



Randomised Controlled Trial

Ultrasound-guided monopolar versus bipolar radiofrequency ablation for genicular nerves in chronic knee osteoarthritis pain: A randomized controlled study

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ABSTRACT

Background: This study compared between monopolar and bipolar radiofrequency (RF) ablation of the genicular nerves using ultrasound guidance (USG) in chronic knee osteoarthritis pain.

Material and methods: This was a prospective, randomized, double-blind study. Fifty patients with knee osteoarthritis pain were equally randomized to either monopolar or bipolar groups. The primary outcome was visual analogue score (VAS). The secondary outcomes were the proportion of successful responders with a reduction of 50% of VAS score at 12 and 24 weeks, the procedure time and pain and oxford knee score (OKS). VAS and OKS were recorded at 1, 4, 12, 24 weeks after intervention. Any complications were reported.

Results: Mean VAS score in bipolar group was ($p < 0.05$) lower than monopolar group at 12 weeks [4.84 ± 0.62 Vs. 3.56 ± 0.71] and 24 weeks [5.44 ± 0.82 Vs. 3.96 ± 0.79]. The Proportion of successful responders with a reduction of at least 50% of VAS score were more in bipolar group than monopolar group at 12 weeks (80% Vs. 12%) and 24 weeks (44% Vs. 4%). Mean OKS score in bipolar group was ($p < 0.05$) lower than monopolar group at 12 weeks [26 ± 3 Vs. 34 ± 3] and 24 weeks [27 ± 3 Vs. 35 ± 3]. The procedure time and pain were ($p < 0.05$) lower in monopolar than bipolar group. The complications were similar in both groups.

Conclusion: USG bipolar RF ablation is more effective than monopolar RF ablation in controlling knee osteoarthritis pain as for the duration and severity of pain without fluoroscopic confirmation.

1. Introduction

Knee osteoarthritis (OA) leads to significant morbidity as pain, stiffness and sleep disturbance [1–3]. Patients with knee pain are offered many treatments, as analgesics, acupuncture or corticosteroid injections [4]. Total knee arthroplasty is a treatment for cases failed to respond to conservative treatments. It is of limited use in high-risk patient [5].

Knee joint is a modified hinge joint with patellofemoral and femorotibial joints [6,7]. It receives nerve supply from the common peroneal, tibial, femoral, Saphenous and the obturator nerves to form the genicular nerves [8].

Radiofrequency ablation (RFA) appears to be effective for treatment of knee pain [9,10]. It acts by interrupting the pain conduction through production of a thermal lesion to interrupt nociceptive signals [11]. A diagnostic genicular nerve block with local anesthetic is performed before genicular nerve RFA, and a positive result indicates the need for genicular RFA [12].

RFA of genicular nerves for knee pain can be done either by fluoroscope or ultrasound. Several studies have reported the effective treatment with RFA under ultrasound guidance instead of fluoroscope. Ultrasound has become used in peripheral nerves localization [13].

Ultrasonography has numerous advantages over fluoroscopy as it is easily repeatable, inexpensive, portable, does not expose the patient or physician to ionizing radiation and is based on anatomical studies that demonstrate that genicular nerves are accompanied by genicular arteries where fluoroscope depend on bony land mark not soft tissue and the genicular nerves have high degree of variability of their courses through the knee [14]. RFA using ultrasound yields significant decrease in knee pain [15].

In conventional monopolar RFA technique, the energy occurs between the intervention needle tip and the grounding plate so the size of the lesion become small [16]. In bipolar RFA, the energy is locally produced between the active and the grounding electrodes on the needle tip so the lesion size become larger than monopolar ablation [17].

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Cooled RFA increase the lesion size to increase the success rate of the genicular nerve ablation by keeping the surrounded tissue temperature at lower level [16].

We hypothesized that, bipolar RFA of genicular nerves is an effective treatment to reduce knee pain compared with monopolar RFA using USG without fluoroscopic confirmation. The primary objective was the knee pain at 1, 4, 12 and 24 weeks after the procedure. The secondary objectives included the proportion of successful responders with a decrease of 50% of VAS score, the procedure time and pain, OKS and the incidence of complication.

2. Material and methods

This prospective randomized double blinded controlled study was carried out from October 2020 to September 2021 after approval by our faculty of medicine local ethical and scientific committee number (MD.19.03.152) registered at clinical [trials.gov](https://www.clinicaltrials.gov) with unique ID, NCT04112264 and obtaining a written informed consent from each patient.

