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EFFECTIVENESS OF FLUOROSCOPY GUIDED CRYOABLATION OF GENICULAR NERVES IN COMPARISON WITH STEROID AND LOCAL ANAESTHETIC BLOCK IN IMPROVING PAIN AND FUNCTION IN PATIENTS WITH GRADE 3 AND 4 OSTEOARTHRITIS OF THE KNEE: A RANDOMISED CONTROLLED TRIAL

Physical Medicine & Rehabilitation

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ABSTRACT

Background & Objectives: Knee osteoarthritis (OA) is a prevalent degenerative joint disease significantly impacting pain and function. Fluoroscopy-guided cryoablation of genicular nerves is an emerging intervention for pain management in knee OA. This study aimed to compare the effectiveness of fluoroscopy-guided cryoablation with local anaesthetic and steroid blocks in improving pain and function in patients with Grade 3 and 4 knee OA. **Methods:** A single-blinded, randomized controlled trial was conducted at the Department of Physical Medicine and Rehabilitation, involving 82 patients with Grade 3 and 4 knee OA. Participants were randomly assigned to receive either fluoroscopy-guided cryoablation or a local anaesthetic and steroid block. Outcome measures included Visual Analog Scale (VAS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores assessed at baseline, 1st, 4th, 12th, and 24th weeks. **Results:** The cryoablation group demonstrated a significant reduction in VAS and WOMAC scores compared to the control group at all follow-ups. **Conclusion:** Fluoroscopy-guided cryoablation of genicular nerves offers superior and sustained pain relief and functional improvement in advanced knee OA compared to local anaesthetic and steroid blocks. It may be a viable option for management in patient who are unfit or unwilling to go for surgery.

KEYWORDS

Cryoablation, Genicular Nerve Block, Knee Osteoarthritis, Steroid Injection, VAS, WOMAC

INTRODUCTION

Osteoarthritis (OA) is a progressive chronic degenerative musculoskeletal disease that mainly affects the weight bearing joints. It is considered as one of the leading causes of disability. The disease processes involve the entire joint, including the articular cartilage, subchondral bone, ligaments, capsule, synovial membrane, and periarticular muscles[1]. Knee osteoarthritis is a major public health issue in the elderly population, among which females are more affected. According to global burden of the disease 2015, approximately 85% of the burden of osteoarthritis worldwide is related to knee OA[2]. Osteoarthritis is the most common rheumatologic problem in India. The prevalence of OA in India is 22% to 39% and knee OA alone contributes to 80% of the osteoarthritis burden[3].It has a multifactorial aetiology. The incidence of knee osteoarthritis increases with age and further increases with a longer lifetime and higher average weight[4]. Mainly, osteoarthritis has been divided into primary and secondary forms. The most common symptoms of knee osteoarthritis include pain, stiffness, swelling and functional limitation of movement. Physical examination findings in patients with knee osteoarthritis include tenderness to palpation, bony enlargement, crepitus, reductions in a range of motion, and occasional effusions, diagnosed by ACR 2016. The KL grading system remains the most commonly used grading system for research purposes[5].

Nonpharmacological strategies and pharmacological treatment are standard for treatment. Pain in the later stages can be managed by a genicular nerve block with local anaesthetics, radiofrequency laser denervation[6,7]. Cryoablation of the genicular nerve is a new modality in the management of chronic OA knee pain. Cryoablation is the process of applying cold temperatures (-20 to -100°C) to a peripheral nerve, leading to Wallerian degeneration while the nerve retains its ability to regenerate[8,9]. Patients who are refractory to conservative treatments or those not fit and not willing for surgery can benefit from it. To date, surgery is the only definite treatment for the advanced stages of the disease. However, it is important to note that around 53% of patients continue to have knee pain even after surgery[10]. Hence it is important to have pain control in the later stages of the disease with newer minimally invasive modalities. There is a growing literature showing that cryoablation of sensory peripheral nerves can provide pain relief for a variety of chronic pain conditions, but most of these studies were not RCTs and no comparative studies between these two modalities in Indian population. We need to find promising short and long-term

results in a variety of chronic pain conditions, mainly grade 3 and grade 4 osteoarthritis of the knee[10]. To our knowledge, this is the first Indian study adding to the literature by evaluating two distinct interventions for pain relief and functional improvement in patients with knee osteoarthritis. This study aimed to compare two minimally invasive treatment modalities for chronic knee pain – local anaesthetic and steroid block with cryoablation of genicular nerves, a novel alternative.

