outpatient private practice.

Methods: After institutional review board approval, we reviewed data of 275 consecutive patients who had undergone a geniculate nerve block at a single-site pain practice between July 1, 2014 and July 1, 2017. A total of 44 patients had a negative response to the geniculate block, and 11 patients had long-term pain relief from the block and declined CRFA. Eight patients underwent knee surgery after the block, and 7 never followed up for further treatment. Finally, 205 patients had undergone CRFA, and 183 (89%) of them returned to provide data.

Results: The average age of the 183 patients was 61 (28-95) years, body mass index 34 (18.5-57), and there were 105 women and 78 men. A total of 137 patients had unilateral knee pain, whereas 46 patients had bilateral knee pain. Eighty percent (146/183) reported at least one or more additional sources of chronic pain (back, shoulder, and others). The average opioid use at baseline was 50 mg morphine sulfate equivalents (median 30 mg). The average baseline pain scores were 8.5, which decreased to 2.2 after the geniculate local anesthetic block, and to 4.2 after CRFA. A total of 65% of the patients claimed > 50% pain relief, whereas 77% had 2 or more Visual Analog Scale points decrease, and 26 (14%) patients reported no pain at all after CRFA. The mean duration of > 50% pain relief after CRFA was 12.5 months (range 0-35 months). There was no significant decrease of opioid use. Patients who underwent a repeated procedure (n = 43) achieved a similar pain relief (P = 0.402). We could not find a statistical difference in geniculate CRFA outcomes between the group who had total knee arthroplasty (TKA; n = 21) and maintained chronic knee pain and patients who had no prior surgery (P = 0.542).

Limitations: Retrospective nature of the study.

Conclusions: This study demonstrates the clinical effectiveness of CRFA in the treatment of chronic knee pain from osteoarthritis, and even in those patients who maintained chronic knee pain after TKA. Our real-life data seems to agree with data previously published in a randomized controlled trial, despite the fact that this was quite a heterogenous patient population with various sources of chronic pain.

Key words: Radiofrequency ablation, chronic knee pain, knee osteoarthritis

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Radiofrequency (RF) ablation for chronic knee pain related to osteoarthritis is an evolving technique with a growing body of literature (1-7). In previous studies, patients treated with cooled radiofrequency ablation (CRFA) demonstrated significantly greater improvements in pain, functional, and global outcome measures when compared with patients treated with intraarticular steroids at 6- and 12-month follow-up (1,7). Those patients undergoing CRFA also had significant and lasting reduction in pain scores (1,7). From an initial pain score of approximately 7 on a 10-point scale, pain ratings at one month after the procedure were approximately 3 in the CRFA group versus 4 in the steroid group (1). At 6 months, 74% of patients assigned to CRFA had at least 50% reduction in pain scores, compared with 16% of those undergoing steroid injection. Nearly 40% of patients in the CRFA group rated their knee function as "satisfactory" at 6-month follow-up, compared with just 3% of the steroid group and contrasting to status at entry of the trial in which patients noted they were moderately to severely impacted by their disease. There were no serious treatment-related adverse events in either group (1).

Previous knee denervation studies using conventional RF ablation provided evidence of lasting and significant pain relief. However, the degree of pain relief may be less than in those who received CRFA (1-6). This is a single-center retrospective study that examines real-life data on use of CRFA in patients with osteoarthritis of the knee, and other etiologies of chronic knee pain including patients who maintained pain after total knee arthroplasty (TKA). In this heterogenous patient population with multiple comorbidities and often other sources of chronic pain, we collected data on pain scores before, immediately after, and long after the procedure, as well as a number of other important parameters (see Methods) that may provide better insight on how effective this procedure is in a pain practice.