Diagnosis of knee OA: 1) History: pain, stiffness and reduced range of movement. 2) Clinical examination: tenderness, effusion and ligament instability [18]. 3) Investigation: plain radiography is the gold standard for the diagnosis of knee OA [19].

This study included patients with one chronic knee osteoarthritis pain not responding to other treatments as physiotherapy, oral analgesics, and intraarticular injection with hyaluronic acids or steroids and with Kellgren–Lawrence grade (2–4). Patients with prior knee surgery, acute knee pain, intra-articular knee corticosteroid in the past 3 months, anticoagulant medication use were excluded. This study was reported in line with CONSORT statement [20].

Patients with chronic knee osteoarthritis pain were randomly allocated by computer generated random numbers and concealed opaque envelopes to one of two groups, monopolar and bipolar groups as shown in patients randomization flow chart (Fig. 1). All the preoperative

baseline and post-procedure outcome measurements at 1, 4, 12 and 24 weeks were performed by an independent physician who was blinded for the type of treatment used. The patients also were not aware of the type of treatment received.

Diagnostic nerve block; It was performed one week before radio-frequency ablation to exclude other causes of connective tissue disease that affect the knee. Lidocaine (2 mL of 2%) which is a local anesthetic was injected at each site of three main genicular nerve under ultrasound guidance. The response was recorded as a positive result if the patient showed a reduction in VAS scores on movement of at least 50% for more than 24 h for one positive diagnostic block.

Genicular nerve radiofrequency ablation; Patients were admitted to the preoperative unit 15 min before the intervention. After intravenous access is established, all patients were monitored by electrocardiogram, non-invasive blood pressure and peripheral oxygen saturation. The intervention was performed by an experienced investigator. The diseased knee joint was sterilized by antiseptic solution and enclosed with sterile drapes. The three main articular nerves were identified by the help of high-frequency (6–13 Hz) linear probe instead of fluoroscope.

The first one is the superior lateral articular nerve which is a branch of nerve to vastus lateralis which is a branch of femoral nerve, the ipsilateral hip was internally rotated to position the lateral aspect of knee joint facing superiorly and the ultrasound transducer was aligned longitudinally at first to show the connection between shaft of femur and lateral epicondyle. The second one is the superior medial genicular nerve which arises from the nerve to vastus medialis which is a branch of the femoral nerve, the ipsilateral hip was rotated externally to the position in which the medial aspect of the knee joint facing superiorly. The ultrasound transducer was aligned longitudinally at first to show the connection between the shaft of femur and the medial epicondyle. The third one is the inferior medial articular nerve which arises from the infra-patellar branch of saphenous nerve. The hip was rotated externally and the knee was flexed. The ultrasound transducer was aligned

