Original Article

Cooled Radiofrequency Ablation of the Genicular Nerve for the Treatment of Chronic Knee Pain Following Total Knee Arthroplasty: An Observational Study

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ABSTRACT

Radiofrequency ablation (RFA) has been shown to be effective in relieving pain in patients with osteoarthritis of the knee. There is a paucity of literature on the effectiveness of RFA in patients with persistent pain following total knee arthroplasty. A prospective observational trial of 20 patients with pain lasting greater than 12 months following a total knee arthroplasty. Patients were treated with a single session of cooled RFA to the genicular nerves under ultrasound guidance. Outcome measures were the numeric rating scale (NRS) for pain, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and patient perceived effect. Patients were followed at 13, 26, and 52 weeks following treatment. Patients showed a significant improvement in NRS pain at 13 (median: 4, interquartile range [IQR]: 3.5), 26 (median: 3, IQR: 4.5), and 52 (median: 5, IQR: 5.5) weeks when compared with baseline (median: 8, IQR: 1.75; $p < 0.05$). Patients also demonstrated significant improvements in WOMAC pain, function, and overall scores from 13 to 52 weeks and WOMAC stiffness from 26 to 52 weeks ($p < 0.05$). This study found that cooled RFA led to decreases in patient-reported pain and increases in patient-reported function through 12 months. Future studies should look to evaluate cooled RFA against a control group and provide longer follow-up to determine the total duration of effect.

Keywords total knee arthroplasty, chronic pain, nerve ablation

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Introduction

Osteoarthritis (OA) is one of the most common progressive musculoskeletal conditions and affects approximately 250 million people across the globe.[1] With an aging population, the prevalence of joint degeneration is increasing and causes patients to lose mobility, suffer from OA-related pain, and experience a lower quality of life.[2] Current treatment options for OA include surgery (i.e., total knee arthroplasty [TKA] or corrective osteotomy) as well as conservative management therapies (i.e., weight loss, bracing, physical therapy, medications, and injections).[3,4] Conservative management serves as a first-line option for most patients, and surgery can be effective, but is not suitable for all patients.[4,5] In cases of failed conservative management and ongoing knee pain due to OA, a TKA is the standard of care.[6] Increasingly, TKA is being used for the treatment of advanced knee OA, with the volume of TKAs increasing 156% between 2000 and 2019.[7] It is projected that in the next 15 years there will be over 1 million TKAs completed in the United States every year.[7] However, patient satisfaction is highly variable, with some research reporting that only 8% of patients are satisfied with the overall treatment outcome.[8] Indeed, an estimated 20% of patients report dissatisfaction after undergoing primary TKA.[9] In part, this can be attributed to persistent pain and limited function.[9] In fact, up to 33% of patients who undergo TKA experience ongoing pain after surgery.[10]

Radiofrequency ablation (RFA) was originally described in 1891 as a technique to destroy the nerves innervating painful tissues and thereby disrupt the transmission of pain-associated nerve signals.[11] In recent years, RFA has been utilized as an option for patients who are not candidates for surgery or who are considered at high-risk for complications.[12] Current literature supports the use of cooled RFA as a minimally invasive option for reducing pain and improving function in knee OA for up to 12-months.[13–15] However, a gap remains in exploring the efficacy of RFA on patients with ongoing pain following TKA. Helping patients who are suffering from pain and disability despite undergoing primary TKA remains a pervasive and important challenge for orthopedic surgeons. Many studies have explored using RFA for managing OA symptoms; however, limited research has explored using RFA to treat pain after TKA.[16] Therefore, this study looked to evaluate the efficacy of RFA for patients experiencing pain after undergoing noncomplicated TKA. This was accomplished primarily by determining the impact of cooled RFA on pain management in painful noncomplicated TKA. Additionally, the study will determine the impact of cooled RFA on adverse events, symptom relief, function, and perceived effect.

Patients/Methods

This study was a single-center, prospective, observational trial evaluating patient-reported outcomes following the application

of cooled RFA in patients with persistent pain after noncomplicated TKA. Prior to initiation of the study, ethics approval was obtained (approval number Pro00054474).

Patient Selection

Patients over the age of 18 with a painful noncomplicated TKA for at least 12 months after surgery, and with a greater than 50% reduction in pain after a genicular nerve block around the knee at a clinic in Ontario, Canada, were approached by a board-certified orthopedic surgeon for participation between April 2022 and August 2024. The exclusion criteria for the study were: (1) active infection; (2) contraindication to receiving genicular nerve injections with local anesthetic or corticosteroids; (3) neuropathy or neurological disease; (4) contraindication to RFA (e.g., pacemaker); (5) inability or unwillingness to provide informed consent; (6) patients who are pregnant or nursing; (7) patients who are unable to complete questionnaires. Written informed consent was obtained prior to performance of study procedures.