MATERIAL AND METHODS

This study was designed as a randomized controlled trial conducted at the Department of Physical Medicine and Rehabilitation. Conducted over a period of two year from March 2023. The study received approval from the Institutional Research Ethics Board of the Regional Institute of Medical Sciences, Imphal (A/206/REBComm(SP)/RIMS/2015/1047/78/2023). All participants provided informed written consent after being educated about the study protocol. Confidentiality was maintained. Participation was entirely voluntary, and free to withdraw at any stage. The data collected were accessible only to the principal investigator and guide. The trial was registered in the Clinical Trials Registry of India (CTRI/2023/12/060703). The study population comprised patients presenting with pain around the knee joint who attended the outpatient department (OPD) of the Department of Physical Medicine and Rehabilitation at RIMS during the study period, aged between 50 to 75 years with a history of knee pain lasting for more than 12 months and a Visual Analogue Scale (VAS) score of ≥4 were included. Osteoarthritis of the knee diagnosed according to the 2016 revised American College of Rheumatology (ACR) criteria and radiological confirmation of K-L grade 3 or 4 and who had a positive response to a diagnostic genicular nerve block and willing to participate in the study and adhere to follow-up protocols were included. Patients with acute knee injury or pain, a history of intra-articular steroid or hyaluronan injection in the past 6 months, neuromuscular or cognitive impairment, prior knee surgery, recent myocardial infarction or stroke, uncontrolled diabetes or hypertension, systemic diseases, coagulation disorders, psychiatric illness, local or systemic infections, or known allergy to the anaesthetic or steroid medications used in the study were excluded. The sample size was calculated based on a study by Kim HD et al[11] assuming a 5% level of significance, 90% power, 10% dropout rate, the final sample size was 82 participants. Participants were recruited from the PMR OPD at RIMS on Mondays and Thursdays. Convenience sampling was employed. Participants were randomized into two groups—Group A (intervention group) and Group B (control group)—using a block of four randomization. Single blinding was ensured by employing a trained staff nurse who acted as the blinded assessor. Independent study variables included age, gender, body mass index, occupation, duration of symptoms, side of knee affection, and K-L grading. The dependent variables were the VAS and WOMAC scores. The tools and equipment used in the study included a pre-tested structured proforma, SIEMENS Multimobil 5E C-arm (manufactured by SIEMENS Ltd., Goa, India), and the Cryo Generator CRYO-S Painless (Metrum Cryoflex, Poland). The device was equipped with a pneumatic cylinder unit, and cryoprobe with integrated nerve stimulation.

Only the superomedial (SM), superolateral (SL), and inferomedial (IM) genicular nerves were targeted, while the inferolateral nerve was avoided to prevent common fibular nerve injury. Patients were positioned supine with the ipsilateral knee elevated using towels to facilitate optimal lateral fluoroscopic views. Using the tunnel technique, a 22G needle was advanced to make bony contact, and the needle tip position was confirmed under both lateral and AP fluoroscopic views to ensure it was halfway across the bone thickness. A diagnostic block was considered positive if the patient experienced ≥50% pain relief for at least 6 hours. In Group A, cryoablation was performed under strict aseptic precautions in a similar position as the diagnostic procedure next day, a cryoprobe was inserted after skin disinfection and cleaning. Sensory and motor stimulation was used to confirm probe placement. Cryoablation was performed in two cycles per nerve: a first cycle with 2 minutes of freezing and 30 seconds of thawing, and a second cycle with 2 minutes of freezing followed by 10 seconds of thawing. The maximum temperature reached was −78°C using CO_2 as the cryogen. In Group B, patients underwent a fluoroscopy-guided genicular nerve block at the SL, SM, and IM nerve locations. Each site received 2 ml of the solution containing 1.5 ml of 0.5% bupivacaine and 0.5 ml (20 mg) of Triamcinolone Acetonide[11].