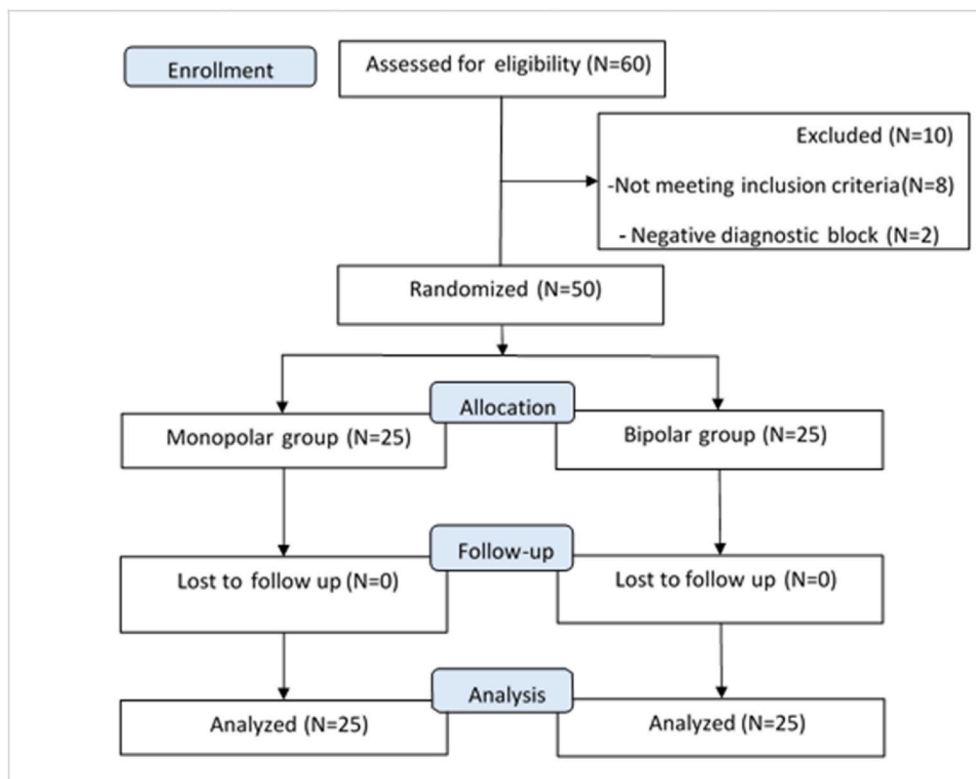


Fig. 1. CONSORT diagram of the study.

longitudinally along the medial collateral ligament and the long axis of the tibia [21].

In monopolar radiofrequency, a 10-cm-long curved radiofrequency cannula (20 G) with 10 mm active tip is advanced under the ultrasound guidance towards the nerve. The final position was confirmed by using the nerve stimulator through elicitation of paresthesia along the area of the knee joint which is supplied by the respected articular nerve by stimulation at 50 Hz and a current of <0.5 mV. The motor stimulation was done at 2 Hz and 2 mV, which was negative at all instances through the stimulation. 1 mL of 2% lignocaine was added through the radiofrequency cannula after negative aspiration of fluid or blood.

Two conventional radiofrequency lesions were done for 120s at 80° of temperature to insure thermal lesion (local anesthetic used in fascia expansion may decrease the temperature of the lesion and increase the difference more than 10°c between the two cannula in bipolar RF which may require second lesion) and to produce large lesion to overcome the variability of the nerve course using the Neurotherm 1100 RF generator for each genicular nerve. RFA can be done for three cycles for 90 s at 90 °C per site, which is a longer duration than employed by any other studies [8].

The patients were observed for 2 h immediately after the intervention. In bipolar radiofrequency, the same technique was used to insert the cannula, but instead of one cannula, two cannula with 10 mm active tip separated from each other by less than 10 mm were used. Also, the same technique used in the visualization of the main three nerves, the final position of the two needles using nerve stimulators and the two conventional radiofrequency lesions with the difference around 10°c between the two cannula were done in bipolar RFA.

The superficial probe was first placed in a coronal plane relative to the tibia or the femur. The cannula was inserted 5 mm away from the probe with an angle of 15–20° to orient the tip of the needle immediately underneath the beam of US (Fig. 3, Fig. 4). First the tip of the curved needle was directed medially toward the bone then redirected laterally to be pushed 10 mm beyond the bone to insure parallism of the nerve. In all procedures, the needle was directed under ultrasound guidance to the fascia expansion (Fig. 5) containing the neurovascular bundles using the out of-plane approach with long axis view then confirmed by the in-plane with short axis view. Long axis view facilitates target recognition whereas out of-plane facilitates needle tip target destination. In-plane short axis view confirms distance between the two needles within 10 mm in bipolar radiofrequency ablation and needle position in relation to the femur and insure sufficient contact distance between the



Fig. 3. The insertion angle of one radiofrequency cannula relative to the US probe.

bone (nerve) and the needle (Fig. 6, Fig. 7). The lesion produced by the monopolar RF is smaller than produced by the bipolar RF.

2.1. Outcome measures

The primary objective was the mean changes from baseline levels of knee pain at 1, 4, 12 and 24 weeks after the procedure during movement, measured using the 10 cm VAS. The secondary objectives included the proportion of successful responders with a decrease of at least 50% of median VAS score, the procedure time and pain, the functional changes in the knee measured by OKS (simple, valid, self-administered, joint-specific 12-item questionnaires ranging from 12 to 60, with 12 referred to the best result) [15] and the incidence of adverse effects.

2.2. Sample size calculation

The sample size was calculated using previous similar studies; [16, 17,22]. By assuming the study power at 90% and the type I error probability associated with the test of this null hypothesis (α) is 0.05, 44 subjects were required to detect the required difference in the Oxford knee score of more than 10. We recruited 50 subjects to take attrition into the account.

