Randomized Trial

Three Needles Approach-A New Technique of Genicular Nerves Radiofrequency Ablation for Pain Relief in Advanced Chronic Knee Osteoarthritis: A Randomized Trial

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Background: Ablation of the genicular nerves (GN) has emerged as a useful alternative therapeutic modality in chronic knee osteoarthritis (OA) specially for high-risk patients. However, in some cases due to the presence of other articular branches or anatomical variability, it may have a poor impact in relieving pain. Ablation of other or additional articular branches might have different outcomes.

Objectives: We aimed to investigate the efficacy and safety of using 3 needles as a new technique in ablation of GN and compare it to the classic single-needle approach.

Study Design: A prospective parallel single-blind randomized study.

Setting: Department of Anesthesia and Intensive Care, Faculty of Medicine, Minia University, Egypt, and Pain Management Unit, Assiut University Hospital, Egypt.

Methods: Fifty patients with advanced knee OA were involved in this clinical study to be treated with radiofrequency ablation of GN using either: the single-needle technique (SN group [n = 25]) or the 3-needle technique (TN group [no = 25]) and assessed for: pain with the Visual Analog Scale (VAS); knee function and disability with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC); and patient satisfaction using global-perceived effect throughout 2 weeks, and 1, 3, and 6 months after the procedure.

Results: Significantly longer and better improvement in perceived pain (VAS), function and disability (WOMAC) with more patients' satisfaction were recorded in the TN group than the SN group at all follow-up time points without untoward events.

Limitations: Short follow-up time; longer period could permit recognition of long-term outcome.

Conclusions: Compared to the conventional single-needle GN ablation technique, the 3-needle approach appears to be a promising, safe, and more effective ablation technique for patients with chronic knee OA.

Key words: Chronic knee osteoarthritis, radiofrequency, three needles

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Chronic knee osteoarthritis (OA) has been proved as a leading cause of chronic pain, disability, and worsened the life quality. Furthermore, OA recorded at earlier ages among Arab patients in their early 40s (1) with a different clinical pattern and a greater severity in comparison to Western world patients. Recently, ablation of the genicular nerves (GN) (2) has emerged as a useful alternative technique for high-risk patients who cannot undergo surgery. Radiofrequency (RF) thermocoagulation (3)

is a minimally invasive, target selective neurolytic technique that uses heat to induce controlled tissue destruction without causing manifestations of nerve damage.

Traditionally, the superior lateral (SL), the superior medial (SM), and the inferior medial (IM) genicular nerves are targeted for ablation in management of chronic OA (4) because of their relatively accessible anatomic positions. Sometimes, GNRF ablation may have no or poor impact in relieving the pain of knee OA because of several causes, such as patient-to-patient variability in GN sites, and fluoroscopic-guided techniques do not provide direct visualization of the target nerves; it is usually done relying on bony landmarks (5). Although the main innervating articular branches for the knee joint are GN, there may be other articular branches as well. Articular branches of the femoral, common peroneal, saphenous, tibial, and obturator nerves have been reported to also be distributed to the human knee (6). This study was designed to investigate our hypothesis that using 3 needles for ablating each nerve of the 3 main GN instead of the traditional single-needle technique may increase the probability of reaching the correct site of the GN and the other articular branches around the knee joint, thus allowing ablation of a larger area with better pain control. Our objectives were to measure the Visual Analog Pain Score (VAPS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores, and any adverse events for outcome of the procedures.

Methods

After obtaining approval from the Research Ethics Committee at the Faculty of Medicine, Minia University on February 6, 2018, and informed consents from all patients, this prospective single–blind, randomized noncontrolled parallel study was carried out on 50 adult patients of both genders in the period from February 2018 to October 2018 in cooperation with the pain management unit of Assuit University Hospital. The study followed the CONSORT Statement for Reporting Trials (as shown in Fig. 1 and had been registered on ClinicalTrials.gov under the number NCT03613610. Patients involved in this study were: greater than 35 years old and had moderate to severe chronic knee pain (scoring ≥ 5 on a 0- to 10-point continuous Visual Analog Scale [VAS] ranging from none [0] to an extreme amount of pain [10]) (7); for > 6 months, unresponsive to conservative treatment modalities (e.g., analgesics and anti-inflammatory drugs, physical therapy, or rehabilitation practices) and fulfilled the criteria of knee OA as defined by the American College of Rheumatology (8); and diagnosed clinically by a consultant of rheumatology and confirmed by radiologic changes of knee OA grade 3 or more based on the Kellgren-Lawrence rating scale (9). The exclusion criteria were patients who had: acute or chronic knee pain due to causes other than OA as radiculopathy, other connective tissue disorders, neuro/psychiatric disorders, or intermittent claudication; severe OA in a location other than the knee joint; or knee effusion. Also, those with joint replacement surgery in the knee or the hip, traumatic injuries (e.g., meniscal tear or tendon damage), or received intraarticular (IA) injection during the previous 3 months. Lastly, active systemic or local knee infections, hematologic disorders, current use of anticoagulants, or antiplatelet medications.

