

Comparative evaluation of functional outcome and pain relief after pulsed radiofrequency of the saphenous nerve within and distal to the adductor canal in medial compartment knee osteoarthritis: A randomized double-blind trial

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Abstract

Background and Aims: Pulsed radiofrequency (PRF) of the saphenous nerve (SN) has shown effective pain relief in knee pain because of knee osteoarthritis (KOA). The adductor canal (AC) contains other sensory nerves innervating the medial part of the knee joint apart from SN. We compared the PRF of SN within and outside the AC for their quality and duration of pain relief in knee osteoarthritis of the medial compartment (KOA-MC).

Material and Methods: We conducted a randomized prospective study in 60 patients with anteromedial knee pain because of KOA-MC. Patients in group A received PRF-SN, and those in group B received PRF-AC. The primary objectives were comparison of pain by Visual Analog Scale (VAS) scores and changes in quality of daily living by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and OXFORD knee scores. The secondary objectives were comparison of analgesic requirements using Medicine Quantification Scale (MQS) scores and block-related complications. Intra-group comparison was performed by analysis of variance. Inter-group normally distributed data were assessed by Student's t-test, non-normally distributed and ordinal data were assessed by Mann-Whitney U-test, and categorical data were assessed by Chi-square test. A *P* value of <0.05 was considered significant.

Results: VAS scores were significantly lower in Gr-B at 12 weeks. The WOMAC scores and OXFORD scores at 4, 8, 12, and 24 weeks were significantly lower in Gr-B compared to Gr-A.

Conclusion: The PRF-AC provides better pain relief and functional outcome than PRF-SN; however, duration of pain relief was not significantly different.

Keywords: Adductor canal, knee joint, osteoarthritis knee, pain management, pulsed radiofrequency treatment, saphenous nerve

Introduction

Knee osteoarthritis (KOA) is a common degenerative disease in the older population, causing pain, stiffness, and dysfunction. The involvement of the medial compartment (KOA-MC) of

the joint is 5–10 times higher than disease in the lateral compartment.^[1,2] The saphenous nerve supplies the anterior and medial parts of the joint, and the interventional management of the saphenous nerve and pulsed radiofrequency (PRF) of the saphenous nerve (SN) have shown long-lasting relief.^[3-5]

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As PRF of SN provides effective pain relief in KOA, we hypothesized that PRF of the adductor canal (AC) which contains SN and other sensory nerves [such as nerve to vastus medialis (NVM), medial femoral cutaneous nerve of thigh, intermediate femoral cutaneous nerve of the thigh, branches of the obturator nerve and related to knee joint innervation on the anterior and medial sides] may provide superior pain relief in KOA-MC. As there was no comparative study available, we conducted this comparative study in patients of KOA-MC with knee pain to assess the quality and duration of pain relief after PRF of SN and PRF of AC.

Material and Methods

After clearance from the ethical committee and registration with Clinical Trials Registry - India, this prospective randomized double-blinded study was conducted at a teaching hospital during May 2019 to February 2021 (including 6 months of follow-up). A total 60 patients of both sexes aged 40–80 years having predominantly medial knee pain because of KOA-MC were included in the study. Inclusion criteria were pain and tenderness for more than 6 months on the anteromedial aspect of the knee owing to KOA and matching X-ray findings of grade 2–4 radiographic changes according to the Kellgren–Lawrence classification.^[6] Exclusion criteria were refusal to participate in the study, the presence of other knee pathologies such as fracture or rheumatic diseases, and previous surgery of the knee or knee synovitis. Patients having any contraindication to nerve blocks

or radiofrequency treatment were also excluded. After written informed consent, all the patients (n = 58) were randomly divided into two equal groups – PRF-SN (Gr-A, n = 29) and PRF-AC (Gr-B, n = 29) [Figure 1] by computer-generated random numbers, and group assignment was performed by sequentially numbered opaque envelopes. All the blocks were performed by a single experienced anaesthesiologist (having an experience of 5 years in ultrasound-guided regional anesthesia) who was not involved in post-procedure observations. Patients were taken to the operating room, and standard monitors (electrocardiogram, non-invasive blood pressure and pulse oxymeter) were attached. The blocks were performed in the supine position with a standard protocol and a strict sterile technique.^[7]