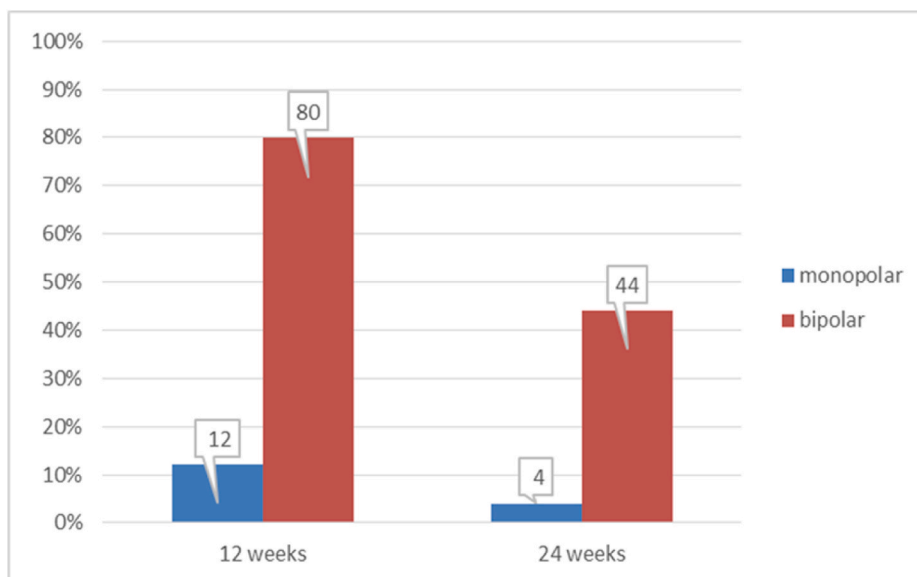


Fig. 2. The proportion of successful responders with a reduction of at least 50% of VAS score.

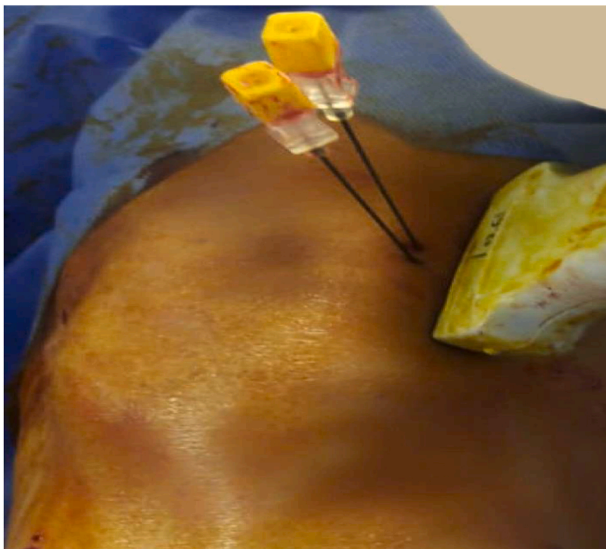


Fig. 4. The insertion angle of two radiofrequency cannula relative to the US probe.

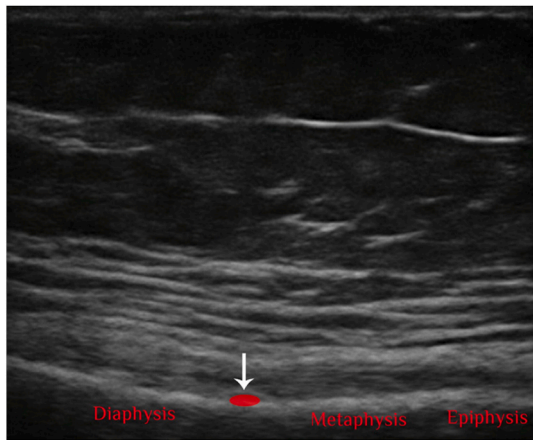


Fig. 5. The fascia expansion (arrow) containing the neurovascular bundle (red spot). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

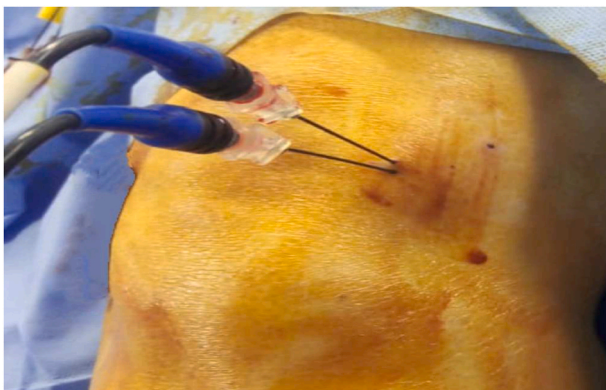


Fig. 6. Bipolar radiofrequency ablation of the superior lateral genicular nerve.

