ORIGINAL ARTICLE

Chemical Ablation of Genicular Nerve with Phenol for Pain Relief in Patients with Knee Osteoarthritis: A Prospective Study

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■ **Abstract**

Background: Radiofrequency ablation of the genicular nerve is performed for knee osteoarthritis (KOA) when conservative treatment is not effective. Chemical ablation may be an alternative, but its effectiveness and safety have not been examined. The objective of this prospective open-label cohort study is to evaluate the effectiveness and safety of ultrasound-guided chemical neurolysis for genicular nerves with phenol to treat patients with chronic pain from KOA.

Methods: Forty-three patients with KOA with pain intensity score (Numeric Rating Scale, NRS) ≥ 4, and duration of pain of more than 6 months were considered for enrollment. Ultrasound-guided diagnostic blocks of genicular nerves (superomedial, inferomedial, and superolateral) with 1.5 mL of 0.25% bupivacaine at each site were performed. Those who reported more than 50% reduction in NRS went on to undergo chemical neurolysis, using 1.5 mL 7% glycerated phenol in each genicular nerve. NRS and Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores were assessed before intervention and at 2 weeks and 1, 2, 3, and 6 months following the intervention.

Results: NRS and WOMAC scores improved at all time points. Mean pain intensity improved from 7.2 (95% confidence interval [CI]: 6.8 to 7.7) at baseline to 4.2 (95%CI: 3.5 to 5.0) at 6-month follow-up ($P < 0.001$). Composite WOMAC score improved from 48.7 (95%CI: 43.3 to 54.2) at baseline to 20.7 (95%CI: 16.6 to 24.7) at 6-month follow-up ($P < 0.001$). Adverse events did not persist beyond 1 month and included local pain, hypoesthesia, swelling, and bruise.

Conclusion: Chemical neurolysis of genicular nerves with phenol provided efficacious analgesia and functional improvement for at least 6 months in most patients with a low incidence of adverse effects. ■

Key Words: osteoarthritis, knee, genicular, neurolysis, phenol

INTRODUCTION

Pain from knee osteoarthritis (KOA) is a leading cause of disability, especially in the elderly and it is also costly to treat.[1] The typical clinical presentation of KOA is joint pain and stiffness.[2] Imaging studies can objectively evaluate the severity of joint destruction in KOA.

Various conservative treatments are recommended to relieve knee pain prior to undergoing invasive

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procedures, but these may provide limited benefits for patients with advanced stage of symptomatic osteoarthritis.[1–3] For example, intra-articular injection therapy offers short-term relief.[4] Therefore, total knee arthroplasty (TKA) is often recommended for patients with moderate to severe KOA symptoms refractory to conservative treatment.

However, TKA may be contraindicated in patients with medical comorbidities. In addition, less developed countries with limited medical resources have limited capability to offer TKA to patients who need it. For example, TKA in Brazil is much less likely to be performed than in countries with more developed medical delivery systems, and wait times for TKA may be 3 to 5 years.[5]

An alternative option for symptomatic patients with KOA may be thermal ablation of the sensory afferents of the anterior knee.[6–10] However, the needles, thermocouples, radiofrequency generator, and other necessary equipment may not be available or affordable. Chemical neurolysis has been reported in patients with KOA with favorable treatment outcomes.[11–13] Its low cost makes this a viable treatment modality for further investigation. Chemical neurolytics such as phenol block pain transmission through Wallerian degeneration of sensory afferent fibers[14] may be ideal for neurolysis of the genicular nerves.[12]

In this study, the primary objective was to evaluate the analgesic effects of chemical ablation of the genicular nerves with phenol in patients with KOA who underwent a chemical ablation of the genicular nerves with phenol. Our secondary objectives were to examine the improvement of function and safety of this procedure.

METHODS

This prospective study was approved by the local research ethics committee (CAAE 89076818.4.0000. 5505) and was registered with clinicaltrials.gov (NCT03601533). All patients were recruited from an outpatient pain clinic and provided consent to participate for free treatment. The enrollment of the study was from August 2018 to August 2019.

