e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2025; 16(12); 142-147

Original Research Article

Prospective, Randomized, Clinical Trial Comparing the Safety and Effectiveness of Cooled Radiofrequency Ablation with Corticosteroid Injection in the Management of Knee Pain from Osteoarthritis

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Received: 16-10-2025 / Revised: 14-11-2025 / Accepted: 16-12-2025
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Conflict of interest: Nil

Abstract:

Background: Knee osteoarthritis is a leading cause of chronic pain and functional limitation. In patients who are unsuitable for or unwilling to undergo surgical intervention, minimally invasive interventional pain management techniques are increasingly utilized. Intra-articular corticosteroid injections provide short-term pain relief, whereas cooled radiofrequency ablation (CRFA) of genicular nerves has emerged as a promising modality for longer-lasting analgesia.

Objectives: To compare the safety and effectiveness of cooled radiofrequency ablation with intra-articular corticosteroid injection in the management of chronic knee pain due to osteoarthritis.

Materials and Methods: This prospective, randomized clinical trial was conducted at a tertiary care center after obtaining institutional ethics committee approval. Eighty patients aged 40–70 years with radiographically confirmed knee osteoarthritis (Kellgren–Lawrence grade III or IV) and baseline Numeric Rating Scale (NRS) pain score >6 were enrolled. Patients were randomly allocated into two groups: the CRFA group (n = 40) and the intra-articular steroid (IAS) group (n = 40). Outcomes were assessed at baseline and at 1-, 3-, and 6-months following intervention. The primary outcome was the proportion of patients achieving a ≥50% reduction in NRS pain score at 6 months. Secondary outcomes included changes in pain scores at follow-up, analgesic consumption, and adverse events.

Results: Both treatment modalities resulted in significant pain reduction during the early follow-up period. However, patients in the CRFA group demonstrated significantly greater and sustained reduction in NRS pain scores at all follow-up intervals compared to the IAS group. At 6 months, a higher proportion of patients in the CRFA group achieved clinically meaningful pain relief and required fewer rescue analgesics. No serious adverse events were observed in either group.

Conclusion: Cooled radiofrequency ablation provides superior and longer-lasting pain relief compared to intra-articular corticosteroid injection in patients with knee osteoarthritis, with a comparable safety profile. CRFA represents an effective minimally invasive treatment option for long-term management of chronic knee pain in patients unsuitable for surgical intervention.

Keywords: Knee Osteoarthritis; Cooled Radiofrequency Ablation; Genicular Nerve; Intra-Articular Corticosteroid Injection; Chronic Knee Pain; Interventional Pain Management.

Introduction

Osteoarthritis (OA) of the knee is a chronic, progressive degenerative joint disorder characterized by deterioration of articular cartilage, subchondral bone remodeling, osteophyte formation, and varying degrees of synovial inflammation. Clinically, it manifests as persistent knee pain, stiffness, reduced joint mobility, and functional impairment, making it one of the leading causes of disability among the elderly population worldwide [1,2]. The global burden of knee osteoarthritis continues to increase due to rising life expectancy, obesity, and sedentary lifestyles, posing a significant socioeconomic and healthcare challenge [3].

Total knee arthroplasty is considered the definitive treatment for end-stage knee osteoarthritis. However, a substantial proportion of patients are either

unsuitable candidates for surgery because of advanced age, significant medical comorbidities, or poor surgical fitness, or are unwilling to undergo major operative intervention. In addition, limited access to surgical facilities and financial constraints further restrict the feasibility of arthroplasty for many patients. Consequently, there has been a growing emphasis on nonsurgical and minimally invasive interventional techniques aimed at achieving sustained pain relief and improving quality of life in patients with knee osteoarthritis [4,5].