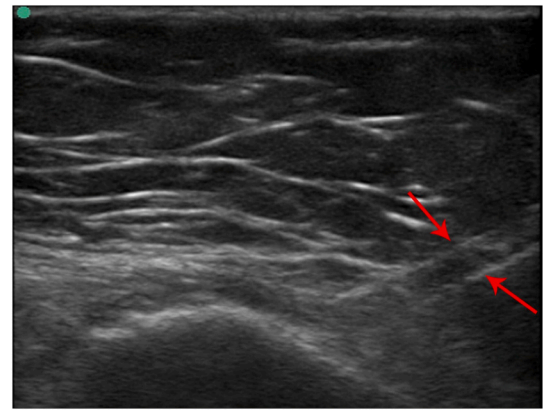


Fig. 7. In plane short axis view of bipolar (Two) radiofrequency cannula (red arrows). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

2.3. Statistical analysis

Statistical analysis was performed by Statistical Package for the Social Science (SPSS) version 22 statistical software. Kolmogorov-Smirnov test was used for data normality specification. The data were expressed as mean \pm standard deviation (SD) for quantitative data, median (range) for nonparametric data and frequency, number & proportion for categorical data. Data analysis was performed to detect the statistical significance between the two studied groups. Statistical tests used for data analysis were Chi-Square test for categorical variables to compare between both groups, Student *t*-test for quantitative parametric variable, to compare between both groups and Mann Whitney *U* test for quantitative non parametric variable, to compare between both groups. P values presented were 2-sided and values of less than 0.05 were considered statistically significant.

2.4. Results

A total of 60 patients were recruited. Ten patients who were excluded, 8 of them not meeting the inclusion criteria and the other 2 patients showed negative response to the diagnostic nerve block in the flow chart (Fig. 1).

There was no statistically significant difference between the two groups regarding demographic data and Kellgren-Lawrence classification. There were a statistically ($p < 0.05$) difference in the procedure time and pain during the intervention between the two groups. The monopolar group was lower than bipolar group in the procedure time [36 ± 6 Vs. 47 ± 5] and pain [4(3–5) Vs. 5(4–6)] (Table 1).

There was a significant interaction between group and time for the

Table 1
Demographic and procedure characteristic; and Kellgren-Lawrence classification in both groups.

	Monopolar, n = 25	Bipolar, n = 25	P value
Age(years)	58 \pm 7	57 \pm 6	0.37
Sex(M/F)	11/14	12/13	0.77
BMI(kg/m ²)	33 \pm 4	32 \pm 3	0.20
Duration of procedure(min)	36 \pm 6	47 \pm 5	<0.001*
Pain during intervention	4(3–5)	5(4–6)	0.002*
Kellgren-Lawrence classification			
2	8(32%)	8(32%)	0.86
3	8(32%)	9(36%)	
4	9(36%)	8(32%)	

Data are expressed as mean \pm SD, median (range) and number (percentage).

*P value is significant if < 0.05 .

mean changes of the VAS pain scores ($p < 0.05$). VAS scores were lower at all post-procedure assessment points compared with baseline ($p < 0.05$) in both groups. The bipolar group shows low VAS score at 12 weeks [4.84 ± 0.62 Vs. 3.56 ± 0.71] and 24 weeks [5.44 ± 0.82 Vs. 3.96 ± 0.79] (Table 2, Fig. 8). The Proportion of successful responders with a reduction of at least 50% of VAS score were more in bipolar group than monopolar group at 12 weeks (80% Vs. 12%) and 24 weeks (44% Vs. 4%) (Fig. 2).

There was a significant interaction between group and time for the oxford knee score ($p < 0.05$). OKS were lower at all post-procedure assessment points compared with baseline ($p < 0.05$) in both groups. A statistically ($p < 0.05$) difference was found in between the two groups. The bipolar group shows low OKS at 12 weeks [26 ± 3 Vs. 34 ± 3] and 24 weeks [27 ± 3 Vs. 35 ± 3] (Table 3, Fig. 9).

There were complications as localized infection, numbness and tingling along the course of saphenous nerve and anesthesia dolorosa in small percentage with no statistically significant difference between the two groups during early or late period of follow-up (Table 4).

