



Comparison of Cooled Radiofrequency Ablation and Genicular Nerve Blockade for the Treatment of Osteoarthritic Knee Pain: A Prospective Randomized Double-Blind Study

Samer Khojah¹, Eyad Mitwali¹, Osama AlAhdal², Abdullah Kaki^{3*}

¹Department of Anesthesia, King Abdullah Medical City, Makkah, Saudi Arabia; ²Department of Pain Medicine, International Medical Center, Jeddah, Saudi Arabia; ³Department of Anesthesiology and Pain management, King Abdulaziz University Hospital, Jeddah, Saudi Arabia

ABSTRACT

Background: Osteoarthritis is a chronic degenerative disease that can represent a source of significant pain. When conservative therapies fail to relieve the pain and surgery is not an option. Other choices like Genicular Nerve Blockade (GNB) using a mixture of local anesthetic agents and steroids or genicular nerve ablation using a Cooled Radio Frequency Ablation (CRFA) will be the option.

Methods: In this prospective randomized double-blind study, 41 patients with chronic osteoarthritic knee pain were randomly assigned to either CRFA (n=21) of genicular nerves or GNB (n=20) at the superomedial, superolateral, and inferomedial aspects of the knee. Pain status and patient function were assessed using numerical pain score and Sfax Western Ontario McMaster Universities Osteoarthritis (WOMAC) index respectively, at 3, 6, 9, and 12 months after the intervention.

Results: The mean age of the patients was 71.2 ± 9.5 (mean $\pm$ SD) years, with marked female dominance (73.2%). Severity of pain, WOMAC score, or the used medications were not significantly different between the groups ($p > 0.05$). Reduction in the average pain score and WOMAC index ($p < 0.05$) after the intervention was significantly different within the groups but not between the groups ($p > 0.05$). Pain relief lasted for a significantly longer duration in CRFA patients (6.8 ± 4.61 months) than in GNB patients (2.9 ± 1.17 months) ($p < 0.05$). There were no reported complications.

Conclusions: Both CRFA and GNB were significantly effective in reducing pain and improving the function of knee osteoarthritis; however, CRFA is superior to GNB regarding the duration of pain relief.

Keywords: Knee pain; Osteoarthritis; Cooled radiofrequency; Genicular nerve blockade; Pain relief

INTRODUCTION

Osteo-Arthritis (OA) is a chronic degenerative disease that can represent a source of significant pain, disability, and reduced quality of life [1]. Osteoarthritic knee pain is an independent risk factor for early mortality and thus, reducing pain due to knee OA is a global health concern [2]. When conservative therapies fail to solve the problem, Total Joint Replacement (TJR) surgery is the last resort for severe OA of knee joints. Not all patients are candidates for such a procedure. Comorbidities, age, or other factors could discourage the orthopedic surgeon from proceeding with TJR [3].

There is a limited number of treatment options available for patients who are not candidates for TJR and/or for whom pharmacological therapy is either ineffective or interferes with their quality of life. Intra-Articular Steroid (IAS) injection provides notable short-term pain relief but requires multiple treatments to maintain efficacy, which in turn increases the risk for serious adverse events such as septic arthritis and may exacerbate cartilage destruction [3-5]. Visco-supplementation, which shows moderate effectiveness, is not recommended in the treatment paradigm for knee OA by most societies due to limited supporting data [4,6].

Correspondence to: Abdullah Kaki, Department of Anesthesiology and Pain management, King Abdulaziz University Hospital, Jeddah, Saudi Arabia, E-mail: amkaki@yahoo.com

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The knee is innervated by branches of several nerves, including the tibial, femoral, saphenous, obturator, and common peroneal nerves. These nerve branches surround the knee from all directions and are called the genicular nerves [7].

Generally, a diagnostic Genicular Nerve Block (GNB) using local anesthetic agents with or without steroids is performed before Radio-Frequency Ablation (RFA) of genicular nerves of the knee, and a positive response to GNB is considered as a good indicator for RFA. However, one study suggested that GNB, when administered together with a corticosteroid, is as effective as RFA of genicular nerves in controlling the pain after knee arthroplasty [8]. Despite this and other reports in which adjuvant corticosteroid therapy could contribute to and prolong the analgesic effect of the local anesthetic, the analgesic effect of corticosteroids on a peripheral nerve block remains controversial [9-12].