A blinded rheumatology physician was authorized to determine the patients eligibility for inclusion into the study. For the eligible patients, a diagnostic nerve block was performed where 1 mL bupivacaine hydrochloride 0.25% was injected under fluoroscopic guidance in each GN namely SM, SL, and IM nerves. Responses to the diagnostic block were considered as positive and the patients can be suitable candidates of GNRF ablation, if they experienced a reduction in numeric pain scores of more than 50% for at least 24 hours.

Then, the patients were randomly allocated by a pain physician using a computer-generated random number table and closed sealed opaque envelopes into 2 equal groups (25 in each one), the SN group: to be treated with GNRF neurotomy using the classic single-needle technique, and the TN group: to be treated with GNRF neurotomy using the 3-needle technique. A blinded senior resident, who did not participate in the research, opened the envelopes and determined group assignments.

Before the procedure, all the eligible patients, who previously consented to participate in the study after explaining the technique, its benefit, and the potential complications, had undergone careful assessment and necessary investigations. Each patient was requested to grade their knee pain severity using the VAPS. Also, a combination of pain, stiffness, and physical function of each knee were assessed using the WOMAC (10). These data were recorded as a baseline pretreatment evaluation.

The technique: (all the procedures were performed by the same pain physician).

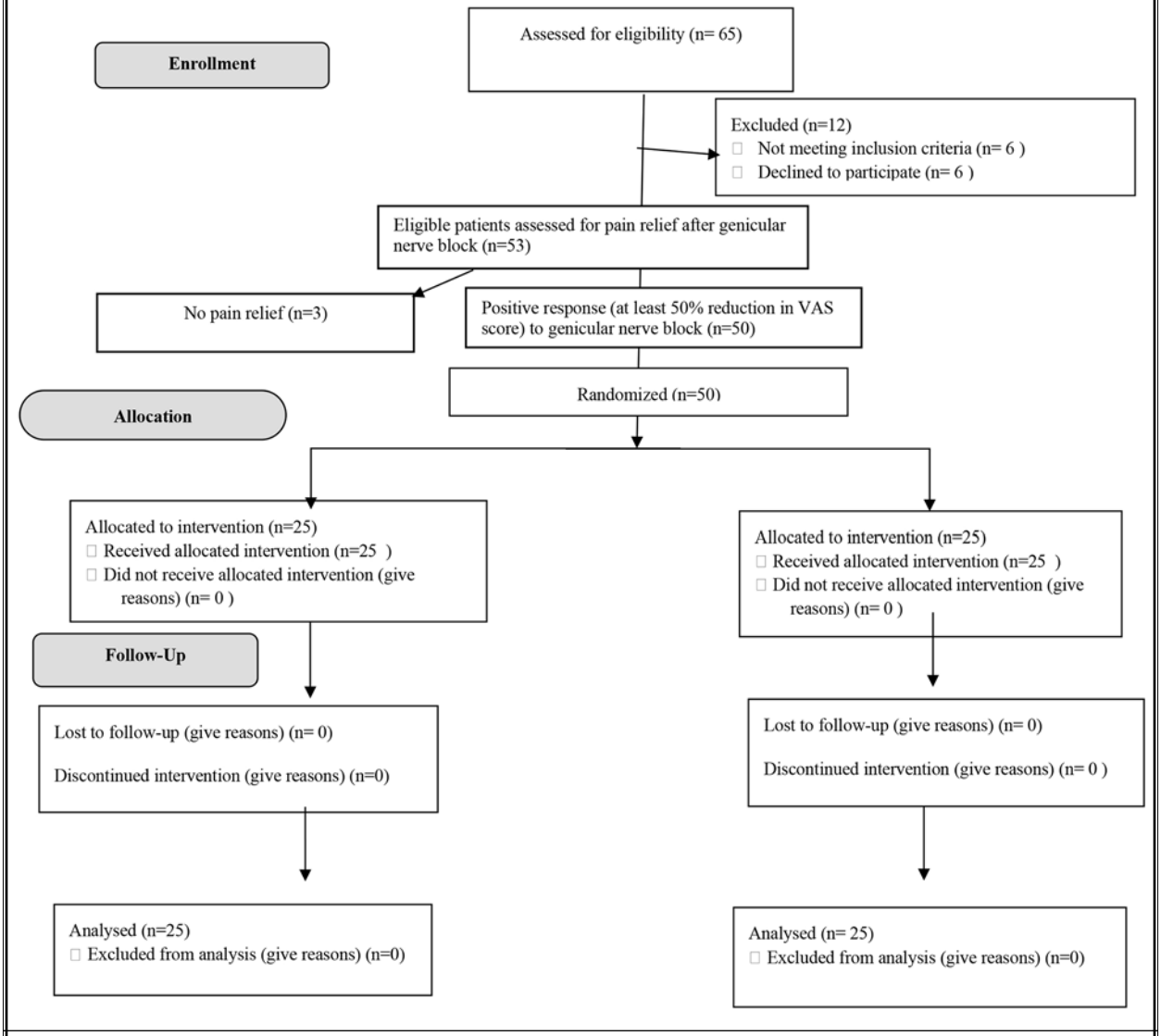

Fig. 1. *Consort flow chart of study.*

In the procedure room, after securing an IV access and basic monitoring (electrocardiogram electrodes, noninvasive blood pressure cuffs, and pulse oximeter), and under aseptic condition, the patient was placed supine on the fluoroscopy C-arm table with one knee flexed to 15° by a pillow beneath the popliteal fossa to alleviate discomfort.

An antero-posterior fluoroscopic view of the tibiofemoral joint was obtained. The image was adjusted to obtain the best one in which the tibiofemoral joint appeared open with equal interspace width on both sides as possible.

The 3 target points for needle insertion (the medial and lateral junctions between the femur shaft and epicondyle and the medial junction between the tibial shaft and epicondyle) were marked. At these 3 points, skin and soft tissue were anesthetized by local anesthetic infiltration of 1 mL lidocaine hydrochloride 2% (Debocaine, Al-Debeiky Pharma).