3. Discussion

Radiofrequency ablation of genicular nerves induces analgesia in patients with chronic osteoarthritis knee pain who fail to respond to conservative therapy. There are many genicular (articular) nerves; but three genicular nerves as superior medial, superior lateral and inferior medial are easily accessible and anatomically consistent. The main target points for radiofrequency ablation are the periosteal areas connecting the shaft of the femur to the bilateral condyles and the medial epicondyle to the shaft of the tibia [16].

Many factors during the procedure that share in the success of RFA include the type of RFA, the temperature and the duration of RF. Cooled RFA created larger lesions than either continuous or Pulsed RF [23]. Cooled RFA can increase the lesion size eight times larger through a closed circuit where intravenous flows by creating an injury for a longer time, at a lower temperature (cooled RFA 60°C Vs. conventional RFA 90°C) [24]. Large lesion and long duration of the ablation are preferred due to high degree of overlap of genicular nerves and wide degree of variability of the course of the nerves. So increasing the lesion is targeted essentially even with the use of US.

The aim of use of bipolar radiofrequency ablation in this study was to yield a greater lesion than produced by monopolar radiofrequency ablation to give better improvement in relief of knee pain [25]. The use of ultrasound in genicular nerve block offered benefits over fluoroscope in the dynamic visualization of neurovascular bundles through the fascia expansion between the muscles and the periosteum to increase the chance of capturing the genicular nerves which may be in variable anatomical sites. Moreover, it provides excellent soft tissue imaging as landmarks other than metaphyseal bony land mark in fluoroscope [14, 26,27].

Table 2
Visual analogue score in both groups.

VAS (0–10)	Monopolar, n = 25	Bipolar, n = 25	Changes from baseline		P value
			Monopolar	Bipolar	
Basal	7.64 ± 0.57	7.52 ± 0.51	Monopolar	Bipolar	0.48
1 week	$5.12 \pm 0.73^*$	$4.84 \pm 0.47^*$	2.52 ± 0.82	2.68 ± 0.56	0.11
4 weeks	$4.36 \pm 0.49^*$	$4.28 \pm 0.46^*$	3.28 ± 0.68	3.24 ± 0.6	0.54
12 weeks	$4.84 \pm 0.62^*$	$3.56 \pm 0.71^*$	2.8 ± 0.87	3.96 ± 0.61	$<0.001^{**}$
24 weeks	$5.44 \pm 0.82^*$	$3.96 \pm 0.79^*$	2.2 ± 0.96	3.56 ± 0.82	$<0.001^{**}$

Data are expressed as mean \pm SD.

*P value is significant if < 0.05 compared to baseline.

**p value is significant if < 0.05 between the two groups.

The primary outcome was osteoarthritis knee pain measured by VAS score which was low in the two studied groups compared to basal value ($p < 0.05$) meanwhile it was significantly lower in bipolar group with p value (<0.001) at 12, 24 weeks compared to monopolar group. This difference was explained by wider area of lesioning in bipolar lesion than monopolar lesion and less power of regeneration of genicular nerves [28]. This explains that the proportion of successful responders with a reduction of at least 50% of VAS score and the patient satisfaction in the bipolar group were more than monopolar group at 12 and 24 weeks.

The results of this study supported a previous study by Gulec who compared between monopolar and bipolar Intraarticular Pulsed Radiofrequency by fluoroscope on 100 patients with 12 weeks follow up time through a randomized, double-blind study in reducing chronic knee pain and reported a significant variance in VAS scores between the two groups at all post-procedure time points from the baseline to three months. 84% in bipolar group and 50% in monopolar group attained at least 50% knee pain relief [17].

The genicular nerve ablation was reported to be more effective in relieving chronic osteoarthritis pain than other technique. For example, Debanjali compared genicular radiofrequency neurotomy to intra-articular hyaluronic acid instillation through a randomized, open label, clinical study with 12 weeks follow up period. They found a reduction in the VAS score at 4 and 12 weeks in radiofrequency group [29]. Other study conducted by Eman who assessed the effectiveness of radiofrequency ablation of genicular nerves by fluoroscope for chronic knee pain to conservative pharmacologic treatment through a single-blind randomized controlled trial on 60 patients with six months follow up time. VAS pain scale were significantly lower in radiofrequency group compared to medical treatment at the follow-up period. These results conducted by fluoroscope were parallel to the results of this study that ultrasound-guided monopolar or bipolar RF ablation were effective in relieving osteoarthritis pain [8].