On the other hand, Cooled Radio-Frequency Ablation (CRFA) has been introduced to the medical field in the last few years and has shown good pain relief in spine-related conditions for at least 12 months [13-16]. Recently, the use of CRFA as a minimally invasive treatment option for pain relief of knee OA has emerged [17]. CRFA of the genicular nerves seems to be a safe and effective therapy for managing intractable knee OA pain. The procedure is performed using a thermal probe that is directed using fluoroscopy or ultrasound guidance to well-described and validated bony landmarks in the paths of the genicular nerves. A current is applied through the probe to induce a thermal injury to the targeted nerve, which in turn disrupts the nerve signals of pain sensation arising from the knee capsule [18].

We conducted this prospective randomized double-blind study to compare the analgesic effect of CRFA of genicular nerves to GNB using a mixture of local anesthetic agents and methylprednisolone on knee osteoarthritic pain.

MATERIAL AND METHODS

Following the principles of the declaration of Helsinki, a prospective randomized double-blind study was conducted at two tertiary care centers in Jeddah, Saudi Arabia: King Abdulaziz University Hospital, and the International Medical Center. After approval from the Research and Ethics Committee (approval number 214-20, dated April 20, 2020), 41 patients with knee OA provided written informed consent to participate in this randomized double-blind study. Patients aged 40 years or above with signs and symptoms of knee OA presenting with pain for 6 months or longer that is unresponsive to conservative therapy (oral medications, physical therapy, and IAS injection or visco-supplementation) and confirmed by physical examination and radiological examinations were included in the study. Patients with causes of knee pain besides OA, those with a bleeding tendency or allergy to the study medications, those with diabetes and polyneuropathy of lower limbs, those with previous knee RFA therapy, and those undergoing TJR were excluded from the study.

Study design

Forty one patients with confirmed osteoarthritic knee pain were included in the study. Patients were randomized into two groups using computer-generated randomization. Patients were blinded to the treatment option. CRFA of genicular nerves and GNB were performed for group I and group II, respectively. The intensity of pain at rest was measured with a Numerical Rating Scale (NRS)

with 11 points from 0 to 10 (0=no pain, 10=most severe pain ever experienced). The use of NRS to assess the severity of pain was described to the subjects. Sfax modified Western Ontario and McMaster's Universities Osteoarthritis (WOMAC) index was used to assess the function of the knee and reflect the patient satisfaction after the intervention. It was explained to the patient prior to the procedure. In group I, CRFA utilizing the coolief system (Halyard Inc, Alpharetta, Georgia) was performed at the superomedial and inferomedial genicular branches of the saphenous nerve and the superolateral branch of the femoral nerve after the patient was placed in the supine position and the skin and soft tissue were anesthetized with 1% lidocaine. A 75 mm or 100 mm, 17-gauge radiofrequency needle was inserted in the proper locations. Needle position was confirmed with a true lateral fluoroscopic examination showing the accurate position of the probe at depth correlated with the middle of the femur and tibia shaft on lateral views at the diaphyseal-metaphyseal junction. An internally cooled 4 mm, 18-gauge active tip electrode was introduced through the needle and position was confirmed with anteroposterior and lateral fluoroscopic views.

Motor stimulation at 2 V was performed to exclude any muscular twitch and sensory stimulation at 0.5 V or less was initiated to ensure proximity of the probe to the aimed nerves in all three points. Three milliliters of 2% lidocaine were injected at each point *via* the inserted needle prior to CRFA at 60°C for 2.5 min. Then, the needle was removed, and the study subjects were observed for 30 min in the post anesthesia care unit before being discharged home. No local anesthetic agent or steroid was injected at the end of the procedure to ensure the proper comparison between the two techniques. Patients were instructed to continue their current medication (either Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or weak opioids) for any post-procedure pain as a rescue medicine.

In group II, the patients underwent fluoroscopically guided GNB. A 22-gauge spinal needle was used to inject 3 ml of bupivacaine 0.5% mixed with 12 mg of methylprednisolone acetate in the middle of the femur and tibia shaft, at each point of the superomedial, inferomedial, and superolateral aspects. Similar to the positioning of CRFA needles. Aspiration of blood was checked before the injection of the study medication.