Eligibility criteria included age 18 years or older, history of moderate knee pain (pain intensity ≥ 4 in a numerical rating scale (NRS) from 0 to 10) for more than 6 months, radiologic evidence of osteoarthritis with Kellgren–Lawrence grade III or IV,[15] and a history of failure of pain relief with conservative therapeutic modalities such as analgesic and physical therapy. Participants enrolled in the study were all on waiting list to undergo TKA for KOA.

Patients were excluded from study participation if they had cognitive impairment, hepatic disease, severe psychiatric diseases, knee pain not attributed to KOA (eg, trauma, complex regional pain syndrome, residual limb pain, prosthesis pain), infection, coagulopathy, or anticoagulant use.

Interventions

Image-guided diagnostic genicular nerve blocks were performed with strict aseptic technique and standard hemodynamic monitoring. The technique for the ultrasound-guided genicular nerve injection has been described by one of the authors (P.P.).[16] For the superomedial (SM) and superolateral (SL) genicular nerves of the knee, a linear 5 to 12-MHz ultrasound probe (Sonosite M-turbo®, Seattle, WA, USA) was placed along the long axis of the femur at the junction of epiphysis and diaphysis. The genicular nerves run in the fascial expansion deep to the vastus medial or intermedius/lateralis muscles in the vicinity of the genicular arteries. The depth of the fascia expansion was measured, and the probe was then turned to obtain the short axis of the femur revealing the fascial expansion of the same depth (Figure 1). A 22G $\times$ 80 mm needle (Stimuplex, BBraun, Melsungen, Germany) was introduced in plane from anterior to posterior direction until the tip was within the fascial plane noted above. Upon hydrolocation with 0.2 mL of saline, 1.5 mL of 0.25% bupivacaine was administered at each of these sites.

For the inferior medial (IM) genicular nerve, the target was the neurovascular bundle deep to the medial collateral ligament at the junction of epiphysis and diaphysis, and 1.5 mL of 0.25% bupivacaine was administered following hydrolocation.

The patients were reassessed 1 week after the diagnostic block. Patients who reported > 50% reduction in knee pain for at least 6 hours were submitted to the neurolytic block. The technique for phenol neurolysis of the SM, SL, and IM genicular nerves was similar to the diagnostic block, but at each target 1.5 mL of 7% glycerinated phenol solution was injected.[17]

Postintervention management

For postprocedure knee pain, study participants could use acetaminophen 500 mg every 6 hours, with a