Although bipolar radiofrequency was more effective in relieving pain than monopolar radiofrequency, the duration of procedure in bipolar group was longer than monopolar group. This may be explained by the use of two cannula for each genicular nerve in bipolar group versus one cannula in monopolar group so the pain during the intervention was more in bipolar group than monopolar group. This may be due to stimulation of pain-sensitive areas such as the ligament insertion sites and the periosteum [22,30].

On the contrary to the results of the current study, the procedural pain was more in the monopolar group compared with the bipolar group. The time taken to perform the intervention was longer in the monopolar group than in the bipolar group in a study conducted by Jadon who compare between monopolar and bipolar RFA in knee osteoarthritis using fluoroscope on 30 patients with six months follow up time. They explained that using two electrodes in bipolar radiofrequency avoid the manipulation needed for accurate localization of the genicular nerves without stimulation of pain-sensitive structures as periosteum which resulted in less procedural pain in the bipolar group when compared with the monopolar group. Moreover, less time was taken in the bipolar radiofrequency to complete the procedure as accurate localization of the articular nerves was not required due to large lesion [16].

The Oxford knee scores were low in the two studied groups compared to the basal value ($p < 0.05$) but showed statistically difference at 12 and 24 weeks with p value (<0.001) in the bipolar group. This was parallel to the results of VAS score which lead to improvement in OKS. Additionally, a study conducted by choi who made radiofrequency ablation for 19 patients and other 19 patients without effective neurotomy to relieve chronic knee osteoarthritis pain through a double-blind randomized controlled trial and follow up period for three months to confirm that radiofrequency was superior to other treatment reported that the Oxford knee scores at 4, 12 weeks in radiofrequency genicular neurotomy by fluoroscope were lower than the control group [22].

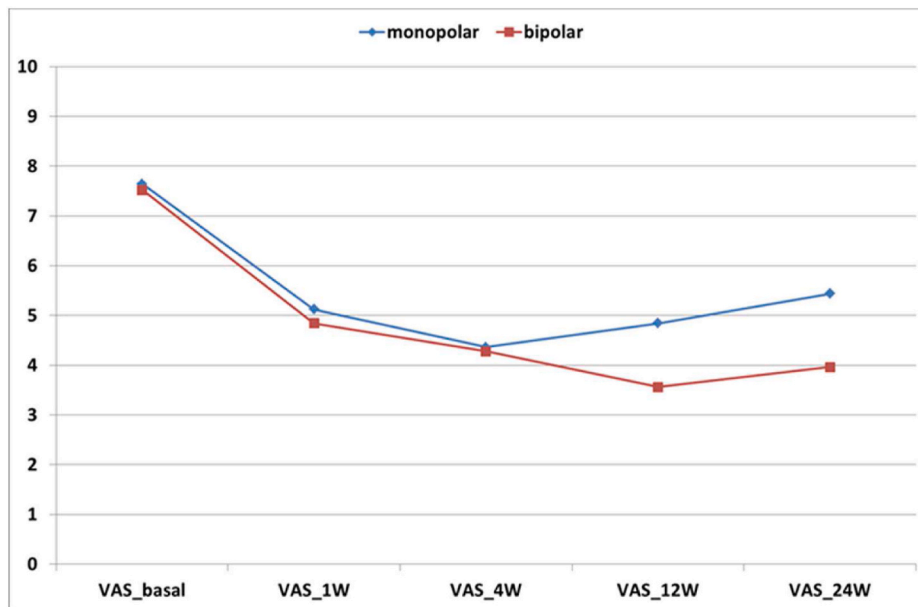


Fig. 8. Visual analogue score in both groups.

Table 3
Oxford knee score in both groups.

Oks(12-60)	Monopolar, n = 25	Bipolar, n = 25	P value
Basal	44 ± 5	42 ± 5	0.16
1 week	31 ± 2*	30 ± 3*	0.12
4 weeks	29 ± 2*	28 ± 2*	0.08
12 weeks	34 ± 3*	26 ± 3*	<0.001**
24 weeks	35 ± 3*	27 ± 3*	<0.001**

Data are expressed as mean ± SD.

*P value is significant if < 0.05 compared to baseline.

**p value is significant if < 0.05 between the two groups.

Three genicular nerves were ablated in this study but in other study, seven genicular nerves were ablated using ultrasound guidance in patients with progressive knee osteoarthritis. The four added genicular nerves blockade (Middle genicular nerve, Lateral retinacular nerve, Posterior genicular nerve plexus and Inferior lateral genicular nerve) lead to sustained and excellent relief of pain as measured by oxford knee scores and it was continued till 6 months [21].