Intra-articular corticosteroid (IAS) injection is one of the most commonly employed interventional modalities for symptomatic management of knee osteoarthritis. Corticosteroids reduce pain primarily by suppressing synovial inflammation and inhibiting pro-inflammatory cytokine activity within the joint. Although IAS injections provide effective short-term pain relief and functional improvement, their clinical benefit is often transient, typically lasting only a few weeks to months. Repeated corticosteroid injections may be required, and prolonged exposure has been associated with potential adverse effects such as accelerated cartilage degeneration, subchondral bone changes, and systemic complications, thereby limiting their utility as a long-term treatment strategy [6,7].

Recent advances in interventional pain management have shifted focus toward neuromodulatory techniques targeting the sensory innervation of the knee joint. Anatomical and clinical studies have demonstrated that the superomedial, superolateral, and inferomedial genicular nerves are key contributors to nociceptive transmission from the knee joint. Targeted interruption of these nerves using radiofrequency-based techniques has emerged as an effective approach for managing chronic knee pain in patients who have failed conservative therapies [8,9].

Cooled radiofrequency ablation (CRFA) represents a technological refinement of conventional radiofrequency ablation. By utilizing internally cooled electrodes, CRFA creates larger and more uniform spherical lesions, allowing more consistent denervation of target genicular nerves while minimizing collateral tissue injury. Compared to conventional radiofrequency techniques, CRFA has been shown to provide longer-lasting pain relief, improved functional outcomes, and reduced reliance on analgesic medications in patients with knee osteoarthritis [9].

Despite the widespread use of both intra-articular corticosteroid injections and cooled radiofrequency ablation in clinical practice, there remains a paucity of prospective randomized studies directly comparing their long-term safety and effectiveness using standardized outcome measures. Therefore, the present prospective randomized clinical trial was undertaken to compare cooled radiofrequency ablation with intra-articular corticosteroid injection in the management of knee pain due to osteoarthritis, with particular emphasis on pain reduction, analgesic requirements, and adverse events over a six-month follow-up period.

Materials And Methods

Study Design and Setting: This prospective, randomized clinical study was conducted in the Department of Anaesthesiology at Gandhi Medical College and Associated Hospitals, Bhopal. The study was carried out after obtaining approval from the Institutional Ethics Committee, and written informed consent was obtained from all participants prior to enrolment. The study aimed to compare the safety and effectiveness of cooled radiofrequency ablation (CRFA) with intra-articular corticosteroid (IAS) injection in patients with chronic knee pain due to osteoarthritis.

Study Population, Sample Size, and Eligibility Criteria: A total of eighty patients diagnosed with knee osteoarthritis were enrolled during the study period based on predefined inclusion and exclusion criteria. The study population comprised patients aged 40–70 years of either sex, classified as American Society of Anesthesiologists (ASA) physical status I or II. All enrolled patients had radiographically confirmed knee osteoarthritis of Kellgren–Lawrence grade III or IV, had failed conservative management, and were unwilling or unsuitable to undergo knee replacement surgery. Eligible patients were required to have a baseline Numeric Rating Scale (NRS) pain score greater than 6 and demonstrate a positive response to a diagnostic genicular nerve block, defined as a reduction of at least 50% in NRS pain score. Patients were randomly allocated into two equal groups: the cooled radiofrequency ablation group (CRFA group, n = 40) and the intra-articular corticosteroid injection group (IAS group, n = 40). The sample size was determined based on feasibility and previously published studies evaluating genicular nerve radiofrequency ablation in knee osteoarthritis. Patients with deranged coagulation parameters, body mass index greater than 40 kg/m², systemic inflammatory disorders such as rheumatoid arthritis, uncontrolled diabetes mellitus, malignancy, prior total knee arthroplasty, or a history of previous radiofrequency block or ablation of the knee were excluded. Additionally, patients with local infection at the injection site or those unwilling to participate in the study were also excluded

Randomization and Follow-Up: Eligible patients were randomized in a 1:1 ratio to receive either cooled radiofrequency ablation or intra-articular corticosteroid injection. Randomization was performed using a computer-generated random number table with concealed allocation. Due to the nature of the interventions, blinding of patients and investigators was not feasible. Follow-up assessments were conducted at 1 month, 3 months, and 6 months after

the intervention. Patients were allowed to use rescue analgesics as required during the study period, while dosages of membrane stabilizers and antidepressants used for pain management were kept constant throughout the follow-up duration.

