Comparative evaluation of monopolar and bipolar radiofrequency ablation of genicular nerves in chronic knee pain due to osteoarthritis

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ABSTRACT

Background and Aims: Monopolar radiofrequency ablation (MRFA) of the genicular nerve is effective in managing chronic knee pain from osteoarthritis (OA); however, the procedure itself is associated with significant pain due to manipulation of electrode to localise tiny genicular nerves. We hypothesised that inserting two electrodes to target the genicular nerves [bipolar radiofrequency ablation (BRFA)] without sensory localisation can decrease the procedural pain with equal analgesic efficacy in treating knee pain. Methods: Thirty patients with chronic knee pain due to OA were randomised to receive either MRFA (n = 15) or BRFA (n = 15), after having 50% pain relief with diagnostic genicular nerve block. Pain during the procedure (assessed by the Numeric Rating Scale [NRS]), time taken to do the procedure and complications were recorded. Knee pain was assessed by the Oxford Knee Score at baseline, 1 week, 1 month, 3 months and 6 months following the procedure. Results: Patients in both groups had good pain relief, and no difference in pain relief and the duration of pain relief was seen between the two groups. The median (range) NRS for procedural pain was significantly lower in the bipolar group [3 (3-5)] than in the monopolar group [5 (3–7), P = 0.013]. There was no significant difference in procedure time and no complications were seen in either group. Conclusion: BRFA is an effective alternative for ablation of genicular nerves in patients with knee pain due to OA. It causes less procedural pain compared with MRFA.

Key words: Bipolar radiofrequency ablation, chronic knee pain, Numeric Pain Rating Scale, Oxford score for knee pain, radiofrequency ablation of genicular nerves

INTRODUCTION

Chronic knee pain due to osteoarthritis (OA) is a debilitating disease.^[1] Many therapeutic options have been used to manage this pain.^[2] Radiofrequency ablation (RFA) of genicular nerves provides effective and prolonged pain relief.^[3,4] In conventional monopolar radiofrequency ablation (MRFA) technique, the localisation of genicular nerves is done through sensory stimulation at the junction of epicondyle with the shaft of femur bone (near periosteum).^[3] This localisation requires manipulation of localising cannula and it is often very painful for the patients. If patients are sedated to provide relief from procedural pain, then getting feedback from patients regarding stimulation

becomes difficult. We hypothesised that bipolar radiofrequency ablation (BRFA) near the target nerve area without manipulation for localisation of genicular nerves may reduce the procedural pain. The efficacy of this procedure is not well established except for a case report where BRFA was found to be effective and safe in patients with pacemaker.^[5]

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METHODS

After taking approval from Hospital Ethical Committee, the study was registered with Clinical Trials Registry - India (CTRI/2017/12/010953). A total of 35 patients with OA grades II-IV (Kellgren and Lawrence scale)^[6] were selected for this study after failed conservative treatment for 3 months and reported more than 50% pain relief after diagnostic genicular nerve block with 2% of 2 mL lidocaine on superior lateral, superior medial and inferior medial genicular nerves. Patients who did not give consent or had contraindications for local anaesthesia and RF treatment, those having severe comorbidity such as cognitive dysfunction, cardiovascular disease and unable to discontinue anticoagulant for 7 days, and patients with bilateral disease were excluded from the study. Thirty-five patients were recruited however, five patients were excluded and remaining thirty patients with one-sided knee pain were randomly divided into two equal groups [Figure 1]. A computer software (GraphPad Software, Inc., USA) was used to generate a random number sequence, and envelope method was used for group allocation. An informed written consent from each patient was taken. The procedure was done in the operation theatre where the patients were placed in supine position and monitors [continuous electrocardiogram, pulse oximeter (SpO2) and noninvasive blood pressure] were attached. In MRFA group (n = 15), RFA of three genicular nerves (superior medial, superior lateral and inferior medial) [Figure 2a-c] was done (as described before).^[3] In BRFA group (n = 15), a similar technique was used to insert the canula, except that, instead of one cannula two cannulae (approximately 10 mm

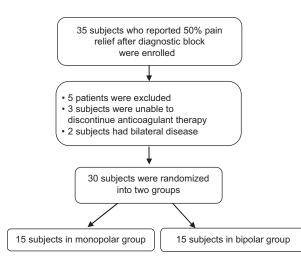


Figure 1: Flow diagram of randomisation and follow-up of enrolled participants

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apart) were inserted and no manipulation of cannulae was done to stimulate the target nerve as done in MRFA. Target areas were similar to monopolar technique [Figure 3a-c].^[5] Each nerve was ablated for 90 s in both the groups. All procedures were done by one pain physician who had more then 10 years' experience of radiofrequency procedures. The pain during the procedure was assessed on Numeric Rating Scale (NRS) of 0-10 (0 = no pain, 10 = maximum pain). The scoring was done by one of the authors who was trained to collect the data. The time taken to complete the procedure and any complications if encountered were also noted. To evaluate the pain relief, Oxford Knee Score^[7] was used. This score assesses the severity of pain and disability to perform daily activities due to knee OA. Assessment is based on 12 parameters, and each parameter has to be ranked on a scale of 0-4 (where 0 = unbearable pain and incapability to do daily activity and 4 = no pain and discomfort). The minimum score can be 0 means severe pain and severe disability and maximum score can be 48 indicating a healthy nonpainful joint (Questionnaire PDF format of Oxford Knee Score is available at https://www. sath.nhs.uk/wp-content/uploads/2016/08/gpinfo OxfordKneeScore.pdf).