METHODS

After the Forsyth Medical Center institutional review board approval (protocol ID: 18-916), we reviewed data of 275 consecutive patients who underwent geniculate nerve blocks in a single-site pain practice between July 1, 2014 and July 1, 2017 (Fig. 1). The vast majority of patients carried a previous diagnosis of knee osteoarthritis. Data

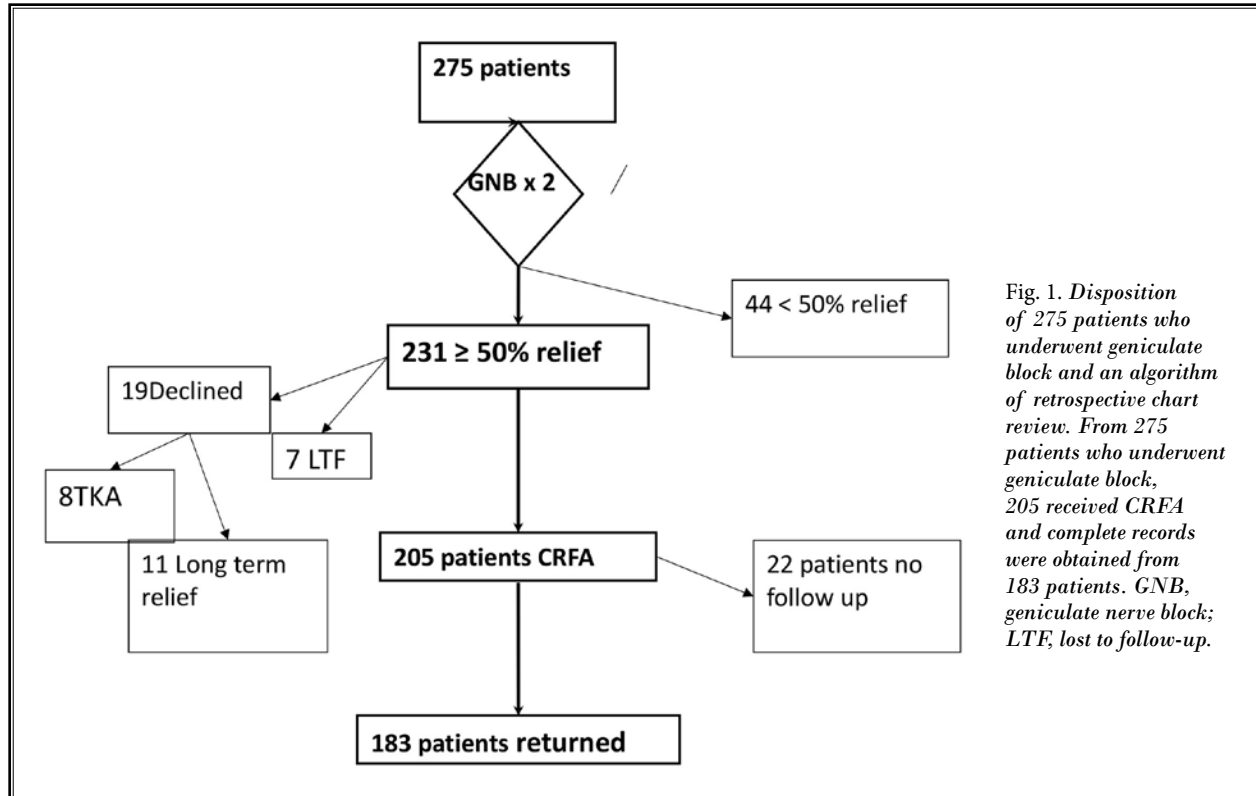


Fig. 1. Disposition of 275 patients who underwent geniculate block and an algorithm of retrospective chart review. From 275 patients who underwent geniculate block, 205 received CRFA and complete records were obtained from 183 patients. GNB, geniculate nerve block; LTF, lost to follow-up.

collected included patients identifier, date of birth, age, gender, body mass index (BMI), baseline numeric pain score, geniculate block (one or 2 diagnostic blocks and numeric pain score after the block(s)), daily total use of opioid medications at baseline (morphine equivalents in mg), daily total use of opioid medications approximately 6 months after the cooled RF of geniculates (morphine equivalents in mg), other sources of chronic pain, number of other chronic pain sources, assessment of opioid dependency/abuse susceptibility (based on opioid risk assessments at baseline and during follow-ups), numeric pain scores approximately (\pm 2 weeks) 3 and 6 months after the procedure and at latest visit, and number of repeated geniculate denervations using cooled RF and numeric pain scores 6-12 months after the repeated procedure. A separate assessment of the degree of osteoarthritis based on magnetic resonance imaging (MRI) in 4 stages as previously reported (1) was made to calculate predictive value.