Diagnostic Genicular Nerve Block: All enrolled patients underwent fluoroscopy-guided diagnostic blockade of the superomedial and inferomedial branches of the saphenous nerve and the superolateral branch of the femoral nerve. Under strict aseptic precautions, 1 mL of 0.5% bupivacaine was injected at each target site using fluoroscopic guidance. A positive diagnostic block was defined as a reduction of 50% or greater in the NRS pain score at least 15 minutes following the injection. Only patients demonstrating a positive response were considered eligible for randomization.

Cooled Radiofrequency Ablation Technique: Patients allocated to the CRFA group underwent cooled radiofrequency ablation of the affected knee under fluoroscopic guidance. The procedure was performed with the patient in the supine position on a radiolucent table, with the knee slightly flexed over a bolster. Following aseptic skin preparation and infiltration of local anesthetic, a 75-mm, 17-gauge CRFA introducer needle was advanced to the target genicular nerve locations using standard fluoroscopic landmarks.

Correct needle placement was confirmed in anteroposterior and lateral fluoroscopic views, ensuring positioning at approximately 50% depth of the femur and tibia. A 4-mm, 18-gauge internally cooled active-tip electrode was introduced through the cannula. Sensory stimulation at <0.5 V reproduced concordant knee pain, while motor stimulation at 2.0 V confirmed the absence of motor response. Prior to ablation, 1% lidocaine was administered at each target site. Cooled radiofrequency energy was then delivered at 60°C for 150 seconds at each site. Upon completion, all needles were removed and patients were monitored before discharge.

Intra-Articular Corticosteroid Injection Technique: Patients randomized to the IAS group received a single intra-articular corticosteroid injection in the affected knee. With the patient in the supine position and under strict aseptic precautions, local anesthetic was infiltrated at the injection site. A 22-gauge spinal needle was introduced into the suprapatellar pouch, and a mixture of 40 mg methylprednisolone acetate with 4 mL of 0.5% bupivacaine was injected into the joint space. Patients were observed for a short period following the procedure and discharged with standard post-procedure instructions.

Outcome Measures: The primary outcome measure was the proportion of patients achieving a reduction of 50% or more in knee pain from baseline at 6 months, assessed using the 11-point Numeric Rating Scale (NRS). Secondary outcome measures included changes in NRS pain scores at follow-up visits, rescue analgesic consumption, and the incidence of adverse events. Pain assessments were based on patient-reported pain intensity during the week preceding each follow-up visit.

Safety Assessment

All patients were evaluated for adverse events and serious adverse events at each follow-up visit. Serious adverse events were defined as events that were life-threatening, resulted in death, or required hospitalization. Procedure-related complications such as infection, neurological deficit, or persistent pain were specifically monitored.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages with corresponding 95% confidence intervals. Between-group comparisons were performed using appropriate parametric or non-parametric tests based on data distribution. All statistical analyses were conducted using two-sided tests, with a p-value <0.05 considered statistically significant. For analysis of opioid analgesic use at 6 months, an adjusted significance threshold of p <0.025 was applied. Patients lost to follow-up were excluded from the final primary endpoint analysis.

Results

A total of 80 patients with radiographically confirmed knee osteoarthritis who fulfilled the eligibility criteria were enrolled and randomized in the study. All randomized patients completed the planned follow-up and were included in the final analysis. Patients were equally allocated into two groups: the cooled radiofrequency ablation group (CRFA group, n = 40) and the intra-articular corticosteroid injection group (IAS group, n = 40). Baseline characteristics were comparable between the two groups, indicating adequate randomization.