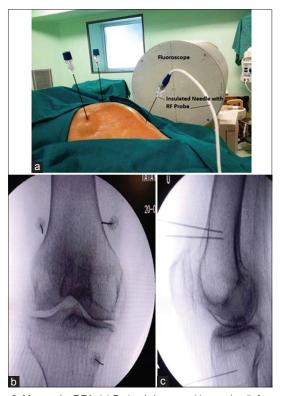


Figure 2: Monopolar RFA. (a) Patient's knee position and radiofrequency needles (one needle for one nerve) in place, (b) fluoroscopic image of needles on target nerves (AP view) and (c) needles' position in lateral fluoroscopic view

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All the patients were reviewed in the pain clinic and Oxford Knee Score at baseline and after 1 week, 1 month, 3 months and 6 months following the procedure were noted and compared between the groups. All the patients were allowed to continue their prescribed medications before and after intervention.

The primary objective was to evaluate the efficacy and procedural pain of BRFA and to compare it with conventional technique (MRFA).

The secondary objectives were to compare the complications and time taken to complete the procedures. The sample size was calculated based on a previous similar study.^[3] Assuming the power of the study at 80% and a clinical significance of 95%, 24 subjects were needed to detect the required difference in the Oxford score of more than 10. We recruited 35 subjects to take attrition into account. Statistical analysis was done using statistical software (MedCalc version 17.9.4).

The demographic characteristics were assessed using Student's *t*-test (two-tailed, unequal variances) and Chi-square test as appropriate. Ordinal data (NRS and Oxford score) were represented as median and range

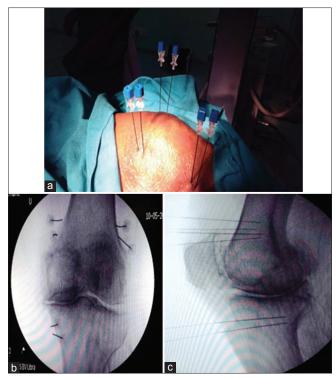


Figure 3: Bipolar RFA. (a) Patient's knee position and radiofrequency needles (two parallel needles approximately 10 mm apart) in place, (b) fluoroscopic image of needles on target nerves (AP view) and (c) needles' position in lateral fluoroscopic view

and were assessed using Wilcoxon test (paired samples) and Mann–Whitney U-test (independent samples). Frequencies and proportions were assessed using Chi-square test. A P value <0.05 was considered significant.

RESULTS

Both the groups were similar on all demographic parameters of age, height and weight [P = 0.81, 0.94]and 0.24 respectively, Table 1]. The median (range) NRS for procedural pain was 5 (3-7) in the monopolar group when compared with 3 (3-5) in the bipolar group [P = 0.013, Table 2]. At all points in the study, all the subjects reported significant improvement in the Oxford scores following the intervention [P < 0.05, Figure 4]. No significant difference was noted in the Oxford scores between the two groups [P > 0.05, Figure 5]. Ten patients had Oxford score >30 at 6 months following the intervention in bipolar group compared with seven patients in the monopolar group [P = 0.031, Table 2]. The time taken to perform the procedure was $31.13 (\pm 3.94)$ min in the monopolar group and 28.80 (± 5.1) min in the bipolar group [P = 0.086, Table 2]. No complications were noted in either of the two groups [Table 2].

DISCUSSION

Our study reported no difference in Oxford scores between the monopolar and bipolar groups at all points of assessment in the study. There was significantly less

Table 1: Demographic variables of the study participants					
Characteristic	Monopolar group (<i>n</i> =15)	Bipolar group (<i>n</i> =15)	P *		
Age (years) (mean±SD)	58.4±12.08	59.33±12.09	0.8114		
Height (cm) (mean±SD)	150.5±4	150.6±4.2	0.9422		
Weight (kg) (mean±SD)	70.06±10.57	69.66±10.75	0.2450		
Male:female	11:4	11:4	-		

SD: Standard deviation. *Unpaired Student's t-test

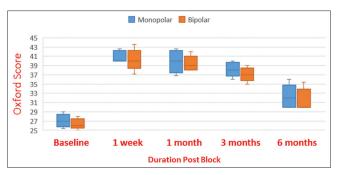


Figure 4: Oxford Pain Score in monopolar and bipolar RFA groups at baseline (preprocedure), 1 week, 1, 3 and 6 months