In the SN group: under fluoroscopic guidance, a 10 cm, 22-gauge RF cannula with 10 mm active tip was inserted at each marked point and advanced percutaneously toward the junction of the shaft with the epicondyle of the medial and lateral sides of the femur and of

the medial side of the tibia with obtaining an end on (tunnel) view. Then, in the lateral fluoroscopic view, the cannula tip was stopped at the junction of the anterior two-thirds and posterior one-third of the bone.

To reach the desired distance between the cannula tip and the target nerve to be ablated, the cannula tip was manipulated till sensory stimulation was elicited at 0.6 V, 50 Hz meaning that the distance between the active tip and the GN was < 0.3 cm).

Also, any inadvertent motor nerve ablation was avoided by checking any fasciculation in the corresponding lower limb area using 2.0 V at 2 Hz current stimulation.

After reaching the target site and before starting the RF, 2 mL lidocaine 2% was injected to avoid pain perceived by some patients during the procedure. Then, the RF electrode (NeuroTherm TM, Morgan automation LTD, Liss, UK) was inserted through the cannula where the tip temperature was raised to 80°C for 90 seconds.

In the TN group: Also, under fluoroscopic guidance, the same steps as in the SN group were done, but by using 3 cannulas, 1 proximal and the 2 others distal, to the main cannula with 1 cm apart from each other. They were advanced percutaneously toward the junction of the shaft and the epicondyle in the end on tunnel technique until bone contact was obtained, then, in the lateral fluoroscopic view, the cannulas' tips were stopped at the junction of the anterior two-thirds and posterior one-third of the bone. This was done upon the 3 GN (upper medial, upper lateral, and lower medial) and then, the process was continued as in the SN group (Fig. 2).

Patients were discharged on the same day and were instructed to have 24 hours rest and to use cold fomentation over the points-of-needle insertion and oral paracetamol (Panadol Extra: 500 mg paracetamol and 65 mg caffeine, GlaxoSmithKline Consumer Healthcare) if they experienced pain or oral diclofenac 150 mg/day as a rescue analgesia for any breakthrough pain.