Records were reviewed for all patients who underwent fluoroscopically guided geniculate nerve blocks as described previously (1), and using 1 mL of local anesthetic bupivacaine at each of 3 sites. CRFA was performed in 205 patients under sedation and using fluoroscopic visualization of anatomic landmarks as described in previous literature (1). Shortly, under light intravenous sedation and after a lidocaine injection of skin and soft tissue, a 17-gauge cooled RF introducer was placed using anterior-posterior and true lateral fluoroscopic visualization. An 18-gauge internally cooled 4-mm active tip electrode was placed into the introducer needle, and sensory stimulation at 50 Hz conducted at < 0.5 volts in all 3 locations with reproduction of concordant knee pain. Lesioning occurred after injection of 0.5 mL of 2% lidocaine at each of the 3 target sites for 2 minutes and 30 seconds with a generator set temperature of 60°C, resulting in the average maximum tissue temperatures exceeding 80°C (12).

Statistical Analysis

Data were summarized using descriptive statistics for continuous variables. We used the Student t test and, when needed, the Mann-Whitney rank sum test to determine whether the Numeric Rating Scale attained following RF denervation of the affected knee using cooled RF system was significantly different than prior to denervation. Similar analyses was carried out to determine changes in the numeric pain scores before and after the geniculate blocks and daily opioid use from before and after RF denervation. We calculated

the percentage of patients who maintained pain relief following RF ablation. All analyses were completed using the Sigma Plot Version 14 software for Windows (SYSTAT Software, San Jose, CA).

RESULTS

The average age of 183 patients was 61 (28-95; median 61) years, BMI 34 (18.5-57; median 33), and there were 105 women and 78 men. A total of 137 patients had unilateral knee pain, whereas 46 had bilateral knee pain. Eighty percent (146/183) reported at least one additional source of chronic pain (back, shoulder, and others). Forty-nine percent (89/183) had 2 or more and 21% (39/183) had 3 or more sources of chronic pain. Average opioid use at baseline was 50 mg morphine sulfate (MSO4) equivalents (range from 0-285 MSO4 mg equivalents; median 30 mg). There was no correlation between the increased BMI, daily opioid use (in MSO4 equivalents), increased age, gender, bilateral or unilateral knee pain, or degree of knee degeneration as observed on MRI with the amount of baseline pain or pain relief achieved after the procedure. A total of 44 patients had a negative response to the geniculate block (< 50% of pain relief), and 11 patients had long-term pain relief from the block and declined CRFA. Eight patients underwent knee surgery after the block(s), and 7 patients never followed up for further treatment. A total of 205 patients underwent CRFA at the Carolinas Pain Institute during their clinical management of knee pain, and 183 (89%) of these patients returned to provide data (Fig. 1).

The average baseline Visual Analog Scale (VAS) pain scores were 8.5 cm, decreased to 2.2 cm after the block, and to 4.2 cm after CRFA (Fig. 2). A total of 65% of the patients claimed > 50% pain relief, whereas 77% had 2 or more VAS points decrease, and 26 patients claimed no pain after CRFA. The mean duration of > 50% of pain relief after CRFA was 12.5 months (0-35 months; median 12 months). There was no significant decrease in opioid use over that time period, despite improved pain scores (Fig. 3). Patients who received a repeated procedure ($n = 43$) achieved a similar pain relief ($P = 0.402$; Fig. 4). In patients who had previous TKA ($n = 21$), improvements were comparable to the rest of treated patients ($P = 0.542$; Fig. 5).