To perform PRF-AC, a high-frequency US probe (6–13 MHz SonoSite-M Turbo®, Fuji India.) was placed in transverse orientation at the mid-thigh level. Sonoanatomy of AC was identified [Figure 2a]. The needle entry point at the skin was anesthetized with 2 ml 1% lidocaine, and a 20-gauge 10 cm long blunt-tip RF cannula with a 10 mm active tip (COSMAN Cannula-RFK™) was inserted toward the nerve complex lateral to the femoral artery using an in-plane view [Figure 2b and c]. Sensory stimulation at 50 Hz (0.5 mV) and motor stimulation at 2 Hz (1 mV) were performed to observe the sensation along the course of SN including on the inferior-medial side of the knee joint and contraction of the vastus medialis muscle, respectively. Once the needle position was confirmed, PRF was performed for 8 minutes (four cycles

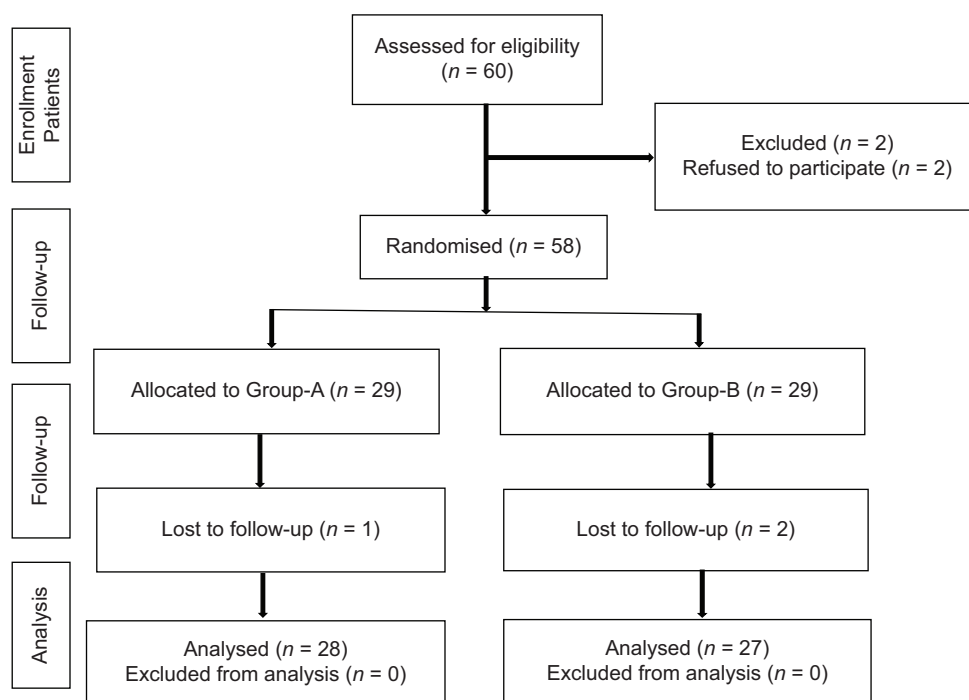


Figure 1: CONSORT flow diagram for enrollment, group allocation, follow-up, and analysis