Also, they were advised to reconsult us at any time if the pain wasn't relieved or if any unexpected change was noticed at their knees.

Assessment

Follow-up for each patient was performed at 2 weeks, and 1, 3, and 6 months after the procedure by a physician who was blind to the patient's assignment. The primary outcomes were the change in baseline knee pain assessed by the VAS score and in disability assessed by the WOMAC score, the latter consists of 3 domains to evaluate pain, stiffness, and physical function in patients with hip and/or knee OA. A higher WOMAC score indicates worsening of the condition.

Secondary outcomes were overall patient satisfaction according to the global perceived effect (GPE) on a 7-point Likert scale (11). The patient may choose between 7 response alternatives: 1 = worst ever; 2 = much worse; 3 = worse; 4 = not improved but not worse; 5 = improved; 6 = much improved; or 7 = best ever. Also, global evaluation of therapy that focuses on assessing the proportion of patients achieved at least 50% reduction of pretreatment VAS scores at follow-up times. In addition, any analgesic requirement and occurrence of any complications, such as infection, hemorrhage, thermal injury, motor weakness, and/or sensory dysfunction (e.g., numbness, paresthesia, or neuralgia) in the corresponding area of the involved nerves.

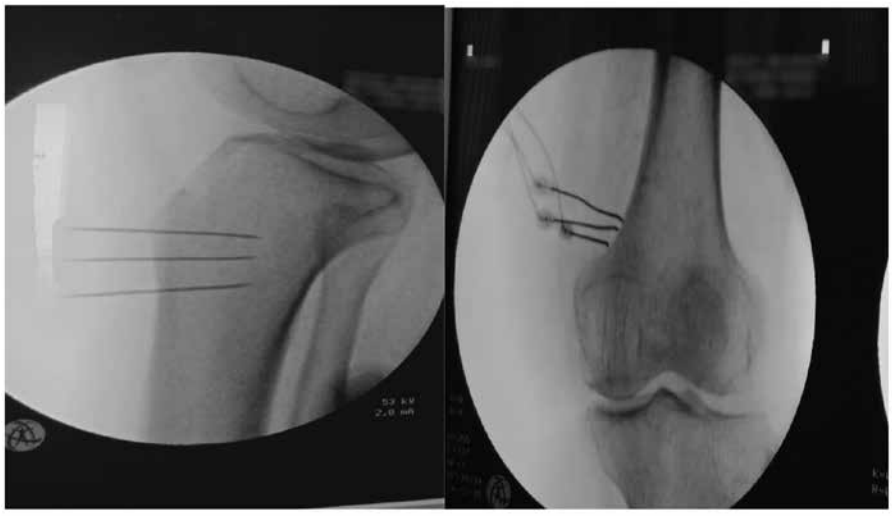

Fig. 2. *Flouroscopic guided three needles insertion at inferior medial GN and superior lateral GN.*

Statistical Method

The collected data were statistically analyzed using SPSS program software version 25.0 (IBM Corporation, Armonk, NY). The level of significance was taken at *P* value < 0.05. Between the 2 groups, analyses were done for parametric quantitative data using independent samples t test, for nonparametric quantitative data using the Mann-Whitney test and, for qualitative data, the chi-square test (if expected value within cell > 5) and the Fisher exact test (if expected value within cell < 5) are applied.

Analyses were done for nonparametric quantitative data between the 4 times using the Friedman test within each group, followed by the Wilcoxon signed rank test between each 2 times.

Sample Size Calculation

The number of patients required in each group was determined after a power calculation according to data obtained from previous studies, through the total WOMAC score which was 47.19 ± 11.98 at baseline then became 42.33 ± 10.95 at 3 months. A sample size of 25 patients in the group was found to provide 80% power for a dependent samples t test at the level of 5% significance using G Power 3.1.9.2 software.

Results

Fifty OA patients eligible for RF treatment were included in this study. Their demographic data and quantifiable characteristics of the disease are presented in Table 1 with no significant difference between the 2 groups.

Pre-interventional (basal) VAPS, total WOMAC score, and its domains (pain, stiffness, and function) were comparable between the 2 studied groups, to become significantly lower (better) in the TN group at all the rest follow-up time points (2 weeks, and first, third, and sixth months post-procedure) when compared to the SN group.

