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Investigation of the use of gabapentinoid drugs in pain management

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ABSTRACT

Objectives: This study aimed to investigate the kind of painful conditions and preferred drug doses for which gabapentinoids were used for pain management for the musculoskeletal and nervous systems.

Materials and Methods: The study included 364 patients over the age of 18 who applied to the physical therapy and rehabilitation outpatient clinic with complaints of musculoskeletal and nervous system pain. Demographic characteristics of the patients including age, gender, body mass index, smoking, disease diagnoses, preferred gabapentinoid drug, and dosage were recorded. Moreover, the estimation of the severity of pain by the Visual Analog Scale (VAS) before and 6 months after the treatments was collected from medical records.

Results: The mean age of the patients was 59.54 ± 11.59 years and 82.1% were female and 17.9% were male. The diseases preferred for drug use were lumbar disc herniation (39.3%), cervical disc herniation (13.7%), spondylolisthesis (11.3%), diabetic neuropathy (11%), frozen shoulder (10.7%), gonarthrosis (10.4%), psoriatic arthritis (8.5%), spondylosis (8%), fibromyalgia (4.9%), carpal tunnel syndrome (4.7%), complex regional pain syndrome (2.7%), restless leg syndrome (1.1%), coxarthrosis (0.8%), postherpetic neuralgia (0.8%), and hemiplegia (0.5%), respectively. There was significant female gender superiority in both pregabalin and gabapentin groups ($P < 0.001$). In whole chronic pain conditions, the VAS scores before and after 6 months of treatment were significantly reduced in both groups, except for restless legs syndrome ($P = 0.066$). According to the results of the study, it was determined that the indication for gabapentinoid use was mainly related to neuropathic pain and gabapentinoid doses were below the recommended amounts.

Conclusion: Originally developed as anticonvulsants, gabapentin, and pregabalin are increasingly used in the treatment of various types of pain, including neuropathic and musculoskeletal pain. Although they raise concerns about addiction, it should not be overlooked that gabapentinoids are useful in the treatment of chronic painful conditions when used in the correct indications and doses.

Keywords: Chronic pain, Gabapentin, Pregabalin

INTRODUCTION

Pain is one of the most common causes why individuals visit health-care facilities and seek medical care. Chronic pain is a debilitating condition that affects millions of people worldwide, causing physical disability and depression and significantly impairing their quality of life.[1] The pharmacological approach to treating chronic pain requires the use of many agents such as acetaminophen, non-steroidal anti-inflammatory drugs (NSAIDs), opioids, and anticonvulsants. Acetaminophen is generally ineffective for moderate-to-severe pain. NSAIDs have limited use in most patients with complex medical conditions. Opioids have the potential to cause addiction.[1,2] To fill this gap in pain management, clinicians are increasingly prescribing gabapentinoids (gabapentin and pregabalin).[1-3] It has been suggested that the increase in gabapentinoid prescribing may be due to the desire to avoid opioid analgesics. Although gabapentinoids were primarily developed as anticonvulsant drugs, their use for pain management has recently increased. Gabapentinoids contribute to the emergence of anticonvulsant, analgesic, and anxiolytic effects by reducing the release of glutamate, noradrenaline (norepinephrine), and substance P by binding to the α2-delta subunit of voltage-gated calcium channels. Gabapentinoids are mostly recommended for the treatment of neuropathic pain and fibromyalgia (FM) in adults, but they are also often used off-label for other pain disorders such as low back pain, sciatica, spinal stenosis, and migraine.[2,4,5] The aim of this study was to investigate the kind of painful conditions in which gabapentinoids were used in the musculoskeletal and nervous systems and the preferred drug doses.

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MATERIALS AND METHODS

Study design

This retrospective study was directed at the Department of Physical Medicine and Rehabilitation at Bezmialem Vakif University. The trial protocol was confirmed by the Ethical Committee of Bezmialem Vakif University (Trial Registration: 2024/40). Written consent was acquired by each patient enrolled.