All participants received a standardized rehabilitation programme which included the use of ice packs, acetaminophen as a rescue analgesic, education on knee joint protection during activities of daily living, range of motion exercises, quadriceps and hamstring strengthening, balance training, and the use of braces or assistive devices as required. Patients were followed up at the end of the 1st, 4th, 12th, and 24th weeks post-procedure. During each follow-up, pain and functional status were reassessed using VAS and WOMAC scores, respectively. Patients were instructed to discontinue any analgesic or anti-inflammatory medications at least 48 hours before each assessment to avoid confounding the results. Outcome data were recorded at baseline and during follow-up visits. The collected data were checked for completeness and internal consistency. Statistical analysis was performed using IBM SPSS version 27. Descriptive statistics including mean, standard deviation, frequency, and percentage were computed. Group comparisons for continuous variables were performed using the independent t-test. Categorical variables were analysed using the Chi-square test. Between-group comparisons of outcome measures were done using the independent t-test, while within-group comparisons across time points were evaluated using repeated measures analysis of variance (ANOVA). A p-value of less than 0.05 was considered statistically significant.

Figure 1. Insertion of Cryoablation Probe into the Targeted Genicular Nerve

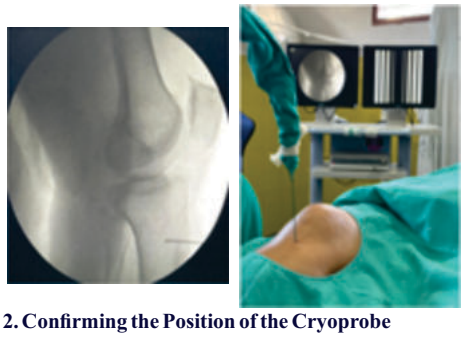

Figure 2. Confirming the Position of the Cryoprobe

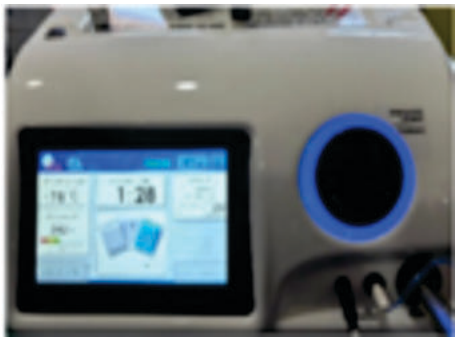

Figure 3. Cryoablation Cycle of Genicular Nerves with -78 Degree with CO2 Gas for 2

RESULTS AND OBSERVATIONS

Table 1: Comparison of Baseline Characteristics and Outcome Measures Between the Study and Control Groups

Characteristic	Cryoablation (N=41) n (%)	Steroid and local anaesthetic Block (N=41) n (%)	p-value
Age (years)* (Mean ± SD)	66.41 ± 5.64	66.54 ± 5.91	0.924
Gender#	0.370		
- Male	17 (42.5%)	21 (52.5%)	
- Female	24 (57.5%)	20 (47.5%)	
Duration of Symptoms*(years)	4.38 ± 0.78	4.07 ± 1.15	0.165
Occupation#	0.998		
- Business	7 (17.1%)	7 (17.1%)	
- Driver	6 (14.6%)	7 (17.1%)	
- Farmer	10 (24.4%)	9 (22.0%)	
- House wife	6 (14.6%)	6 (14.6%)	
- Manual labourer	7 (17.1%)	8 (19.5%)	
- Weaver	5 (12.2%)	4 (9.8%)	
Site of Affection#	0.122		
- Right	25 (61.0%)	18 (43.9%)	
- Left	16 (39.0%)	23 (56.1%)	
KL Grade#	0.154		
- Grade 3	31 (75.6%)	25 (61.0%)	
- Grade 4	10 (24.4%)	16 (39.0%)	
BMI (kg/m²) *	28.3± 2.1	27.9± 2.3	0.194
VAS Score*	7.44 ± 0.27	7.54 ± 0.28	0.108
WOMAC Score*	80.51 ± 2.63	79.61 ± 3.58	0.197