Baseline Demographic and Clinical Characteristics: The baseline demographic and clinical characteristics of the study population are presented in Table 1. The mean age of patients in the CRFA group was 58.6 ± 6.8 years, while that in the IAS group was 57.9 ± 7.2 years. The gender distribution was similar between the two groups. ASA physical status, radiographic severity of osteoarthritis based on Kellgren–Lawrence grading, and baseline NRS pain scores were also comparable. No statistically significant differences were observed between the groups for any baseline parameter (p > 0.05), confirming homogeneity of the study population.

Table 1: Baseline demographic and clinical characteristics of the study population (n = 80)

Parameter	CRFA Group (n = 40)	IAS Group (n = 40)	p-value
Age (years), Mean ± SD	58.6 ± 6.8	57.9 ± 7.2	0.64
Gender (Male/Female), n	22 / 18	21 / 19	0.82
ASA Physical Status (I / II), n	18 / 22	17 / 23	0.83
Kellgren–Lawrence Grade (III / IV), n	24 / 16	23 / 17	0.81
Baseline NRS pain score, Mean ± SD	7.9 ± 0.8	7.8 ± 0.7	0.59

Post-Intervention Pain Scores: Post-intervention pain intensity assessed using the Numeric Rating Scale at baseline and at 1, 3, and 6 months is shown in Table 2. Both treatment modalities resulted in significant pain reduction during early follow-up. However, patients in the CRFA group demonstrated significantly greater and sustained reduction in pain scores at all follow-up intervals.

At 1 month, the mean NRS pain score was significantly lower in the CRFA group compared to the IAS group. This difference became more pronounced at 3 months and was maintained at 6 months. In contrast, although the IAS group showed initial improvement, pain scores increased progressively over time, indicating a decline in analgesic efficacy.

Table 2: Comparison of NRS pain scores at baseline and follow-up

Time Interval	CRFA Group (Mean ± SD)	IAS Group (Mean ± SD)	p-value
Baseline	7.9 ± 0.8	7.8 ± 0.7	0.59
1 month	3.9 ± 1.1	4.5 ± 1.2	0.02*
3 months	3.2 ± 1.0	5.1 ± 1.3	<0.001*
6 months	2.9 ± 1.1	6.0 ± 1.4	<0.001*

*Statistically significant

Clinically Meaningful Pain Relief and Analgesic Requirement: Clinically meaningful pain relief, defined as a ≥50% reduction in NRS pain score at 6 months, was achieved by a significantly higher proportion of patients in the CRFA group compared to the IAS group. In addition, patients treated with CRFA required significantly fewer rescue analgesics during the follow-up period. Mean daily analgesic consumption was also significantly lower in the CRFA group, indicating prolonged and effective pain control (Table 3).

Table 3: Pain relief outcomes and analgesic consumption at 6 months

Parameter	CRFA Group	IAS Group	p-value
≥50% reduction in NRS score, n (%)	29 (72.5%)	11 (27.5%)	<0.001*
Patients requiring rescue analgesics, n (%)	12 (30%)	26 (65%)	0.003*
Mean daily analgesic use (tablets/day), Mean ± SD	0.8 ± 0.6	1.9 ± 0.9	<0.001*

*Statistically significant

Safety and Adverse Events: Both treatment modalities were well tolerated, and no serious adverse events were observed during the study period. Minor adverse events were infrequent, transient, and resolved spontaneously. No cases of infection, neurological deficit, or procedure-related hospitalization were reported in either group. The adverse event profile is summarized in Table 4.

Table 4: Adverse event profile in both groups

Adverse Event	CRFA Group (n)	IAS Group (n)
Transient procedural pain	4	2
Local swelling	2	3
Infection	0	0
Neurological deficit	0	0
Serious adverse events	0	0

Discussion

Knee osteoarthritis is a major cause of chronic pain, functional limitation, and reduced quality of life, particularly in the elderly population. When conservative management fails and surgical intervention is either contraindicated or deferred, interventional pain management techniques play a crucial role in symptom control. The present prospective randomized clinical study demonstrated that cooled radiofrequency ablation (CRFA) provided significantly superior and more sustained pain relief compared to intra-articular corticosteroid (IAS) injection over a six-month follow-up period.