DISCUSSION

This study describes the clinical effectiveness of CRFA for treating chronic knee pain from osteoarthritis and provides evidence of long-term improvements in

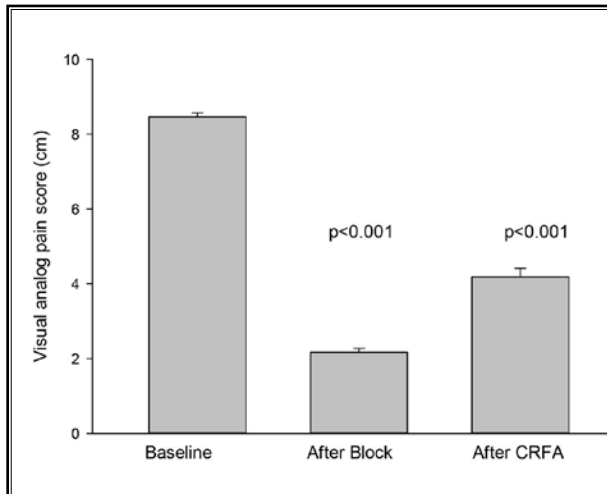


Fig. 2. Improvements in pain scores as documented after the geniculate nerve block and CRFA compared with baseline ($n = 183$). Pain relief was somewhat less prominent after CRFA, but significant when compared with baseline pain level ($P < 0.001$).

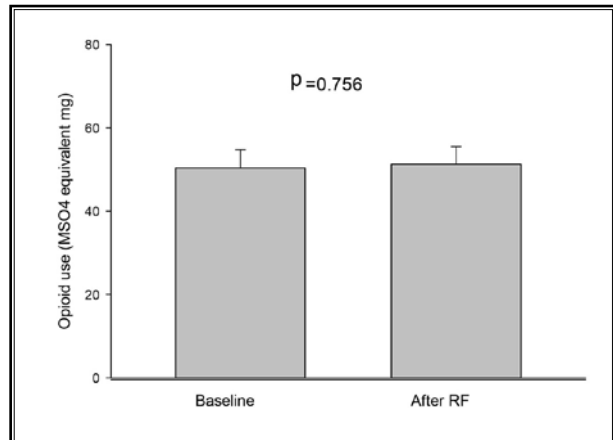


Fig. 3. Use of opioids at the baseline and approximately 6 months after CRFA. There was no significant decrease of opioid use ($P = 0.756$; $n = 183$).

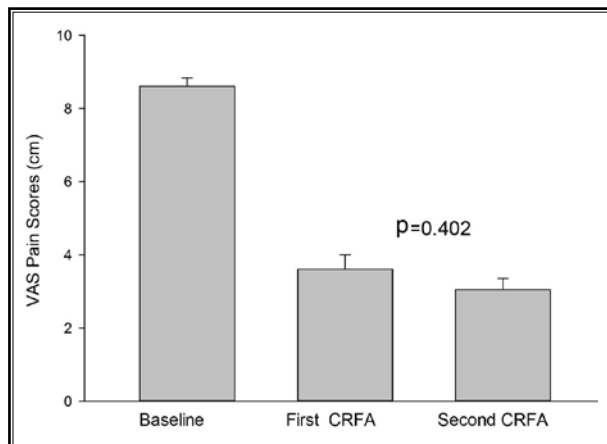


Fig. 4. Repeated CRFA procedure outcomes in the same patients. Shown are the pain scores following a first and second RF procedure ($n = 43$). No statistically significant difference in magnitude of pain relief could be found after first and second denervation.

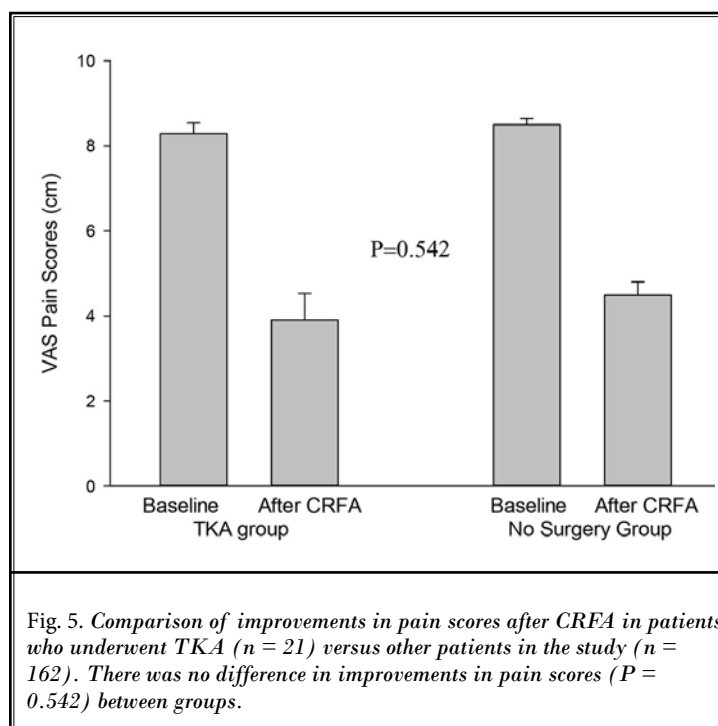
pain scores. Our real-life data seems to agree with the data that was previously published in a randomized controlled trial (RCT) (1), despite the fact that this was a more heterogenous patient population with various other sources of chronic pain. Indeed, our patients suffered from back pain, shoulder, hip, sacroiliac joint pain, and headaches in addition to their most intense pain source, chronic knee pain. Improvements in pain