NRS score and WOMAC questionnaire was completed by a blind observer to assess the reduction of pain and the improvement in the function at 3, 6, 9, and 12 months after the intervention. In addition to demographic data, clinical data were reported on a data collection sheet.

We adapted a validated Arabic version of the WOMAC index to evaluate the limitation of physical function, but we excluded the questions related to pain intensity and specific joint stiffness. This scale consists of nine questions for the assessment of physical function. All items are rated on a four-point score (0 to 4) for a total of 36 points, developed to help in the assistance of the subject's functionality post procedures [19]. Complications related to the procedure were reported. All patients were approached *via* phone call for 9 and 12-month assessments without any dropouts.

Statistical analysis

Data were coded and analyzed using SAS version 9.4 (SAS Institute Inc.). Qualitative variables are summarized and presented as frequency distribution using bar charts. For quantitative data, a

test for normality was initially carried out using the one-sample Kolmogorov Smirnov test. Normally distributed variables are presented in mean and standard deviation, while non-normally distributed variables are presented as median and Inter-Quartile Range (IQR), with boxplot graphs for distribution of data. The chi-square test was used to test the significance of categorical variables. For normally distributed quantitative variables, an independent sample t-test was used to find the differences in mean and standard deviation between the two groups; the Mann Whitney test was used for non-normally distributed quantitative variables. Wilcoxon test was used to test for significance in the pre and post-intervention changes. $p < 0.05$ was considered statistically significant.

RESULTS

Forty-one patients with knee OA were randomly assigned to one of two arm interventions, either CRFA (n=21) or GNB (n=20), the pre and post-intervention clinical features and the outcome of the intervention in the patients were assessed.

Table 1 show that the mean age of the patients was 71.2 ± 9.5 years, with marked dominance of female (73.2%), Saudi (82.9%), married (73.2%), unemployed (65.9%) and non-smoker (82.9%) patients. Overall, there was no significant difference between the two groups regarding socio-demographic characteristics ($p > 0.05$).

Table 1: Comparison of demographic characteristics of patients according to type of intervention.

Variables	Study group intervention			P values
	CRFA (n=21)	GNB (n=20)	Total	
Gender*				0.095
Male	8 (38.1%)	3 (15.0%)	11 (26.8)	
Female	13 (61.9%)	17 (85.0%)	30 (73.2%)	
Age**				0.102
Mean ± SD	74.0 ± 7.54	69.2 ± 10.82	71.2 ± 9.5	
Nationality*				0.053
Saudi	15 (71.4%)	19 (95.0%)	34 (82.9%)	
Non Saudi	6 (28.6%)	1 (5.0%)	7 (17.1%)	
Education level*				0.51
Elementary	9 (42.9%)	6 (30.0%)	15 (36.6%)	
High school	7 (33.3%)	6 (30.0%)	13 (31.7%)	
University & postgraduate	5 (23.8%)	8 (40.0%)	13 (31.7%)	
Marital status*				0.796
Married	15 (71.4%)	15 (75.0%)	30 (73.2%)	
Single/divorced/ widowed	6 (28.6%)	5 (25.0%)	11 (26.8%)	
Employment*				0.44
Employed	6 (28.6%)	8 (40.0%)	14 (34.1%)	
Unemployed	15 (71.4%)	12 (60.0%)	27 (65.9%)	

Smoking status*				
Non smoker	16 (76.2%)	18 (90.0%)	34 (82.9%)	0.24
Ever smoker	5 (23.8%)	2 (10.0%)	7 (17.1%)	

Note: *Based on chi-square test; **Based on independent samples test.

Abbreviation: CRFA: Cooled Radio-Frequency Ablation; GNB: Genicular Nerve Block.

Clinically, most patients were either obese (41.5%) or morbidly obese (31.7%), and almost half of them were in a wheelchair (48.8%). Regarding comorbidities, 75.6% of patients were diagnosed as hypertensive, and one third as diabetic (31.7%). Rheumatological illness and joint injury were reported in 73% of patients. There was no significant difference between the two study groups regarding clinical characteristics ($p > 0.05$) as shown in Table 2.