A diagnostic block was performed using an in-plane ultrasound-guided technique. A 25-gauge needle was advanced along the long-axis view of the transducer to the target site. At each location (superomedial genicular nerve, superolateral genicular nerve, and inferomedial genicular nerve), 2 mL of a local anesthetic mixture (1% lidocaine and 0.25% bupivacaine) was administered. Patients were instructed to rest for 24 hours and contact the office in 1 week to describe the amount of pain relief they achieved. A minimum of 50% reduction in pain was required to proceed with therapeutic ablation. The surgeon who performed the diagnostic block was the same surgeon who performed the cooled RFA.

Intervention

Patients were treated with cooled RFA (COOLIEF, Avanos Medical Inc., Alpharetta, Georgia, United States), which uses an internally-cooled probe to ablate nervous tissue. The cooled RFA was applied by a board-certified orthopedic surgeon with the patient in the supine position after draping and sterilization. Local infiltration anesthesia was performed using a mixture of lidocaine (1%) and bupivacaine (0.25%). Injection sites were performed under ultrasound guidance, and if joint effusion was present, aspiration was conducted. Ultrasound-guided localization of the genicular nerves was performed at three standard anatomic sites: superomedial genicular nerve: the linear transducer was positioned parallel to the medial distal femur to identify the metaphyseal–diaphyseal junction. The superomedial genicular artery and accompanying nerve were identified adjacent to the periosteum and confirmed using color Doppler imaging; superolateral genicular nerve: the transducer was positioned parallel to the lateral distal femur to identify the metaphyseal–diaphyseal junction. The superolateral genicular artery and corresponding nerve were localized near the periosteal surface and confirmed with color Doppler; inferomedial genicular nerve: the transducer was placed longitudinally along the proximal medial tibia to identify the metaphyseal–diaphyseal junction deep to the insertion of the medial collateral ligament. The inferomedial genicular artery and nerve were visualized adjacent to the periosteum and confirmed using Doppler imaging.

The anesthetic was injected into the inferomedial genicular nerve, superomedial genicular nerve, and superolateral genicular nerve. Cooled RFA was administered using a 17-gauge needle with either a 4.5 or 5.5 mm active tip, which was guided by ultrasound. Lesioning was performed with a probe set temperature of 60°C (corresponding with a tissue temperature of 80°C) for 2 minutes and 30 seconds on each target genicular nerve: the inferior medial genicular nerve, superior medial genicular nerve, and superior lateral genicular nerve. At the end of the procedure, another injection of the anesthetic mixture was given at all sites, and sterile dressings were applied. Postcare instructions and follow-up instructions were provided.

Outcomes

The primary outcome measure of this study is pain as measured by a numeric rating scale (NRS). The NRS measures pain on a 0 to 10 scale, with 0 indicating no pain and 10 indicating the worst pain imaginable.[17] Secondary measures included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), patients' perceived effect, and adverse events.

The WOMAC is a validated instrument consisting of three domains measuring pain (0–20 points), stiffness (0–8 points), and function (0–68 points), as well as an overall score (0–96 points).[18] Patient perceived effect of treatment was assessed using an 11-point Likert scale with ranges from −5 (much worse) to +5 (much better), with 0 indicating no change since before treatment.[19] Adverse events were monitored at the time of treatment as well as at all follow-up time points. Data were collected at baseline, 13, 26, and 52 weeks following treatment.

Statistical Analysis

As this was a pilot study, a convenience sample of 20 patients was selected. Baseline characteristics were performed using descriptive statistics as a mean and standard deviation for normally distributed continuous variables or median and interquartile range for nonnormally distributed variables, and count with percentage for categorical variables. Normality of data was tested using the Shapiro–Wilks test and visualization of residual Q–Q plots. For continuous outcome measures, data were analyzed using a linear regression model with a factor of time. All statistical analyses were conducted in R Version 4.3.2 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient demographic information is summarized in **Table 1**. A total of 20 patients were enrolled in this study. Five patients were lost to

Table 1 Patient demographics

	Cooled RFA patients ($n = 20$)
Sex (n)	
Female	17
Male	3
Age (y)	72.4 (10.5)
Height (cm)	167 (8.37)
Weight (kg)	86.6 (17.3)
BMI (kg/m^2)	31.3 (6.18)
Duration of pain (mo)	47.1 (33.0)