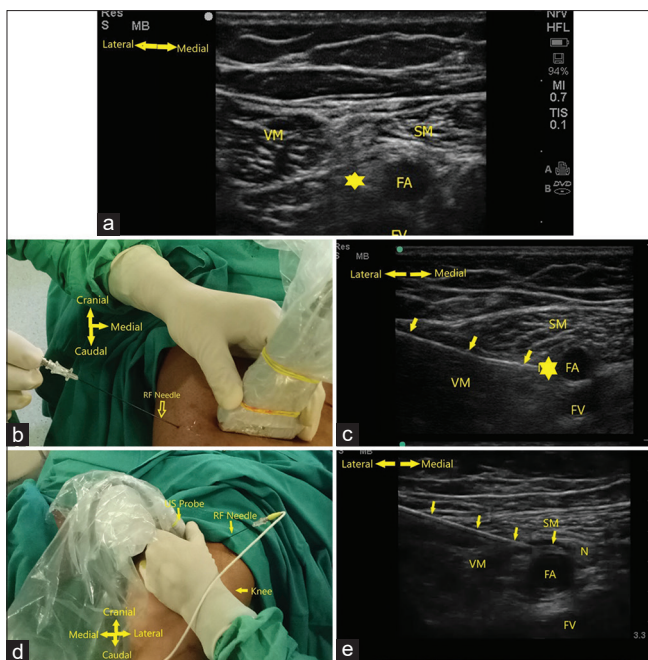


Figure 2: (a) Sonoanatomy of AC, (b) Needle entry from the lateral to medial side under a high-frequency US probe, (c) needle positioned on the nerve complex lateral to the femoral artery, (d) needle entry from the lateral to medial direction at the distal part of the thigh toward SN using in-plane view, and (e) radiofrequency needle in contact with SN. FA-femoral artery, FV-femoral vein, VM-vastus medialis, SM-sartorius muscle, * nerve complex (SN + VM)

of 120 seconds each at 42°C and 50V). After completion of PRF, a 5 ml mixture of 0.25% bupivacaine and 40 mg of methyl-prednisolone acetate (Depot. preparation) was given.

To perform PRF-SN, after identifying the sonoanatomy of AC [Figure 2a], the US probe was moved distally to follow the course of the SN. When the SN was medial and a little away from the artery, the block needle was inserted toward the SN using an in-plane view [Figure 2d and e]. Sensory stimulation at 50 Hz (0.5 mV) and motor stimulation at 2 Hz (1–2 mV) were performed. We observed the tingling sensation along the course of SN including the inferior-medial side of the knee joint; however, there was no motor response. Once the needle position was confirmed, PRF was performed for 8 minutes (four cycles, 2 minutes each at 42°C, 50V). After completion of PRF, a 5 ml mixture of 0.25% bupivacaine and 40 mg of methylprednisolone acetate (Depot. preparation) was injected via the cannula. Patients were discharged after observation for 1 hour. Patients were allowed to take medicines (topical analgesics, non-steroidal anti-inflammatory drugs, gabapentinoids, tricyclic anti-depressants, and tramadol) as before the intervention. If required, patients were advised to take tablet paracetamol 500 mg as desired up to a maximum of 3 tablets/24 hours for 2–3 days to manage procedural pain. After 48 hours, all the patients were called, and a structured physiotherapy session for 10 days at the physiotherapy out-patient department was performed with

the help of a professional physiotherapist, followed by guided home-based exercises. Follow-up was performed at 4, 8, 12, and 24 weeks. Primary objectives were to compare pain and changes in quality of daily living in Gr-A and Gr-B. VAS score (0–100) was used to assess the pain relief and WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) and OXFORD knee scores (OKSs) were used to assess the functional outcome (quality and activity of daily living). The WOMAC used in this study was the Likert version 3.1 consisting of 24 self-administrated questions that were answered for each item on a 5-point Likert scale (none-0, mild-1, moderate-2, severe-3, and extreme-4). It was reported as three separate sub-scales: pain, physical function, and stiffness. The WOMAC pain sub-scale had five questions with scores 0 to 4 and was considered invalid if more than one item was missing; hence, it had a range of 0 (no pain) to 20 (maximal pain), and the total score range was between 0 and 96. In the event of a missing item, the remaining four items were averaged and then multiplied by 5.^[8] In OKS, the original scoring system was used, where the symptom score ranges from 1 to 5, where score 1 represented the best outcome (a lesser score is better).^[9] In OKS reporting, if there were one or two missing answers, a mean answer from the patient's other answer was entered. If a question had more than one answer, the smallest number was used for calculations.^[9] The secondary objectives were to compare the analgesic requirements using Medicine Quantification Scale (MQS) and block-related complications. Assessments of WOMAC, VAS, and MQS were performed by a resident of anesthesia/pain management who was unaware about the group allocation. The OKS assessment was performed by an observer of the orthopedic department who was also unaware about the protocol and the group allocation. The data were entered in an Excel sheet. The results were analyzed using the statistical software (MedCalc version 20.0). Within each group, comparison of various scores (pre-intervention or base line values up to 24 weeks) was performed using one-way analysis of variance (ANOVA). To compare Gr-A and Gr-B, the continuous data were assessed for normality using the Kolmogorov–Smirnov test of normality. Normally distributed data [represented as mean ± standard deviation (SD)] were assessed using Student's t-test (two-tailed, unequal variances). Non-normally distributed data and ordinal data [represented as median and interquartile range (IQR)] were assessed using the Mann–Whitney U-test. Chi-square statistics was used for categorical data. *AP* value < 0.05 was considered significant.