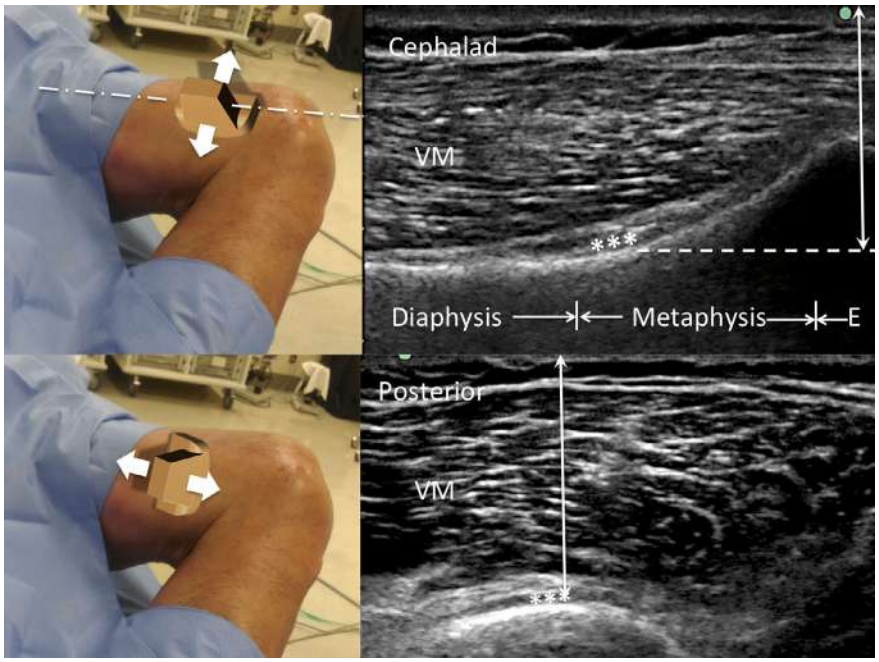

Figure 1. Ultrasound-guided superior medial genicular nerve block. (Upper panel) The long axis of the femur, from cephalic to caudal, at the junction of epiphysis (E) and diaphysis. The genicular nerves ran in the fascial expansion (***) deep to the vastus medial muscles (VM) in the vicinity of the genicular arteries. (Lower panel) The short axis of the femur revealed the fascial expansion of the same depth.

maximum daily dose of 2 grams per day. If necessary, they could use tramadol (50 mg) as needed up to a maximum 400 mg/day. The patients were advised strengthening exercises for the knee muscle both verbally and with pictures.

Assessment

Participants reported NRS and Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores before the intervention and again 2 weeks and 1, 2, 3, and 6 months after the intervention. The data were collected in person. WOMAC is widely used in the evaluation of KOA. It is a self-administered questionnaire composed of 24 items divided into three subscales: pain, stiffness, and physical function.[18] The use of supplementary analgesic was also recorded.

Adverse events following the procedure were recorded, and included swelling, numbness, paresthesia, motor weakness, and pain. The adverse events were recorded by a checklist in 2 weeks and 1, 2, 3, and 6 months after the intervention.

In all follow-up visits, the patients were assessed by study personnel who were not involved in the selection of participants or in the conduct of diagnostic or therapeutic blocks.

Statistical analysis

The primary outcome of the study was the improvement in knee pain intensity by NRS during the 6-month follow-up after chemical neurolysis with phenol. Secondary outcomes included WOMAC scores and the incidence of adverse events.

We considered a 30% improvement in the NRS in patients with KOA a meaningful improvement. At the 2.5% unilateral significance level, a sample size of 36 patients would have 80% power to detect this improvement between baseline and end of the study. Factoring in an attrition rate of 30% and the successful response rate of 85% to the diagnostic block, the initial sample size was 60 patients.

The data were analyzed with SPSS Statistics version 17 (Chicago, IL). Demographic data were presented with descriptive statistics. The pain scores and WOMAC scores were reported as means and 95% confidence interval. To compare the time points, an ANOVA model was used for repeated measures, adjusting for age, body mass index (BMI), and gender.

Tukey's multiple comparison test was used for the analysis.

RESULTS

A total of 68 patients were approached for study inclusion, and 63 were allocated to diagnostic blocks. Sixty-one patients reported > 50% reduction in pain with diagnostic blocks and then underwent chemical ablation of the genicular nerves with phenol. Of the 61 participants who underwent the study intervention, 18 patients were lost to follow-up (30.0%) leaving 43 in the final analysis, as shown in the flow diagram (Figure 2). Baseline demographics are presented in Table 1. Ten patients, who were from other cities were lost to follow-up due to transportation and access problems or did not respond to phone calls and emails from study personnel. Four patients underwent surgical procedures not related to knee pain and received pain medications outside our protocol. Another four patients received intra-articular injections with orthopedic surgery providers.

There was significant reduction of pain intensity after the chemical ablation in all evaluated periods (Table 2). The proportion of patients with ≥ 50% pain relief at 6 months was 46%. The need for supplementary analgesics is presented in Table 3. Less than 5% of the patients required tramadol after the procedure throughout the 6-month follow-up period.

Compared with baseline, there was significant improvement in knee WOMAC pain and function subscale as well as the composite scale in all evaluation periods throughout the first 6 months (Table 2). The improvement in the total WOMAC score was 62% by 6 months (Table 2). Sixty five percent of patients showed at least 50% improvement in composite WOMAC scores at 6 months after the intervention.

In the model of analysis of variance (ANOVA) adjusted for age, BMI, and gender, significant differences were observed between the times points (Table 2).

The noted adverse effects were local pain, swelling, bruise, and hypoesthesia (Table 4). The adverse side effects of this study were minor and of short duration. No new additional adverse events were noted after the 1-month follow-up visit. There were no cases of dysesthesia at any time point.