Table 2 Patient reported outcomes

	Baseline (median [IQR])	13 wk (median [IQR])	26 wk (median [IQR])	52 wk (median [IQR])
WOMAC stiffness	5.5 [2]	4 [4]	3 [2][a]	3.5 [3.25][a]
WOMAC pain	12 [6]	5 [8][a]	7 [9][a]	6 [9.5][a]
WOMAC function	47 [25]	22 [27][a]	22 [18][a]	34 [42]
WOMAC index	66 [31]	31 [33][a]	32 [32][a]	29.5 [55.5][a]
Patient perceived effect[b]	–	2.5 [3]	1 [3]	1.5 [3]

[a]Denotes $p < 0.05$ compared with baseline.
[b]No change from baseline statistical analysis performed.

follow-up at 1-year posttreatment (**Fig. 1**). The mean age of patients was 72.4 years, and 85% were female. The mean duration of knee pain following their TKA was 47.1 months.

Patient Reported Outcome Measures

A significant decrease in NRS pain was seen in patients who received cooled RFA when compared with baseline (**Fig. 1**). This improvement was seen as early as 13 weeks and was maintained through 52 weeks. Significant differences were also seen in all subscales of the WOMAC, as well as the overall WOMAC score through all time points with the exception of WOMAC stiffness at 13 weeks ($p = 0.0513$; **Table 2**).

Adverse Events

One patient experienced a fall during study follow-up. No other adverse events were reported in the study population during the duration of the trial.

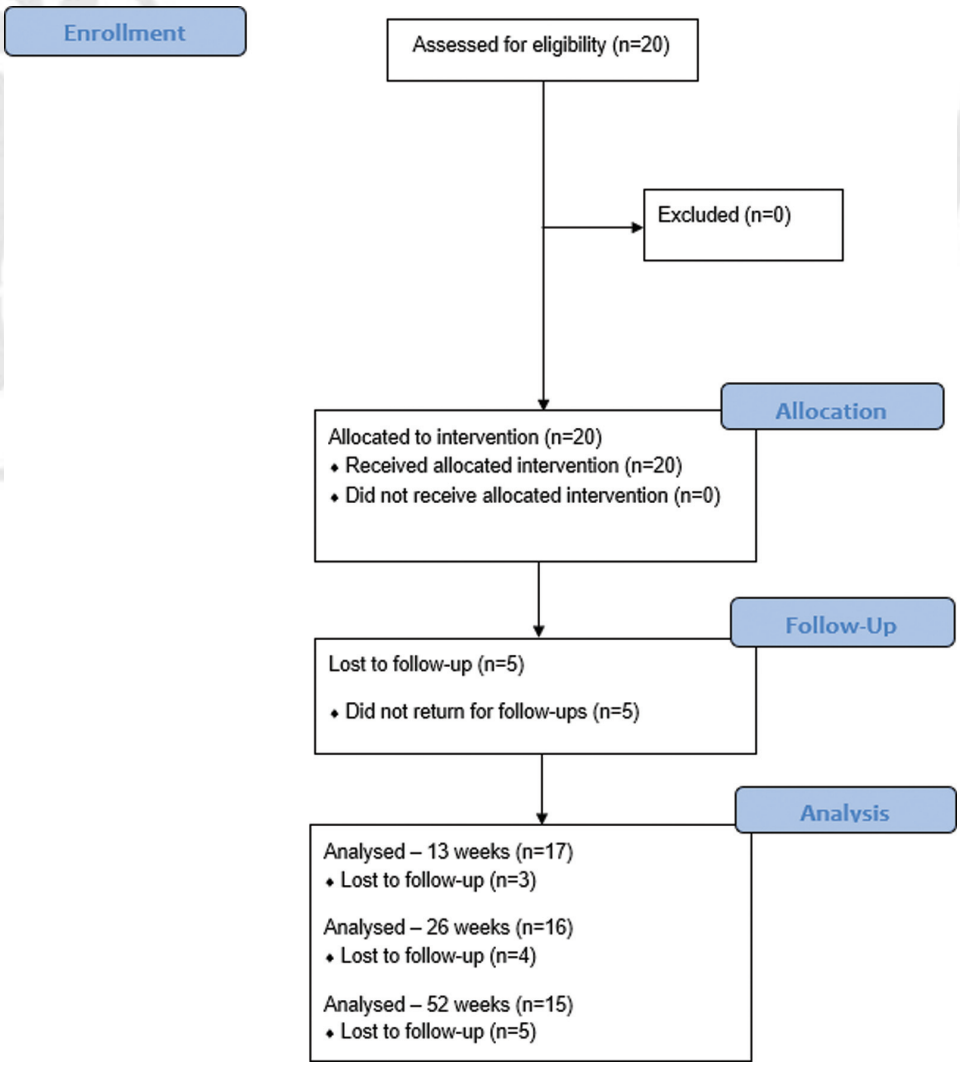

Fig. 1 CONSORT diagram.