Significantly lower VAPS and WOMAC scores (improvement) were recorded at follow-up periods in each individual group when compared to their corresponding basal value. In the SN group, as the improvement began to decay before the sixth month, the scores at that time regressed to the point that they had become comparable to those of 2 weeks and significantly higher than the first and third months. However, in the TN group, this decay did not occur and the improvement continued up to the sixth month, thus scores at the first, third, and sixth months were comparable to each other and significantly better than that of 2 weeks (Table 2).

Table 1. *Demographic and Clinical Data*

Variable		SN Group (n = 25)	TN Group (n = 25)	*P* value
Age (y) Range		(41-73) 55.6 ± 9.4	(40-72) 54.9 ± 6.9	0.765 (-)
Gender (Men/Women)		10/15	11/14	0.775 (-)
BMI (kg/m^2)		27.77 ± 4.74	27.36 ± 3.53	0.714 (-)
ASA class (II/III)		5/20	6/19	0.733 (-)
Disease duration (y)		(3-25) 13.1 ± 7.4	(2-25) 10.2 ± 5.4	0.765 (-)
Last IA injection (mo)		17.9 ± 9.3	22.1 ± 22	0.730 (-)
X-ray finding (Grades 3/4)		19/ 6	19/6	1 (-)
Affected Side	RT LT	11 (44%) 14 (56%)	13 (52%) 12 (48%)	0.473 (-)

Abbreviations: SN,single needle; TN, three needle; BMI, body mass index; ASA, American Society of Anesthesiologists; IA, intraarticular.

Significantly higher patients ratio required analgesia in the SN group (84%) when compared to those in the TN group (24%) (*P* > 0.001), analgesics mostly required during the first week after intervention.

Patients satisfaction of therapy (GPE) and the proportion of patients that achieved more than 50% reduction in VAPS showed significantly higher values in the TN group than the SN group at all assessment points (Table 3 and Fig. 3). Apart from temporary pain at the site of needle insertion relieved with conventional analgesics, no complication (0%) related to the procedure recorded in either group.

Discussion

Chronic knee OA is one of the commonest forms of joint diseases that cause disability and decreased quality of life. Up to 68% of populations older than 55 years have radiographic evidence of knee OA and nearly 10% to 30% of those have considerable pain and functional impairment (12).

Although the GN serve as one of the primary innervating branches, additional innervation exist. Consequently, pain transmission may continue, despite RF treatment. Ablation of other or additional articular branches may have different results (13).

RF lesions are intended to interrupt conduction of nociceptive signals, and therefore 'block' pain transmission. The duration of effect is mediated by the length of time taken for coagulated nerves to regenerate (14).

Based on these scientific facts, this prospective double-blind study was conducted to induce RF abla-

Table 2. *Follow-up of changes in VAPS and WOMAC scales.*

Variable	SN Group	TN Group	*P* value
VAS Pain			
Pre-intervention (Mean + SD) Median/ IQR	8.1 ± 0.6 8 (8-8)	7.9 ± 0.4 8 (8-8)	0.133
2 week (Mean + SD) Median/ IQR	4.9 ± 2.1# 4 (3-7)	3.5 ± 1.9# 3 (2-4)	0.008*
1 month (Mean + SD) Median/ IQR	3.6 ± 1.8# † 3 (2-5)	2.7 ± 1.3# † 2 (2-3)	0.046*
3 months (Mean + SD) Median/ IQR	4 ± 1.5# † 4 (2.5-5)	2.8 ± 1.3# † 3 (2-3)	0.009*
6 months (Mean + SD) Median/ IQR	4.5 ± 1.6#†¥± 5 (3.5-6)	2.8 ± 1.4#† 2 (2-4)	0.001*
WOMAC Pain			
Pre-intervention (Mean + SD)	15.8 ± 0.9	15.8 ± 0.9	0.958
2 week (Mean + SD)	8.1 ± 4.4#	5.7 ± 2.3#	0.023*
1 month (Mean + SD)	6.8 ± 3.5#†	5.1 ± 2.4#†	0.034*
3 months (Mean + SD)	7.2 ± 3.1#†	5.3 ± 3.3#†	0.004*
6 months (Mean + SD)	9.1 ± 3.8#†¥±	5.3 ± 2.7#†	< 0.001
WOMAC Stiffness			
Pre-intervention (Mean + SD)	7 ± 0.7#	6.9 ± 0.8#	0.667
2 week Mean ± SD	4.1 ± 1.7#	3.1 ± 1.3#	0.038*
1 month Mean ± SD	3 ± 0.9#†	2.2 ± 1.2#†	0.003*
3 months Mean ± SD	3.2 ± 1.5#†	2.4 ± 1.5#†	0.027*
6 months Mean ± SD	4.1 ± 1.6#¥±	2.6 ± 1.4#†	0.001*
WOMAC Function			
Pre-intervention (Mean + SD)	54 ± 2.4	54.4 ± 3.6	0.992
2 week Mean ± SD	35.4 ± 11.9#	26.4 ± 11.6#	0.003*
1 month Mean ± SD	27.7 ± 6.4#†	23.6 ± 9.8#†	0.001*
3 months Mean ± SD	28 ± 6.7#†	23.6 ± 9.6#†	0.003*
6 months Mean ± SD	37.4 ± 10.1#†¥±	24 ± 9.9#†	< 0.001*
Total WOMAC			
Pre-intervention (Mean + SD)	76.8 ± 3.9	77 ± 5	0.946
2 week Mean ± SD	47.6 ± 16.6#	35.2 ± 14.9#	0.001*
1 month Mean ± SD	37.6 ± 9.5#†	30.9 ± 13#†	0.001*
3 months Mean ± SD	38.3 ± 9.5#†	31.2 ± 14.1#†	< 0.001*
6 months Mean ± SD	50.6 ± 14.5#†¥±	31.9 ± 13.4#†	< 0.001*