Table 2: Comparison of clinical characteristics of patients according to type of intervention.

Variables	Study group intervention			P*values
	CRFA (n=21)	GNB (n=20)	Total	
Mobilization				
Walking but in pain	4 (19.0%)	5 (25.0%)	9 (22.0%)	0.866
Using walking aids	6 (28.6%)	6 (30.0%)	12 (29.3%)	
Using wheelchair	11 (52.4%)	9 (45.0%)	20 (48.8%)	
BMI categories				
Normal & overweight	5 (23.8%)	6 (30.0%)	11 (26.8%)	0.328
Obese	11 (52.4%)	6 (30.0%)	17 (41.5%)	
Morbid obesity	5 (23.8%)	8 (40.0%)	13 (31.7%)	
Hypertensive				
Yes	17 (81.0%)	14 (70.0%)	31 (75.6%)	0.484
No	4 (19.0%)	6 (30.0%)	10 (24.4%)	
Diabetic				
Yes	7 (33.3%)	6 (30.0%)	13 (31.7%)	0.819
No	14 (66.7%)	14 (70.0%)	28 (68.3%)	
Rheumatological illness				
Yes	2 (9.5%)	1 (5.0%)	3 (7.3%)	0.519
No	19 (90.5%)	19 (95.0%)	38 (92.7%)	
Joint injury				
Yes	0 (0.0%)	3 (15.0%)	3 (7.3%)	0.107
No	21 (100.0%)	17 (85.0%)	38 (92.7%)	
Other comorbidities				
Yes	10 (47.6%)	9 (45.0%)	19 (46.3%)	0.558
No	11 (52.4%)	11 (55.0%)	22 (53.7%)	

Note: *Based on chi-square test. **Abbreviation:** CRFA: Cooled Radio-Frequency Ablation; GNB: Genicular Nerve Block.

Table 3 demonstrates that almost one-half of the patients were categorized as having severe OA (stage IV), either on the right (53.7%) or left knee (46.3%). The median WOMAC index was 25 (IQR:19.5-28) and the pain score in right and left knee was 4 (IQR: 4;4-5) with no significant difference between the two groups. The duration of pain ranged from less than 1 year up to more than 10 years, which was constant in 39.0% of patients and worsened with activities to the extent that 82.9% of patients expressed that pain was limiting their activities. In 46.3% of patients, the pain was waking them up from sleep, with no statistical significance between the two groups ($p>0.05$).

Table 3: Comparison of pre-intervention clinical assessment of patients according to type of intervention.

Variables	Study group intervention			P values
	CRFA (n=21)	GNB (n=20)	Total	
Severity of osteoarthritis (right)				
Minimal (Stage I)	0 (0.0%)	3 (15.0%)	3 (7.3%)	NA
Mild (Stage II)	1 (4.8%)	0 (0.0%)	1 (2.4%)	
Moderate (Stage III)	11 (52.4%)	4 (20.0%)	15 (36.6%)	
Severe (Stage IV)	9 (42.9%)	13 (65.0%)	22 (53.7%)	
Severity of osteoarthritis (left)				
Minimal (Stage I)	0 (0.0%)	1 (5.0%)	1 (2.4%)	NA
Mild (Stage II)	2 (9.5%)	2 (10.0%)	4 (9.8%)	
Moderate (Stage III)	10 (47.6%)	7 (35.0%)	17 (41.5%)	
Severe (Stage IV)	9 (42.9%)	10 (50.0%)	19 (46.3%)	
WOMAC score; median (IQR)	24 (17-26.5)	25.5 (23.3-28.8)	25 (19.5-28)	0.182
Pain scale right; median (IQR)	4 (4-4.5)	4 (4-6)	4 (4-5)	0.089
Pain scale left; median (IQR)	4 (4-5)	4 (3-5)	4 (3-5)	0.715
Duration of pain				
≤ 1 year	2 (9.5%)	4 (20.0%)	6 (14.6%)	NA
3 years	7 (33.3%)	1 (5.0%)	8 (19.5%)	
5 years	7 (33.3%)	6 (30.0%)	13 (31.7%)	
7-10 years	1 (4.8%)	6 (30.0%)	7 (17.1%)	
>10 years	4 (19.0%)	3 (15.0%)	7 (17.1%)	
Frequency of pain				
Constant	9 (42.9%)	7 (35.0%)	16 (39.0%)	0.606
Episodic	12 (57.1%)	13 (65.0%)	25 (61.0%)	
Worsening of pain with activity				
Strongly agree	12 (57.1%)	8 (40.0%)	20 (48.8%)	0.272
Somewhat agree	9 (42.9%)	12 (60.0%)	21 (51.2%)	