DISCUSSION

This is the first large prospective study, assessing the analgesic efficacy and adverse effect of genicular nerve

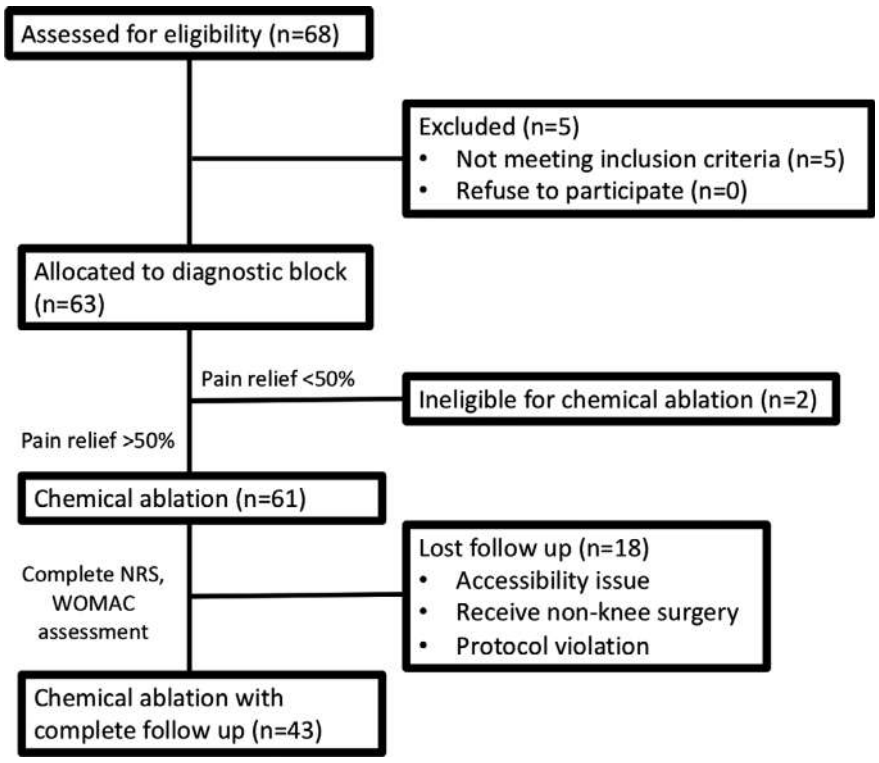

Figure 2. Flow chart. NRS, numerical rating scale; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

Table 1. Demographic Data

Gender (M F)	5:38
Age (years)	67.8 ± 9.4
Weight (kg)	77.5 ± 13.0
Height (cm)	156.3 ± 9.9
BMI (kg/m^2)	31.8 ± 5.2

The age, weight, height, and body mass index (BMI) were presented in mean ± standard deviation.