The sample size was based on our pilot study of 20 patients where the VAS at 6 months was 42 ± 10.49. Considering 20% change as significant and using the formula $(N = 2\sigma^2 (z_{1-\beta} + z_{1-\alpha/2})^2 \div (\mu_0 - \mu_1)^2)$, 2,

$N = 2 (10.492 + 10.492) (0.84 + 1.96) 2 \div (8) 2$, $N = 54$), 27 patients in each group were required with 95% confidence, 80% power, and $P < 0.05$, where μ_0 = population mean, μ_1 = mean of the study population, N = sample size of the study population, σ = variance of the study population, α = probability of type I error (0.05), β = probability of type II error (0.2), and z = critical Z value for a given α or β . We enrolled 60 patients to take care of attrition.

Results

A total of 60 patients were enrolled, and 58 were randomized and 55 were finally analyzed (two patients were excluded before randomization, and three patients opted out before final follow-up at 24 weeks) [Figure 1]. The demographic profiles of patients including mean age, weight, body mass index (BMI), male/female ratio, radiological severity of KOA, and number of cases with bilateral affection were comparable in both the groups [Table 1]. The WOMAC scores at 4, 8, 12, and 24 weeks were significantly lower in Gr-B compared to Gr-A; $P = 0.004, 0.008, 0.034$, and 0.013 , respectively. The OXFORD scores were significantly lower in Gr-B at 4, 8, 12, and 24 weeks; $P < 0.0001, <0.0001, <0.0001$, and $P = 0.02$, respectively. VAS scores were comparable in Gr-A and Gr-B at 4, 8, and 24 weeks; $P = 0.827, 0.852$, and 0.754 , respectively, but significantly lower in Gr-B at 12 weeks, $P = 0.010$ [Table 2]. In both the groups, there was significant reduction in pain and improvement in the functional outcome when compared within the group (one-way ANOVA) at all the follow-up periods ($p < 0.0001$). In both the groups, there was significant reduction in WOMAC and OKS at 24 weeks compared to pre-intervention levels $P < 0.0001$ [Figure 3]. The MQS scores were comparable in Gr-A and Gr-B at 24 weeks $P = 0.123$ [Table 3]. No patient in any group had any complication related to PRF intervention.

Discussion

We conducted a double-blinded randomized study to compare the efficacy of PRF-SN with PRF-AC to treat pain in KOA-MC. There was significant pain relief and improvement in the functional scores from pre-intervention values at all the follow-up periods (4–24 weeks) in both the groups. This reduction in functional improvement was significantly better in Gr-B (PRF-AC) compared to Gr-A (PRF-SN).

SN is a terminal sensory branch of the femoral nerve and supplies the anterior and medial parts of the joint capsule. It plays an important role in the pain management of the knee

Table 1: Demographic variables, Kellgren–Lawrence Score (KJ grades of arthritis) and sides of the knee involved in patients of Gr-A and Gr-B

Variables	Gr-A (n=28)	Gr-B (n=27)	P
Age (years)	59.6±11.9	63.3±11.2	0.216*
Male/Female	11/17	10/16	0.923†
Weight (Kg)	64.6 (± 12.5)	60.6 (± 13.1)	0.220*
Mean Height Cm (± SD)	160.8 (± 9.1)	161.9 (± 10.3)	0.651*
Mean BMI Kg/m ² (± SD)	24.3 (± 5.4)	24.8 (± 4.4)	0.692*
Affected Side (Left/Right)	18/10	17/10	0.911†
Bilateral knee involved (number of cases)	4	4	-
Kellgren–Lawrence Score			
Grade 2	16 (57%)	16 (59%)	0.754†
Grade 3	9 (32%)	8 (30%)	
Grade 4	2 (7%)	3 (11%)	