Table 2: Comparison of Outcome Measures in the Cryoablation Group From Baseline to 1 Week, 4 Weeks, 12 Weeks and 24 Weeks

Time Point	Cryoablation Group (n=41)	
	VAS Score	WOMAC Score
Baseline	7.44 ± 0.27	80.51 ± 2.63
Week 1	5.02 ± 0.49	60.10 ± 0.50
Week 4	3.49 ± 0.49	44.93 ± 0.42
Week 12	2.52 ± 0.47	30.02 ± 0.42
Week 24	1.52 ± 0.35	20.02 ± 0.52
p-value*	<0.001	<0.001

Table 3: Comparison of Outcome Measures in the Steroid and Local Anaesthetic Group from Baseline to 1st Weeks, 4th Weeks, 12th Weeks and 24th Weeks

Time Point	Minimally invasive percutaneous steroid and local anaesthetic injection Group (n=41)	
	VAS Score	WOMAC Score
Baseline	7.54 ± 0.28	79.61 ± 3.58
Week 1	5.46 ± 0.47	65.39 ± 0.45
Week 4	4.55 ± 0.53	54.61 ± 0.47
Week 12	3.95 ± 0.42	49.88 ± 0.41
Week 24	3.47 ± 0.54	44.98 ± 0.45
p-value*	<0.001	<0.001

Table 4: Comparison of Mean Changes of VAS Between the Two Groups from Baseline to 1st Week, 4 Weeks, 12 Weeks and 24 Weeks Follow-up

Time Point	Cryoablation (Mean ± SD)	Steroid Block (Mean ± SD)	p-value*
Baseline	7.444 ± 0.267	7.541 ± 0.278	0.108
Week 1	2.429 ± 0.370	2.081 ± 0.420	<0.001
Week 4	3.959 ± 0.424	2.995 ± 0.434	<0.001
Week 12	4.922 ± 0.415	3.590 ± 0.389	<0.001
Week 24	5.920 ± 0.384	4.068 ± 0.363	<0.001

Table 5: Comparison of Mean Changes of WOMAC Between the Two Groups from Baseline to 1st Week, 4 Weeks, 12 Weeks and 24 Weeks Follow-up

Time Point	Cryoablation	Steroid Block	p-value
Baseline	80.51 ± 2.63	79.61 ± 3.58	0.197
Week 1	20.415 ± 3.633	14.220 ± 5.121	<0.001
Week 4	35.585 ± 4.478	25.000 ± 4.995	<0.001
Week 12	50.488 ± 3.912	29.732 ± 4.561	<0.001
Week 24	60.488 ± 4.342	34.634 ± 5.053	<0.001

DISCUSSION

The present study was performed to compare between two non-surgical intervention that were steroid and local anaesthetic block and cryoablation of genicular nerves for pain management and functional improvement in grade 3 and 4 osteoarthritis of knee.