Table 2. Descriptive Statistics and Adjusted Means per Time Point

	Time Point	Mean	SD	95% CI	Adj. Mean	*P* value*
Numeric Rating Scale	Baseline	7.21	1.44	6.8 to 7.7	7.41	
	2 weeks	4.05	1.80	3.4 to 4.6	4.25	<0.001
	1 month	3.49*	2.06	2.9 to 4.2	3.69	<0.001
	2 month	3.79*	2.17	3.1 to 4.5	4.00	<0.001
	3 month	3.91*	2.64	3.1 to 4.7	4.11	<0.001
	6 month	4.23*	2.50	3.5 to 5.0	4.44	<0.001
WOMAC composite score	Baseline	48.77	17.61	43.5 to 54.2	56.10	
	2 weeks	25.16*	10.64	21.9 to 28.4	32.50	<0.001
	1 month	18.16*	9.20	15.3 to 21.0	25.50	<0.001
	2 months	19.56*	11.46	16.0 to 23.1	26.90	<0.001
	3 months	18.60*	11.56	15.1 to 22.2	25.90	<0.001
	6 months	20.67*	13.11	16.6 to 24.7	28.00	<0.001
Pain subscale	Baseline	10.00	4.01	8.8 to 11.2	9.33	
	2 weeks	5.16*	2.33	4.7 to 6.0	4.50	<0.001
	1 month	4.21*	2.42	3.5 to 5.0	3.54	<0.001
	2 months	4.77*	2.79	4.0 to 5.6	4.10	<0.001
	3 months	4.35*	3.39	3.3 to 5.4	3.68	<0.001
	6 months	5.00*	3.82	3.8 to 6.2	4.33	<0.001
Stiffness subscale	Baseline	4.02	2.54	3.2 to 4.8	4.86	
	2 weeks	1.91*	1.70	1.5 to 2.6	2.74	<0.001
	1 month	1.05*	1.19	0.7 to 1.4	1.88	<0.001
	2 months	1.28*	1.69	0.8 to 1.8	2.12	<0.001
	3 months	1.05*	1.43	0.6 to 1.5	1.88	<0.001
	6 months	1.14*	1.63	0.6 to 1.6	1.98	<0.001
Function subscale	Baseline	34.93	12.46	31.1 to 38.8	41.40	
	2 weeks	18.09*	8.54	15.3 to 20.5	24.60	<0.001
	1 month	12.93*	6.98	10.8 to 15.1	19.40	<0.001
	2 months	13.74*	8.59	11.1 to 16.4	20.20	<0.001
	3 months	13.37*	7.89	10.9 to 15.8	19.80	<0.001
	6 months	14.74*	8.67	12.1 to 17.4	21.20	<0.001

The numeric rating scale (NRS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC) subscales and composite score were presented as mean and 95% confidence interval (CI). Comparing each postintervention pain and WOMAC scores with subscale baseline (T0) using a model of analysis of variance (ANOVA) for repeated measures without adjusting variables all showed a statistical difference ($P < 0.001$). T0 > 2 weeks; T0 > 1 month; T0 > 2 months; T0 > 3 months; T0 > 6 months; $P < 0.001$.
*Compared with baseline.

ablation with phenol in patients with KOA. Our study revealed a significant improvement in pain and function up to 6 months, with minor and short-term adverse effects.

In developing countries, patient access to TKA is very limited with long waiting times.[5,19,20] Genicular nerve ablation with phenol offers a new and seemingly safe modality to treat KOA and improves pain intensity as well as physical functioning. It thereby improves quality of life and the conditions for physical rehabilitation, making the waiting time for the surgery tolerable.

In much of the world, genicular nerve ablation is commonly performed with radiofrequency thermal technique.[6,7,21] However, the needles and the equipment are of high cost for developing countries and may not be available.[8,9] In this context, the cost of chemical neurolytic agent is much lower than the radiofrequency needle. Similar to the results of previous studies with radiofrequency ablation,[9,22] the pain intensity and functional outcome were sustained up to a 6-month follow-up with chemical ablation at a cost 100 times less.[8,10,22,23] However, the percentages with > 50% pain relief at 6 months are higher in those studies with radiofrequency ablation.[8,10,22] The optimal concentration, volume, and type of neurolytic agent have yet to be defined. In this study we use phenol 7%, and the neurolytic effect can potentially be prolonged if a stronger neurolytic agent such as 100% alcohol is used.

Among the neurolytic agents, phenol is one of the most commonly used. Phenol causes precipitation of cellular proteins and lipids, myelin sheath separation, axonal edema, and consequently axonal degeneration. The neurolytic effect may be evaluated after 24 to 48 hours, but it may not be evident until 3 to 7 days after the procedure.[11] The duration of the effect varies from 2 months to 2 years in neurolytic blocks.[12,14]

Safety is an important issue when considering chemical ablation of the genicular nerves. In our series, the adverse events were infrequent, minor, and self-limiting. The most common event was knee swelling which was reported in 30% of patients within the first 2 weeks and 12% at 1 month. There were no new adverse events reported after the first month following the intervention.