†Chi-square test, *Student t-test SD-standard deviation, BMI-Body mass index, Gr-A; Pulsed radiofrequency of the Saphenous nerve, Gr-B; Pulsed radiofrequency of the Adductor canal

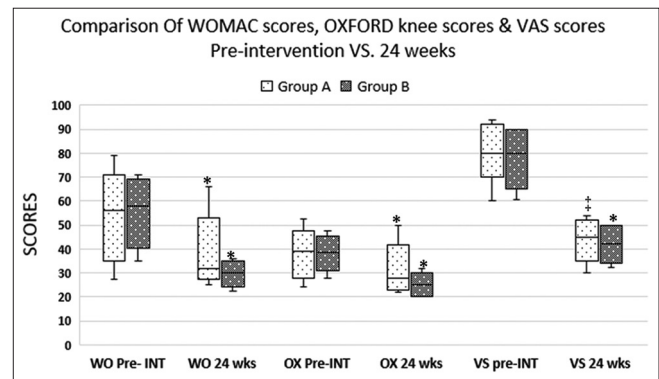


Figure 3: Comparison of various scores at pre-intervention (baseline level) and at 24 weeks

joint. Akbas *et al.*^[4] investigated 115 patients with chronic knee pain after 8 minutes of PRF-SN. All patients showed remarkable improvement in their VAS and WOMAC scores ($p = 0.001$). Vas *et al.*^[10] used PRF of multiple nerves to manage pain of KOA, and PRF-SN was one of the components of the management strategy. Recently, Baysal *et al.*^[5] have concluded that PRF-SN is a safe and function-sparing technique for KOA. However, there was a lacuna in the literature as only a few studies are available where PRF-SN has been used to treat the chronic pain in KOA and comparative studies with PRF-AC were lacking.

SN is consistently present in AC and to achieve motor sparing in the SN block; it is advised to block it in the distal part of AC where it is away from the branches of the nerve to vastus medialis (NVM). Therefore, we performed PRF-SN at the distal part of AC after confirming the absence of motor stimulation to achieve the selective sensory block of SN.

Over the years, the AC block has been effectively used for pain relief after total knee arthroplasty (TKA)^[11] for knee joint

Table 2: Comparison of WOMAC, OXFORD, and VAS scores at various follow-up periods in Gr-A and Gr-B

Variables	Gr-A (n=28)	Gr-B (n=27)	t [†] or z [‡]	P
WOMAC Scores, Mean (± SD)				
Pre-intervention	53.32±17.49	56.83±13.61	t=-0.87	0.386
4 weeks	36.06±14.04	28.06±4.96	t=-2.94	0.004*
8 weeks	35.51±15.31	27.7±3.50	t=-2.72	0.008*
12 weeks	34.06±13.90	28.43±3.69	t=-2.14	0.036*
24 weeks	37.00±13.62	30.23±5.13	t=-2.55	0.013*
OXFORD knee Scores				
Pre-intervention	38.61±10.40	38.23±6.53	t =-0.17	0.865
4 weeks	30.80±6.22	24.16±2.66	z=5.049	< 0.0001*
8 weeks	29.00±4.71	23.13±5.69	z=5.25	< 0.0001*
12 weeks	28.06±5.01	22.56±3.22	z=4.76	< 0.0001*
24 weeks	30.51±9.95	24.46±5.99	t=-2.39	0.021*
VAS Scores				
Pre-intervention	81.35±10.60	79.83±10.25	z=0.51	0.060
4 weeks	38.80±7.95	39.23±7.32	t=-0.22	0.827
8 weeks	36.80±6.31	36.43±8.97	t=-0.187	0.852
12 weeks	41.51±7.75	36.10±8.21	t=-2.64	0.010
24 weeks	43.16±7.64	42.56±7.28	t=-0.314	0.754

Gr-A, Pulsed radiofrequency of the saphenous nerve; Gr-B, Pulsed radiofrequency of the adductor canal; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; VAS, visual analogue scale; SD, standard deviation; * P<0.05 (significant); †Student t-test; ‡Mann-Whitney U-test

Table 3: Comparative MQS scores at 24 weeks in Gr-A and Gr-B

Groups	Median, IQR	Z score [†]	p
Gr-A (n=28)	3.3 (3.4-2.2)		
Gr-B (n=27)	2.25 (3.3-2.2)	1.54	0.123