Fifty-six patients (68%) of the participants that complained of knee pain had radiological OA KL grading 3, while only 32% (n=26) had KL grade 4. Although it has been said that radiological OA shows poor correlation with knee pain, study by Neogi T et al[13] has mentioned that a factor can be strongly causally associated with an outcome, yet it may be not be a strong predictor of the outcome on its own because several other factors may contribute to the outcome. This is partially true when studying pain, which is a subjective experience and unique to each and cause for pain in knee OA is not only because of cartilage degeneration and inflammation but also by a) Inflammation of synovium, b) microfracture of subchondral bone or medullary hypertension caused by distortion of blood flow by thickened subchondral trabeculae, c) stretching of nerve endings in the periosteum covering osteophytes, d) inflammation, distension and stretching due to joint instability, e) stretching of ligaments due to joint instability, and f) muscle spasm[14].

In this study, the group who received cryoablation of genicular nerves showed decrease in VAS score from 7.44± 0.27 at baseline to 5.02± 0.49 at 1 week and 1.52±0.35 at 24 weeks. Group B receiving steroid and local anaesthetic also showed decrease in VAS score 7.54± 0.28 at baseline to 5.46±0.47 at 1 week and 3.47± 0.54 at 24 weeks. Maximum improvement was seen in both the groups at 1 week, however at 24 weeks, cryoablation group had better pain relief than steroid and local anaesthetic block. This finding is comparable to the study by Perry TA et al[15], who reported that the addition of steroid prolongs the action of local anaesthetic by causing vasoconstriction and slowing absorption; however, in our study, the effect lasted only for 12 weeks. Comparison of VAS scores between demonstrated statistically significant improvement in both groups at baseline and at 24 weeks; however, the cryoablation group achieved superior and more sustained pain relief over the 24-week follow-up (mean difference 5.92 ± 0.38 vs. 1.85; $p < 0.05$). Consistent results were found with WOMAC sub scores and total score. WOMAC score decreased from 80± 2.63 to 60± 0.50 at 1 week and 20.02 ± 0.52 at 24 weeks in cryoablation group. This shows that pain and function are directly related as improvement in the pain leads to ease in performing daily activities, hence better functional score. Das et al[16] also found similar finding of improvement in WOMAC with pain improvement after cryoablation.

Our study showed cryoablation offered superior and sustained pain relief and functional improvement in all the follow ups. Cryoablation uniquely disrupts pain pathways while preserving nerve structure, enabling natural regeneration. Robust evidence to support the integration of cryoablation into treatment guidelines for advanced OA. Kim et al[17] evaluated cryoablation's impact on pain relief using the VAS at 12 weeks. The study reported significant and sustained reductions in pain compared to traditional nerve blocks, establishing cryoablation as a reliable option for OA management. Lee et al[18] assessed both pain and function in OA patients using VAS and WOMAC scores. With follow-ups at 1, 4, and 12 weeks, the study demonstrated substantial improvements in mobility and joint function, confirming the safety and efficacy of cryoablation. Chen et al[20] conducted a six-month follow-up study using VAS and WOMAC as outcome measures. The findings highlighted cryoablation's long-term benefits in pain relief and functional improvement with minimal adverse effects. There were few cases reported increased pain after procedure, managed conservatively, other side effects are vascular injury, swelling which are self-limiting.

Limitations of the study include the small sample size, single-centre design, relatively short follow-up period, and blinding and the exclusion of patients with KL grade 1 and 2. Future recommendations based on our study include conducting larger multicentre trials with longer follow-up to evaluate long-term efficacy, safety, and cost-effectiveness.

CONCLUSION

The study found that both fluoroscopy-guided cryoablation of the genicular nerve and steroid and local anaesthetic block of the genicular nerves provided pain relief and functional improvement in all follow-up assessments. However, fluoroscopy- guided cryoablation demonstrated superior and sustained pain relief and functional improvement compared to steroid and local anaesthetic blocks from the first week to 24 weeks. Therefore, cryoablation of the genicular nerves is a minimally invasive, safe, and effective alternative for

patients who are unfit for or unwilling to undergo surgery. It is revolutionizing the non-surgical management of advanced knee osteoarthritis with precision and long-term efficacy.

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Conflict of Interest
None declared.

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