Abbreviations: SN, single needle; TN, three needle; VAS, visual analog scale; SD, standard deviation; IRQ, interquartile range.

* Significant difference at *P* value < 0.05; #Statistically significant change in comparison to the pre-intervention; † Statistically significant change in comparison to 2 week; ¥ Statistically significant change in comparison to 1 mo ± statistically significant change in comparison to 3 mo.

tion of the SM, SL, and IM genicular nerves with a novel method using 3 RF needles for each nerve site and compare it to the traditional method of a single-needle approach, with sparing the lower lateral nerve to avoid injury of the motor common peroneal nerve.

Our main findings were that GNRF ablation induced statistically significant improvement in the VAPS and WOMAC scores in both studied groups when compared with the pretreatment in those patients with severe degree (grades 3 to 4) knee OA unresponsive to conservative therapy with significant better results achieved at the TN group than the SN group and no fluctuation in the quality of this improvement was noticed up to 6 months, so the scores at the first, third, and sixth months were comparable but better than that of the first week. However, in the traditional approach group (SN), the improvement was more gradual, and peaked at the first and third months, but began to decay at the sixth month to become significantly less than the previous 2-time points and comparable to that of the first week but still better than that of the pretreatment. Indeed the improvement in the VAS detected in this research was accompanied by a corresponding improvement in the WOMAC index; so many studies rely on the WOMAC index as a reflection of improvement in daily life quality and explained that chronic pain could abstain the patients from using their joints during their everyday activities which may initiate muscle wasting and increasing the stiffness (15).

Therefore, lower analgesic requirements with higher satisfaction were recorded in the TN group

along with all follow-up periods as 60%, 84%, 76%, and 72% of patients experienced more than 50% reduction in the VAPS at the first week and first, third, and sixth months, respectively. Even in the SN group, 32% of patients had more than 50% reduction in the VAPS at the sixth month after the procedure without notable side effects.

Worth mentioning that, some of the patients in our study who underwent 3-needle neurotomy (16) have gained pain-free periods of more than 24 months, unfortunately our follow-up protocol was up to 6 months only. Those beneficial effects are considered satisfactory in these patients with longstanding suffering (mean duration of the disease 10.2 ± 5.4 [range 2-25 years]).

In this study, on performing the ablation, we used three 22-gauge needles with 10 mm active tips that are commercially available and certainly produce larger lesions as compared with those generated by (23-gauge/5 mm) or (22-gauge/5 mm). This type of needle is considered economically inexpensive compared to the cost of monthly treatment expenses or the other methods of ablation as cooled RF. In the TN group, the needles were positioned parallel to each other, and perpendicular to the targeted nerve with the distance in-between about 1 mm to ensure optimal width that secure coagulation without tissue escaped as approved by previous studies (16) and the resultant total volume of horizontally coagulated tissue could be greater than that produced by a single large bore needle. Ablation of a wide tissue area, minimizes the occurrence of any technical failure due to incomplete coagulation and prolong the time of pain relief as the latter is proportional to the width of coagulated nerve (17).