Participants and data extraction

Patients over the age of 18 who applied to the physical therapy and rehabilitation outpatient clinic with complaints of musculoskeletal and nervous system pain between June 2023 and December 2023 were included in the study. Exclusion criteria were patients under 18 years of age, patients with cancer-related pain, headache or perioperative pain, and patients with a history of drug abuse. Demographic characteristics such as age, gender, body mass index (BMI), smoking, and comorbidities (hypertension, diabetes mellitus, hypothyroidism, hyperlipidemia, etc.) were questioned. Moreover, the disease diagnoses that led to the initiation of gabapentinoid medications, the preferred gabapentinoid, and the dose were collected from hospital records. In addition, the estimation of the severity of pain by the Visual Analog Scale (VAS) before and 6 months after the treatments was collected from medical records. VAS is a unidimensional measure of pain intensity, which has been widely used in diverse adult populations. For pain intensity, the scale is most commonly anchored by "no pain" (score of 0) and "pain as bad as it could be" or "worst imaginable pain" (score of 10).[5]

Statistical analysis

Descriptive statistics were given with median (minimum–maximum) and frequencies with percentages. Variables' distribution was examined with the Shapiro–Wilk test. Categorical variables comparisons were analyzed with the Chi-square test and Fisher's exact test, and treatment group and continuous variables comparisons were analyzed with the Mann–Whitney U-test. Comparison of VAS scores before and after treatment for pregabalin and gabapentin analyzed with Wilcoxon signed-rank test. The statistical significance level was taken as 0.05, and IBM Statistical Package for the Social Sciences Statistics for Windows (Version 28.0. Armonk, NY: IBM Corp) was used for analysis.

RESULTS

The mean age of the patients was 59.54 ± 11.59 years and 82.1% were female and 17.9% were male. The indications for gabapentinoid utilization are presented in Figure 1. The diseases preferred for drug use were lumbar disc herniation (LDH) (39.3%), cervical disc herniation (CDH) (13.7%),

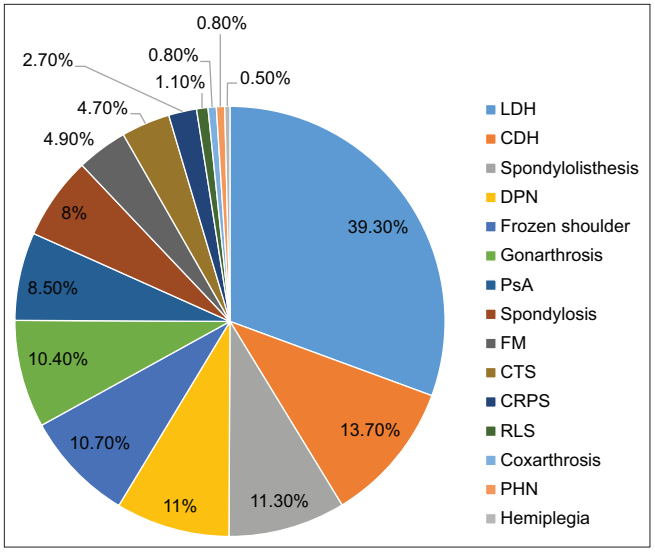

Figure 1: The indications for gabapentinoid utilization. LDH: Lumbar disc herniation; CDH: Cervical disc herniation; DPN: Diabetic peripheral neuropathy; PsA: Psoriatic arthritis; FM: Fibromyalgia; CTS: Carpal tunnel syndrome; CRPS: Complex regional pain syndrome; RLS: Restless le syndrome; PHN: Postherpetic neuralgia.

spondylolisthesis (11.3%), diabetic peripheral neuropathy (DPN) (11%), frozen shoulder (39, 10.7%), gonarthrosis (10.4%), psoriatic arthritis (PsA) (8.5%), spondylosis (8%), FM (4.9%), carpal tunnel syndrome (4.7%), complex regional pain syndrome (CRPS) (four distal radius fracture, four humerus fracture, one distal tibia fracture, and one distal fibula fracture) (2.7%), restless leg syndrome (RLS) (1.1%), coxarthrosis (0.8%), postherpetic neuralgia (PHN) (0.8%), and hemiplegia (0.5%), respectively. There was significant female gender superiority in both pregabalin and gabapentin groups ($P < 0.001$). BMI was significantly greater in the pregabalin group ($P = 0.027$), whereas smoking was significantly higher in the gabapentin group ($P = 0.004$). Gabapentin was more preferred in the treatment of LDH, CDH, and DPN ($P < 0.001$, $P = 0.020$, and $P < 0.001$, respectively). Pregabalin was more preferred in the treatment of spondylolisthesis, frozen shoulder, gonarthrosis, FM, PsA, and CRPS ($P < 0.001$, $P < 0.001$, $P = 0.002$, $P = 0.001$, $P = 0.001$, and $P = 0.026$, respectively) [Table 1]. In whole chronic pain conditions, the VAS scores before and after 6 months of treatment were significantly reduced in both groups, except for RLS ($P = 0.066$) [Table 2 and Figure 2]. It was determined that the indication for gabapentinoid use was mainly related to neuropathic pain and gabapentinoid doses were below the recommended amounts [Table 3].