Pain limits activities				
Yes	18 (85.7%)	16 (80.0%)	34 (82.9%)	0.687
No	3 (14.3%)	4 (20.0%)	7 (17.1%)	

Pain interferes with sleep				
Sleep comfortably	11 (52.4%)	11 (55.0%)	22 (53.7%)	0.867
Wake up because of pain	10 (47.6%)	9 (45.0%)	19 (46.3%)	

Abbreviation: CRFA: Cooled Radio-Frequency Ablation; GNB: Genicular Nerve Block.

The overwhelming majority of the patients (97.6%) were using pain medications, mostly NSAIDs (61.0%), acetaminophen (46.3%) and tramadol (48.8%) with no significant difference between the two groups ($p>0.05$). On the other hand, while a significantly higher proportion of the patients in group II were using opioids (60.0%), a significantly higher proportion of patients who underwent CRFA (66.7%) were using topical medications ($p<0.05$). Only seven patients reported that they had attempted other treatment modalities such as IAS injection (9.8%), intra-articular platelet-rich plasma injection (4.9%), and intra-articular hyaluronic acid injection (2.4%) (Table 4).

Table 4: Comparison of study patients according to medications used before intervention and treatment modalities.

Medications and treatment modalities	Study group intervention			P*values
	CRFA (n=21)	GNB (n=20)	Total	
Medications				
Pain medications	21 (100.0%)	19 (95.0%)	40 (97.6%)	0.488
Tramadol	12 (57.1%)	8 (40.0%)	20 (48.8%)	0.272
Opioid	4 (19.0%)	12 (60.0%)	16 (39.0%)	0.007
NSAIDs	10 (47.6%)	15 (75.0%)	25 (61.0%)	0.071
Acetaminophen	9 (42.9%)	10 (50.0%)	19 (46.3%)	0.647
Antidepressant	8 (38.1%)	4 (20.0%)	12 (29.3%)	0.203
Anticonvulsant	12 (57.1%)	7 (35.0%)	19 (46.3%)	0.155
Topical	14 (66.7%)	5 (25.0%)	19 (46.3%)	0.006
Transdermal patch	2 (9.5%)	2 (10.0%)	4 (9.8%)	0.678
Other attempted modalities				
Intra-articular hyaluronic acid injection	0 (0.0%)	1 (5.0%)	1 (2.4%)	NA
Intra-articular platelet rich plasma injection	1 (4.8%)	1 (5.0%)	2 (4.9%)	
Intra-articular steroid injection	3 (14.2%)	1 (5.0%)	4 (9.8%)	
None	17 (81.0%)	17 (85.0%)	34 (82.7%)	

Note: *Based on chi-square test. **Abbreviation:** CRFA: Cooled Radio-Frequency Ablation; GNB: Genicular Nerve Block.

There was no significant difference between the two study groups regarding their demographic and clinical characteristics, which might indicate a good matching between the two groups. The differences in the outcome between the two groups might be attributed to the type of intervention.

Figure 1 illustrates that the interventions were performed mainly bilaterally in the two groups. Table 5 and Figure 2 show that there was a significant reduction in the average pain score after the intervention within the two groups either on the right or left knee, with a significant reduction in the WOMAC index ($p < 0.05$). The comparison for the magnitude of reduction in pain and WOMAC index (difference between pre and post-intervention scores) revealed that there was no significant difference between the two study groups ($p > 0.05$). Most patients expressed that there was an improvement in their function and a decrease or no change in intake of pain medication. Almost three-quarters of them reported that they were satisfied, with no significant difference between the two groups ($p > 0.05$).