Another adverse effect is related to the inadvertent spread of the phenol. Study on cadavers showed that 4 mL injected in each genicular nerve has good periarticular dispersion, but it reached the posterior area of the knee.[24]

Table 3. Analgesic Consumption

	Baseline	2 weeks	1 month	2 months	3 months	6 months
Supplement analgesic						
Simple	43(100%)	28 (64%)	22 (51%)	26 (61%)	21 (49%)	16 (37%)
Tramadol	0	2 (5%)	1 (2%)	1 (2%)	2 (5%)	2 (5%)

Table 4. Number of Patients with Side Effects and Complications

	2 weeks	1 month	2 months	3 months	6 months
Local pain	2 (5%)	0	0	0	0
Hypoesthesia	6 (14%)	0	0	0	0
Swelling	13 (30%)	5 (12%)	0	0	0
Bruise	9 (21%)	0	0	0	0

Therefore, we chose a lower volume of 1.5 mL, as in the literature (0.5 to 2 mL in each genicular nerve). We also used 7% glycerinated phenol as the spread is more predictable and the recommended concentration varies from 3 to 12%.[14] The total dosage used was 315 mg, much lower than the maximum daily dosage that is 1 g.[23] However, there are no studies that show the ideal volume for a chemical neurolysis of genicular nerves. It is not known whether higher volumes could lead to better results.[14]

This study has some limitations. First, the loss in follow-up was high, related to the lack of patient access to healthcare facilities.[19] Second, it is unclear whether glycerinated phenol is the most ideal chemical neurolytic to utilize for this procedure. More research needs to be carried out in order to study the effectiveness and safety of other chemicals, such as aqueous solutions of phenol or alcohol. Third, our methodology of a prospective, open-label cohort study may introduce bias,[25] although the design was prospective and the assessments were not performed by the physician who provided the injection or ablation. Fourth, recent anatomic dissection studies suggested that the anterior knee received innervation from up to 10 articular branches.[26,27] Of those, the superior medial genicular nerve (SMGN), superolateral genicular nerve (SLGN), and inferior medial genicular nerve (IMGN) were chosen as common targets for denervation. In the denervation literature, it is not necessary to denervate all articular branches of large joints which may lead to the risk of Charcot joint. Instead, the concept of partial denervation is usually applied.[28] A recent review of knee denervation also supports the analgesic efficacy of partial denervation with target on SMGN, SLGN, and IMGN.[21] The research question that remains is the optimal combination of the articular branches for maximum analgesic efficacy and safety.[21,29,30] There is a possible difference in the lesion from chemical and thermal ablation. The lesion from thermal ablation depends on a few factors, but it is quite discrete in the size of 0.5 to 1 cm^3 for monopolar radiofrequency probe.[31] Therefore, the needle tip is required to be in close proximity of the articular branches. The literature in dye injection suggested that a volume of 1 mL may spread beyond what a typical monopolar radiofrequency lesion can achieve.[32] Thus, it is conceivable that the chemical ablation lesion may cover more than the three typical articular branches.

In conclusion, the ultrasound-guided genicular nerve blocks with glycerinated phenol provided good, long term analgesia and functional improvement in most patients, with rare adverse events. Compared with radiofrequency thermal ablation, the procedure time is much shorter and the cost is substantially lower. This study affirms the feasibility of chemical ablation of the genicular nerves in patients with KOA, but more controlled studies are needed to validate our findings and to compare chemical with thermal neurolysis procedures with regard to efficacy, safety, cost, and duration of analgesic and functional effects. Further, investigations into the ideal volumes to be used for neurolysis as well as the use of alcohol in these procedures warrant further study.

AUTHORS' CONTRIBUTION

Roberta Cristina Risso: Evaluation of the patients and writing of the manuscript. Leonardo Henrique Cunha Ferraro: Performing the blocks on patients and the writing of the manuscript. Thiago Nouer Frederico: Writing of the manuscript. Philip W.H. Peng: Standardization of the technique performed and the writing of the manuscript. Marcus Vinicius Luzo: Selection of the patients and writing of the manuscript. Pedro Debieux Vargas Silva: Selection of the patients and writing of the manuscript. Rioko Sakata: Writing of the manuscript.

CONFLICT OF INTEREST

None of the authors has any conflict of interest relevant to this manuscript.

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