Table 4
Complication in both groups.

Complication	Monopolar, n = 25	Bipolar, n = 25	P value
Infection	1(4%)	2(8%)	0.55
Numbness	1(4%)	2(8%)	0.55
Anesthesia dolorosa	2(8%)	3(12%)	0.64
Motor weakness	Nil	Nil	-

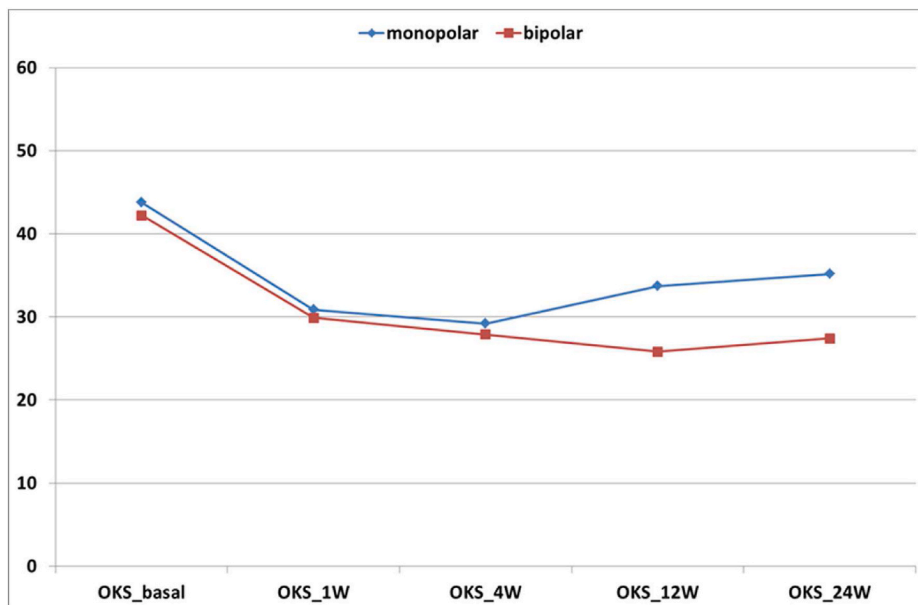


Fig. 9. Oxford knee score in both groups.

There were complications as localized extra-articular infection responding to five days of antibiotic course in small percentage of patients, self-limited numbness and tingling along the course of saphenous nerve and anesthesia dolorosa in small percentage with no statistically significant difference between the two groups during early or late period of follow-up. There were no motor weakness in both groups.

This study was conducted between two types radiofrequency ablation (monopolar and bipolar) for six months, in the future studies we can compare between different types of radiofrequency (monopolar, bipolar, tripolar, cooled) for a longer duration as one year or two years.

The limitations of the study were: 1) radiofrequency ablation for only three main articular branches not for all articular branches innervating the knee joint. 2) This study involved patients with osteoarthritis grades II–IV (Kellgren and Lawrence scale); however, it did not compare outcomes related to the severity of grades. These limitations may be overcome in the future by further studies making radiofrequency ablation for the seven genicular nerves of the knee and also comparing between the severity of the disease.

4. Conclusion

Ultrasound-guided bipolar radiofrequency ablation without fluoroscopic confirmation is more effective than monopolar radiofrequency ablation in controlling chronic osteoarthritis knee pain.

Ethical approval

Local Ethical approval was obtained from Mansoura University, Egypt: MD.19.03.152.

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This study did not receive any funding from governmental or private organizations.

Author contribution

Study concept or design: HMM, EME, OTA, SAM. Data collection: HMM, EME, OTA. Data interpretation: HMM, EME, OTA. Literature review: HMM, EME, OTA, SAM. Data analysis: HMM. Drafting of the paper: EME. Editing of the paper: EME. Manuscript revision: EME.

Trail registry number

ClinicalTrials.gov (ID, NCT04112264).

Guarantor

Dr. Hanaa M. Mohammed.

Availability of data and materials

The data that support the findings of this study are available from the corresponding author upon request.

Disclosure of interest

The authors report no financial or non-financial conflicts of interest in this work.

Consent for publication

Written informed consent was taken from all patients.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Declaration of competing interest

The authors declare no conflict of interest.

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