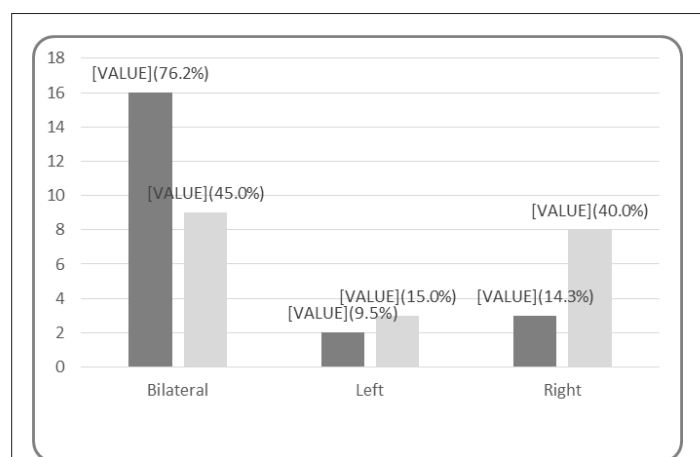


Figure 1: Side of the procedure according to the study patients. Note: (■) C-RFA; (■) GNB.

Table 5: Comparison of outcome of patients according to type of intervention.

Variables	Study group intervention			P values
	CRFA (n=21)	GNB (n=20)	Total	
Pain scale right; median (IQR)				
Pre-intervention	4 (4-4.5)	4 (4-6)	4 (4-5)	0.66
Post-intervention	2 (1.5-3)	2 (1.25-3)	2 (1.5-3)	
P	<0.001	0.001	<0.001	
Average reduction	2 (0.5-3)	3 (0-3)	2 (0-3)	
Pain scale left; median (IQR)				
Pre-intervention	4 (4-5)	4 (3-5)	4 (3-5)	0.595
Post-intervention	2 (1-3.5)	2 (1.25-4)	2 (1-4)	
P	<0.001	0.003	<0.001	
Average reduction	2 (0.5-3)	1.5 (0-2.75)	2 (0-3)	

WOMAC score; median (IQR)				
Pre-intervention	24 (17-26.5)	25.5 (23.3-28.8)	25 (19.5-28)	0.785
Post-intervention	13 (8-19.5)	15.5 (11.25-26.75)	14 (9-24.5)	
P	<0.001	0.001	<0.001	
Average reduction	7 (4-11)	7 (9-12.75)	7 (2.5-12)	
Patient functionality				
Improved	15 (71.4%)	13 (65.0%)	28 (68.2%)	NA
No change	5 (23.8%)	4 (20.0%)	9 (22.0%)	
Worsened	1 (4.8%)	3 (15.0%)	4 (9.8%)	
Pain medication				
Decreased	10 (47.6%)	6 (30.0%)	16 (39.0%)	NA
No change	11 (52.4%)	9 (45.0%)	20 (48.8%)	
Increased	0 (0.0%)	5 (25.0%)	5 (12.2%)	
Satisfaction				
Satisfied	15 (71.4%)	15 (75.0%)	30 (73.2%)	0.796
Not satisfied	6 (28.6%)	5 (25.0%)	11 (26.8%)	

Abbreviation: CRFA: Cooled Radio-Frequency Ablation; GNB: Genicular Nerve Block.

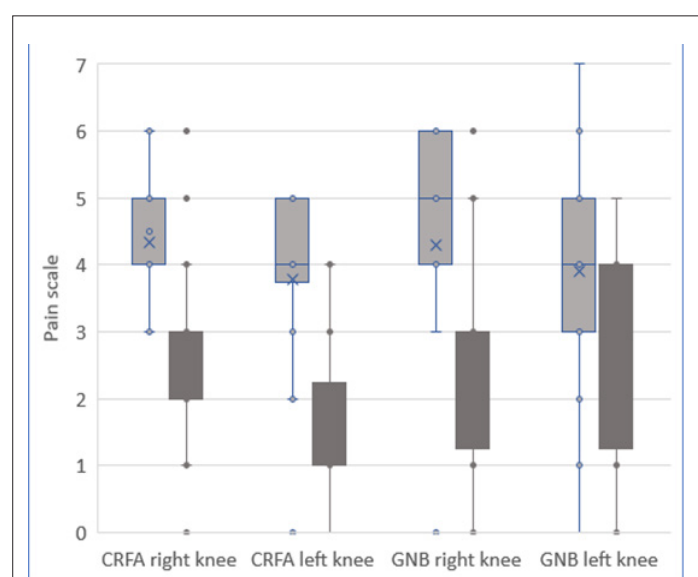


Figure 2: Pre-post intervention changes in pain scores according to side and study groups. Note: (■) Pre; (■) Post.