The suggestion of using a single needle of larger diameter would have fulfilled the purpose of creating a large lesion area was relied on by some previous clinical trials where thicker curved needles were being used (RF cannula 18 or 20 gauge) for treatment of painful conditions to create a larger lesion and increase the effect of RF (denervation by RF of the medial branch nerve for the zygapophyseal joint) (16,18,19), however, this is argued by others who found that a large bore needle has the disadvantage of being more traumatic to the tissues during insertion; moreover, the heat is dissipated not only in the horizontal but also in the vertical direction, the latter is not needed and can cause undesirable tissue damage. Also, their ex-vivo porcine model study confirmed that lesioning by 2-needle electrodes (20) produced a wider coagulated tissue area more accurately than previous studies where only a single needle was used .

Table 3. *Patients satisfaction and analgesic requirement.*

Variable	SN Group (n = 25)	TN Group (n = 25)	*P* value
Global Perceived Effect (Mean ± SD)			
2 week	4.6 ± 0.8	5.2 ± 0.7	0.014*
1 month	5.1 ± 1.4	6.0 ± 0.9	0.028*
3 months	4.8 ± 1.5	5.9 ± 1.2	0.005*
6 months	4.6 ± 1.6	5.8 ± 1.3	0.004*
Pt. Required Analgesia When Required	21 (84%)	6 (24%)	<0.001*
2 week	11 (44%)	3 (12%)	
1 month	2 (8%)	-	
3 months	3 (12%)	1 (4%)	
6 months	5 (20%)	2 (8%)	

Abbreviations: SN, single needle; TN, three needle; SD, standard deviation.
* Significant difference at *P* value < 0.05

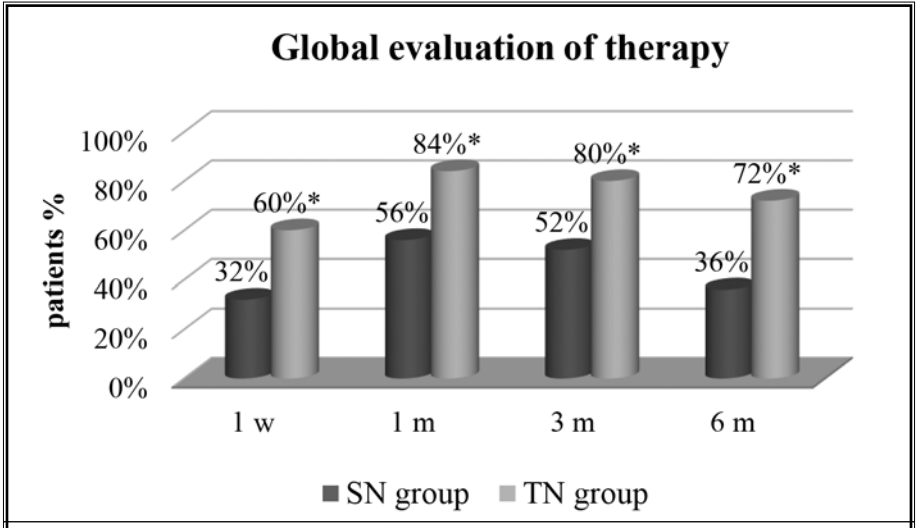

Fig. 3. *Global evaluation of therapy.*

In the present research, we can say that the ablation time in the three needles technique was nearly equal to that of the single needle (90 seconds) as we used three needle electrodes that were applied and heated simultaneously not sequentially thus no extra time was needed. The insertion was done under fluoroscopy guidance, with the same expert physician that shortened the time consumed. Really, the results and clinical outcome had been recorded of this new technique worth even if more effort was done, as some patients experienced no pain for more than 2 years after a long period of suffering as pain relief is proportional to the length of nerve coagulated.

Lastly, apart from transient pain at the site of needle insertion which could be due to irritation of pain sensitive structures, patients in this clinical trial had not reported any complication during the follow-up period, such as hemorrhage, infection, sensory, or locomotor affection. This can be explained in the light of the opinion that deficiencies in proprioceptive feedback induced by partial sensory denervation after RF treatment, presumably can be compensated for by afferent information through other undamaged/untreated articular nerve endings (15).

Limitation to our study was the short follow-up time; a longer period could allow tracking of long-term outcomes and adverse events.

Conclusions

Three-needles RF neurotomy of GN seems to be a safe technique and a more effective therapeutic procedure than the single needle for chronic severe OA pain refractory to other conservative treatments.

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