Both treatment modalities resulted in significant pain reduction during the early post-intervention phase. However, the analgesic benefit of intra-

articular corticosteroid injection diminished progressively with time, whereas pain relief following CRFA was maintained throughout the follow-up period. These findings are consistent with previous studies reporting that intra-articular corticosteroids offer only short-term symptomatic relief in knee osteoarthritis, with benefits typically lasting a few weeks to three months Chen AF et al. [10]. Repeated steroid injections may be required, which limits their long-term utility due to potential adverse effects on cartilage and subchondral bone Guermazi et al. [11].

The sustained analgesic efficacy observed with CRFA can be attributed to its mechanism of action. The genicular nerves, including the superomedial, superolateral, and inferomedial branches, are the principal sensory nerves transmitting nociceptive input from the knee joint. Cooled radiofrequency ablation produces larger and more uniform thermal lesions compared to conventional radiofrequency techniques, resulting in consistent denervation of these nerves and prolonged interruption of pain signaling pathways Bianco GL et al. [12]; Kocayiğit H et al. [13]. This mechanism likely explains the durable pain reduction and lower analgesic requirements observed in the CRFA group in the present study.

In this study, patients treated with CRFA demonstrated significantly greater reductions in Numeric Rating Scale pain scores at all follow-up intervals. Furthermore, a significantly higher proportion of patients in the CRFA group achieved clinically meaningful pain relief, defined as a reduction of at least 50% in pain scores at six months. These results are in agreement with previously published randomized controlled trials and observational studies that have reported sustained pain reduction and functional improvement following genicular nerve radiofrequency ablation Hunter C et al. [14]; Kapural L et al. [15]; Lyman J et al. [16].

Another clinically relevant finding was the reduced requirement for rescue analgesics among patients in the CRFA group. Reduced analgesic consumption reflects improved overall pain control and may decrease the risk of adverse effects associated with long-term use of non-steroidal anti-inflammatory drugs and opioids. Similar reductions in analgesic use following genicular nerve radiofrequency ablation have been reported in earlier studies, further supporting its role as a long-term pain management strategy in knee.

With respect to safety, both CRFA and IAS injections were well tolerated in the present study. No serious adverse events such as infection, neurological injury, or procedure-related hospitalization were observed in either group. Minor adverse effects were transient and self-limiting. These findings are consistent with existing literature demonstrating a favorable safety profile for genicular nerve radiofrequency procedures when performed under image guidance by trained practitioners.

Despite the strengths of this study, certain limitations should be acknowledged. The follow-up duration was limited to six months, and longer-term studies are required to assess the durability of pain relief beyond this period. Functional outcome measures such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) or Knee injury and Osteoarthritis Outcome Score (KOOS) were not included, which may have provided additional insight into functional improvement and quality of life. Additionally, the single-center design and relatively small sample size may limit the generalizability of the findings.

Overall, the findings of this study suggest that cooled radiofrequency ablation is a safe and effective minimally invasive intervention that provides superior and longer-lasting pain relief compared to intra-articular corticosteroid injection in patients with knee osteoarthritis. CRFA may therefore be considered a valuable treatment option for patients with chronic knee pain who are unwilling or unsuitable for surgical intervention.

Conclusion

Cooled radiofrequency ablation provides superior and sustained pain relief compared to intra-articular corticosteroid injection in patients with knee osteoarthritis. While both interventions are effective in reducing pain during the early post-intervention period, the analgesic benefit of corticosteroid injection diminishes over time, whereas cooled radiofrequency ablation maintains significant pain reduction up to six months. In addition to improved pain control, cooled radiofrequency ablation is associated with reduced analgesic requirements and a favorable safety profile. These findings support cooled radiofrequency ablation as a safe and effective minimally invasive treatment option for long-term management of chronic knee pain in patients who are unsuitable for or wish to defer surgical intervention.

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