Figure 3 displays the average duration of pain relief in months after the intervention. Pain relief lasted for a significantly longer

duration in CRFA patients (mean $\pm$ SD; 6.8 ± 4.61 months) than in GNB patients (2.9 ± 1.17 months) ($p < 0.05$).

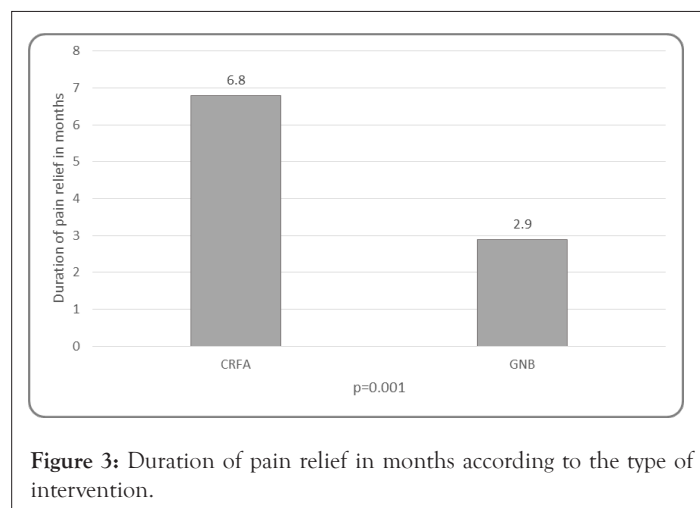


Figure 3: Duration of pain relief in months according to the type of intervention.

None of the patients in either group reported any post procedure complications such as muscle weakness, paresthesia, or neuralgia.

DISCUSSION

The main finding of our study is the comparative effect of both CRFA and GNB on pain reduction and function improvement, but with a significantly longer duration of effect of CRFA. The ability of CRFA to decrease pain and improve daily function in patients with OA of the knee has been well established in previously published studies [16,17]. Qudsi-Sinclair et al. reported a reduction in pain and improvement of function during the first 3-6 months in patients with chronic pain post total knee arthroplasty, using both the conventional RFA of genicular nerves and GNB with local anesthetic and steroid [8]. However, we reported a longer duration of pain relief in the CRFA group, which might be related to bigger lesion size resulting from CRFA, documented in a previously published study [20].

In contrary to conventional radiofrequency, CRFA is a novel technology that utilizes thermal ablative mechanisms to create a greater neuronal lesion and increase the chance of effective denervation [21]. The effectiveness and safety of CRFA in relieving pain and improving function in patients with symptomatic knee OA has been demonstrated in a randomized clinical trial [17,21].

In several systematic reviews and meta-analyses, the addition of steroids to local anesthetic agents during peripheral nerve blockade provided a better quality of postoperative analgesia and lower pain scores [22-24].

Carlone et al. reported that patients with self-reported psychological comorbidities, smoking history, and diabetes mellitus were significantly more likely to not respond to GNB. They suggested that these failures are not related to technical factors, but rather patient-specific peripheral and central pain processing [25]. This is in conflict with the finding of our study in which patients with diabetes had a good response to GNB. Selection bias cannot be ruled out, particularly in studies with small sample sizes, which requires further studies for clarification.

CONCLUSION

Targeting the genicular nerve branches has had a profound clinical benefit in controlling knee osteoarthritic pain. Both CRFA and

GNB are significantly effective in reducing pain and improving the function of knee OA; however, CRFA is superior to GNB regarding the duration of pain relief. Both techniques provide novel promising treatment options for patients not responding to conservative therapies and not suitable for surgical treatment.

LIMITATIONS OF STUDY

The small sample size is one of the limitations of our study. Furthermore, power analysis was not performed as we could not estimate the prevalence of patients who would respond to the block or ablation. Despite these limitations, this is the first publication comparing CRFA to GNB among knee OA patients.

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