[†]Mann-Whitney U test, MQS; Medicine Quantification Scale. Gr-A, Pulsed radiofrequency of the saphenous nerve; Gr-B, Pulsed radiofrequency of the adductor canal

rehabilitation^[12] and also to manage chronic knee pain.^[13,14] The main reason of its efficacy is that it blocks multiple nerves including SN, NVM, branches of the obturator, and other branches of femoral nerves which are involved in pain transmission either directly or contributing in the formation of the nerve plexus around the knee (sub-sartorial plexus, peripatellar plexus).^[15-17]

When the neurovascular structures pass through the AC, the nerves change their course (direction) and relation. Therefore, contents of AC depend upon which part of the canal is being observed (proximal, middle, or distal).^[18,19] It has been stated that the NVM lies outside in the distal part of the AC in about 90% of the cases.^[20,21] However, other studies do not support this view and have observed that NVM has many branches entering the AC and the mid-portion of the AC is an optimal site to block both the target nerves (SN and NVM).^[15] In our study, we selected proximal AC where motor stimulation confirmed the presence of the NVM in close proximity with SN. PRF in this area would have included the SN, NVM, and other sensory nerves contributing to knee pain and therefore resulted in better analgesia in Gr-B compared to Gr-A.

Genicular nerves are terminal sensory nerves supplying the knee joint, and the radiofrequency ablation (RFA) and PRF of genicular nerves are established techniques to manage KOA pain.^[22] Previous studies have shown that the deep genicular branches originate from a deep plexus with mixed contribution from both the SN and the NVM.^[15,23] Therefore, from the observations of the present study, it can be extrapolated that the PRF of SN and AC might have neuromodulated the sensory inputs at the source of origin of these genicular nerves (SN and NVM).

To assess the functional outcome of any analgesic intervention in KOA, WOMAC score is commonly used. It assesses three components, namely, pain, stiffness, and function. However, WOMAC reporting is inadequate in 53% of the studies.^[23] Therefore, we have also incorporated the VAS (0–100) (measured by independent observers) and OKS, which have good evidence for its internal consistency and construct validity.^[9] Intake of analgesics by patients may work as a confounding factor; therefore, we incorporated the MQS (version III). The MQS (version III) is a method of quantifying different pain drug regimens by evaluating the use of 22 distinct drugs. The score is calculated on the basis of the type of medicine and the amount taken in reference to the therapeutic range [1 = Sub-therapeutic dose or occasional use (PRN), 2 = Lower 50% of the therapeutic dose range, 3 = Upper 50% of the therapeutic dose range, 4 = Supra-therapeutic dose range].^[24] In our study, as the pain relief was significantly better in Gr-B at 12 weeks, it was expected to have lesser use of medications. However, MQS scores were comparable in Gr-A and

Gr-B at 24 weeks, and reasons could be other than the pain itself.^[25]

The RFA of genicular nerves is although an effective technique to manage pain in KOA, but safety of RFA has been questioned.^[26] Initially, Choi *et al.*^[27] have suggested three targets for RFA. However, it became a more difficult and time-consuming procedure as new research with revised anatomical targets has suggested five targets to provide effective pain relief.^[28] Contrary to that, we used single target procedures for PRF-SN and PRF-AC and found a high acceptance among patients and a lesser procedural time. However, PRF of SN has been used to treat pain of KOA^[4] and research is underway to evaluate the effectiveness of PRF in AC for the treatment of knee pain.^[29,30] The present study is a novel study because no such comparison has been published earlier to our knowledge. However, there were a few limitations in the present study. First of all, we have included only those patients suffering with antero-medial knee pain, and therefore, the effect of such treatment cannot be extrapolated for lateral knee pain. Second, we did not analyse the grades of severity with outcome. Last, the use of steroids with local anesthetics after the pulsed RF could have been a confounder to influence the pain relief.

Conclusion

PRF of SN and AC effectively reduced pain of KOA-MC and improved the functional outcome. The PRF-AC provided better functional outcome than PRF-SN; however, the duration of pain relief was not significantly different.

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Conflicts of interest

There are no conflicts of interest.

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