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Table 2: Procedural pain, Oxford score >30 at 6 months after intervention and complications				
Variables	Monopolar group (<i>n</i> =15)	Bipolar group (<i>n</i> =15)	P *	
Procedural pain, median (range)	5 (3-7)	3 (3-5)	0.013	
Time taken for procedure (min), mean (SD)	31.13 (±3.94)	28.80 (±5.1)	0.086	
Oxford score >30 at 6 months following the intervention	7 patients	10 patients	0.031	
Complications	Nil	Nil	-	

SD: Standard deviation. *Unpaired Student's *t*-test

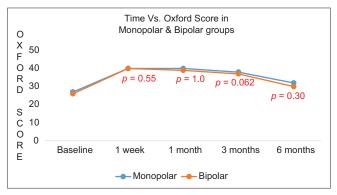


Figure 5: Comparison of median Oxford scores between the two groups at different points in the study

procedural pain in the bipolar group when compared with the monopolar group. The time taken to perform the procedure was more in the monopolar group but not statistically significant. No complications were reported in either of the two groups.

RF genicular neurotomy is a means of inducing analgesia in patients with chronic knee pain due to OA who fail to respond to conservative treatment. It is an effective, minimally invasive method for the treatment of chronic knee OA pain and loss of function.^[8] The use of RF for chronic knee pain requires the identification of anatomic landmarks for nerves innervating the knee joint. All three major nerves of the lower limb; sciatic, femoral and obturator project articular branches to the knee, which are known as the genicular nerves.^[9] There are many genicular nerves; however, only three genicular nerves (superior medial, superior lateral and inferior medial) are anatomically consistent and easily accessible.^[10] These nerves crosses the junction of femoral shaft with the condules and shaft of tibia with medial epicondyle of tibia. Therefore, the target points for RF neurotomy included periosteal areas connecting the shaft of the femur to bilateral condyles and the shaft of the tibia to the medial epicondyle.^[3,8]

The principle of RF neurotomy includes a correct placement of the electrode close to the target nerves.^[11] However, localising the genicular nerves can be difficult because of anatomical variations.^[12,13] Added to this, the procedure can be distressing when

during localisation of genicular nerves the RF cannula comes in contact with pain-sensitive structures such as the periosteum and ligament insertion sites.^[14] These limitations can be partly overcome using bipolar RF. Placing two electrodes avoids manipulation required to localise the genicular nerves with inadvertent stimulation of pain-sensitive periosteum. This is validated by the fact that significantly less procedural pain was noted in the bipolar when compared with the monopolar group.

The novel idea to use bipolar RFA in this study was to produce a larger lesion, thus minimising the chance to miss the lesion of genicular nerves. Jacobson et al.^[15] have described the concept of bipolar RFA in lumbar facets as an adjunct to conventional radiofrequency to increase the lesion size and thus better improvement in pain relief in facet arthropathy. The size of the lesion produced by bipolar RF is larger than the lesions produced by monopolar RF.^[16] This explains the improvement in Oxford scores in the bipolar group of our study. Additionally, less time was taken to complete the procedure in the bipolar group since accurate localisation of the genicular nerves was not required [Table 2]. Bipolar RF can therefore be used as an alternative to monopolar RF with equal efficacy and decreased need to localise the genicular nerves thereby improving patient acceptability.

Recently, cooled RFA technology is being used to increase the success rate of genicular nerve ablation.^[17] The principle of cooled RFA is to increase the lesion size by keeping the temperature of the surrounded tissue at lower level.^[18] Recently, ultrasound guidance has been used to locate the genicular nerves with improved success rates even in the situation of tremendous variabilities in the anatomy of the nerves.^[12,19] However, both techniques require sophisticated equipment and have a learning curve before one becomes equipped with the procedure.

None of the patients in either group had any complication during or after the procedure. However, serious concerns regarding injury to the genicular arteries which are very close to genicular nerves have been raised in a recent review.^[20] Pulsed RF treatment of genicular nerves may be a safe alternative to RFA to avoid possible injury by conventional RFA.^[21]

The limitations of the study were a small sample size and that patients were not followed up for long term. Participants were not blinded to group assignment, which introduces the possibility of response bias. We included patients with OA grades II–IV (Kellgren and Lawrence scale); however, we did not compare outcomes related to the severity of grades between the two groups. The patients were asked to inform whether there was any change in regular drug requirements. However, comparison of change in drug intake (increase or decrease in dosages of previously prescribed drugs) was not done.

CONCLUSION

Bipolar radiofrequency ablation is an effective alternative for ablation of genicular nerves in patients with knee pain due to OA. It has similar analgesic efficacy but much less procedural pain when compared with MRFA.

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Conflicts of interest

There are no conflicts of interest.

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