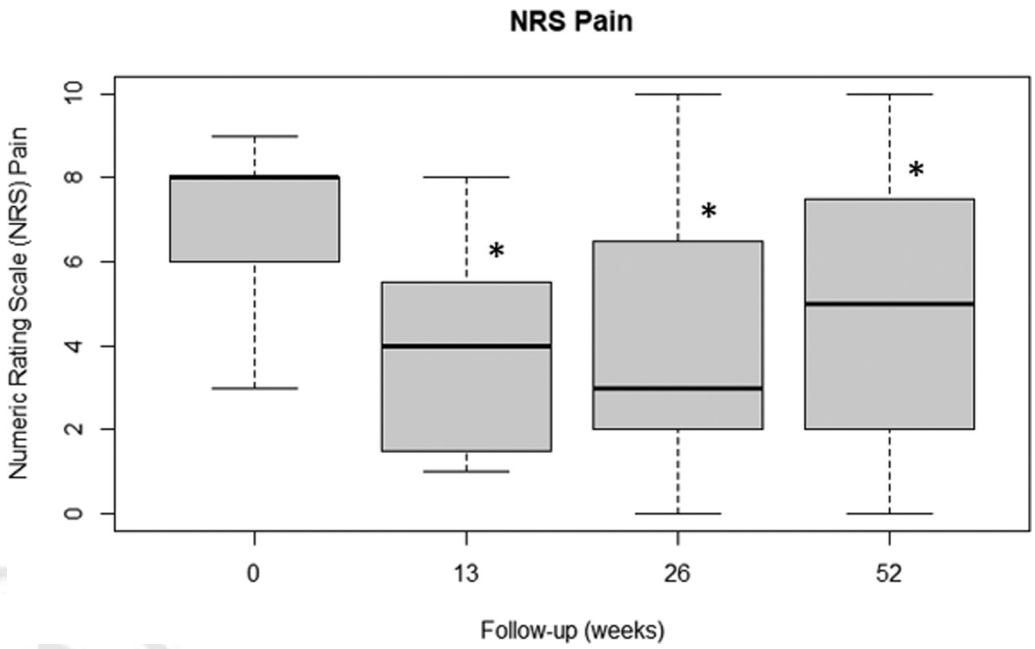

Fig. 2 Numeric rating scale pain. *Denotes $p < 0.05$ compared with baseline.

Discussion

We conducted a prospective, observational study evaluating the effects of cooled RFA in patients with persistent knee pain following noncomplicated TKA. The study indicated that patients who received cooled RFA demonstrated improvements in pain, function, and stiffness when compared with baseline. There were also no reported adverse events in the patients who received cooled RFA.

TKA is commonly seen as a life-changing intervention for patients with end-stage OA, although many patients can experience persistent pain and loss of function following TKA with limited options for providing relief.[4,5] Patients in the current study demonstrated reductions in pain on two evaluation metrics (NRS and WOMAC pain), as well as improved function and decreased stiffness up to 12 months following cooled RFA. This indicates that cooled RFA may be an option for patients suffering from persistent pain following noncomplicated TKA.

The ablation of the genicular nerves leads to an interruption in pain-related sensory information, thus leading to a decrease in patient-perceived pain.[20] While not directly affecting functional components of the knee, cooled RFA can reduce the barrier of pain, which may lead to the increases seen in function and stiffness.[21] Patients, on average, showed a perceived benefit of cooled RFA as indicated by the patient-perceived effect, which is likely due to a combination of the improvements seen in perceived pain, function, and stiffness.

The present study has limitations. First, the lack of a comparison group means that the efficacy seen in this study could potentially be due to a placebo effect. In addition to this, the patients' baseline pain was high, and the decrease over time could be due to a gradual reduction over time as opposed to the intervention. Future trials should look to compare cooled RFA to control groups and other active treatments to further examine its efficacy, and could examine longer follow-ups. Second, as only three of the participants were male, this limits the generalizability of these results to the population. As there is a difference in pain perception following TKA between men and women, the results presented here may have limited generalizability to the male population.[22] A potential sex difference in the response to treatment cannot be ruled out, although this cannot be examined in the current study. Third, data were not collected regarding pain medication use by patients in the trial. Changes in pain medication use throughout the trial cannot be ruled out as a potential confounder on the pain responses seen in the study.

In patients with persistent pain following noncomplicated TKA, the use of cooled RFA resulted in reductions in pain and improvements in function and quality of life for up to 12 months, with no reported incidences of adverse events. This provides promise for cooled RFA as a potential treatment for patients with pain following noncomplicated TKA.

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Statements and Additional Information

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