scores after knee CRFA should be considered profound and greatly maintained over the extended time period considering that 80% of treated patients had one additional pain source and 50% of patients had at least 2 additional chronic pain sources. In a prospective, randomized study, approximately 75% of the patients claimed 50% or more pain relief at 6 months after CRFA, whereas 65% had the same pain at 12 months (1,7). Our data, despite the fact that we included patients with numerous sources of other chronic pain, were similar in pain relief than was achieved during the RCT (1). Again, 65% of the patients achieved > 50% of pain relief over an average time period of 12.5 months. This outcome could also be influenced by the treatment of both knees in this retrospective study, whereas during the prospective trial (1,7) only one "index" knee was treated.

It may be difficult to compare our outcomes to previously published data on knee denervation using CRFA (8,9). The McCormick et al (9) study, for example, reviewed outcomes of the same procedure when an active tip of cooled RF electrode was anatomically placed, assuming consistent denervation. In this study, we used sensory stimulation at 50 Hz to find the best possible location for an extensive denervation. Moreover, the anatomic variability in location of the small geniculate branches that was recently reported (10) may suggest that sensory stimulation prior to denervation can be advantageous. A frequency map of geniculate nerve passage in 15 cadavers was wide and unexpectedly variable (10). At this time, it is not clear how extensive RF denervation should be to provide the best possible

long-term outcome and still maintain procedural safety virtually free from serious side effects (11,12).

We could not find any correlation between the degree of radiologic findings before patients underwent CRFA to outcome of block, CRFA procedure and longevity of the pain relief after the procedure. In addition, there was a substantial subgroup of the patients ($n = 21$; Fig. 5) who were treated for chronic knee pain after receiving TKA whose data are also included in this study. There was no difference in pain degree or longevity of pain relief (Fig. 5; $P = 0.542$) between these 2 groups. This was similar to previous reports using various imaging guidance (13-15). A total of 21 patients in this dataset had prior TKA and reported continued pain with no specific etiology identified. Their response to CRFA was profound and did not differ from those who had no TKA (Fig. 5). Therefore, this therapy should be considered for post-TKA patients who have very few therapeutic options. The use of opioids did not change significantly after CRFA in this retrospective study, despite the significant improvements in claimed pain scores. There may be a few reasons for this discrepancy, first the time interval from CRFA and our assessment of the opioid level may be too short to conduct proper weaning of the opioid. Second, our patients had multiple sources of chronic pain in which approximately 80% reported at least one, 50% at least another 2, and approximately 20% even 3 additional sources of chronic pain. Therefore, in those who used opioids, it may be used to treat chronic pain sources other than the knee.



Forty-three patients required a repeat CRFA procedure owing to the return of their chronic knee pain. Repeating CRFA provided a similar time interval and intensity of pain relief (Fig. 4). There were no reported issues or events following the repeated procedures, providing evidence that repeating this procedure is safe and effective. There were no serious side effects noted after the procedure. However, as expected, mild postprocedural pain was observed in 6 patients lasting 2 to 8 days. No sensory or motor deficits were recorded.

CONCLUSIONS

Real-life data from this study provides evidence that in a more heterogenous patient population, CRFA can afford long-term pain relief from chronic knee pain. Improvements in pain scores at 6 and 12 months seems to correspond with the previously published randomized prospective study.

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