DISCUSSION

Despite limited indications approved by the U.S. Food and Drug Administration (PHN for both gabapentin and pregabalin;

Table 1: The demographic and characteristic features of patients.

Variables	Total patients (364)	Pregabalin group (201)	Gabapentin group (163)	*P*-value
Gender (%)				
Female	82.1 (299)	89.6 (180)	73 (119)	**<0.001**
Male	17.9 (65)	10.4 (21)	44 (27)	
Age (year)	59.54±11.59	58.78±10.83	60.49±12.43	0.148
Body mass index	29.63±5.88	30.03±6.53	29.13±4.93	**0.027**
Smoking (%)				
Yes	20.3 (74)	14.9 (30)	27 (44)	**0.004**
No	79.7 (290)	85.1 (171)	73 (119)	
Indications (%)				
Lumbar disc herniation	39.3 (143)	24.4 (49)	57.7 (94)	**<0.001**
Cervical disc herniation	13.7 (50)	10 (20)	18.4 (30)	**0.020**
Spondylolisthesis	11.3 (41)	18.4 (37)	2.5 (4)	**<0.001**
Diabetic peripheral neuropathy	11 (40)	4.5 (9)	19 (31)	**<0.001**
Frozen shoulder	10.7 (39)	18.9 (38)	0.6 (1)	**<0.001**
Gonarthrosis	10.4 (38)	14.9 (30)	4.9 (8)	**0.002**
Psoriatic arthritis	8.5 (31)	12.9 (26)	3.1 (5)	**0.001**
Spondylosis	8 (29)	8.5 (17)	7.4 (12)	0.701
Fibromyalgia	4.9 (18)	8.5 (17)	0.6 (1)	**0.001**
Carpal tunnel syndrome	4.7 (17)	3.5 (7)	6.1 (10)	0.233
Reflex sympathetic dystrophy*	2.7 (10)	4.5 (9)	0.6 (1)	**0.026**
Restless leg syndrome	1.1 (4)	2 (4)	0 (0)	0.131
Coxarthrosis	0.8 (3)	1 (2)	0.6 (1)	1.000
Postherpetic neuralgia	0.8 (3)	1 (2)	0.6 (1)	1.000
Hemiplegia	0.5 (2)	1 (2)	0 (0)	0.504
Chronic diseases (%)				
Hypertension	57.4 (209)	54.7 (110)	60.7 (99)	0.249
Diabetes mellitus	41.5 (151)	42.8 (86)	39.9 (65)	0.575
Hyperlipidemia	14.3 (52)	10.4 (21)	19 (31)	**0.020**
Hypothyroidism	12.4 (45)	13.4 (27)	11 (18)	0.491

Bold values are significant at $p<0.05$. *Reflex sympathetic dystrophy: complex regional pain syndrome

Table 2: The comparison of VAS scores before and after treatment for pregabalin and gabapentin.

Variables	Pregabalin group		*P*-value	Gabapentin group		*P*-value
	Before VAS	After VAS		Before VAS	After VAS	
Total patient	8.34±0.67	3.41±1.21	<0.001	8.15±0.64	3.90±1.05	<0.001
Lumbar disc herniation	8.31±0.62	3.84±0.94	<0.001	8.09±0.60	3.90±1.00	<0.001
Cervical disc herniation	8.25±0.72	3.80±0.89	<0.001	7.97±0.67	3.70±0.95	<0.001
Spondylolisthesis	8.59±0.50	4.14±1.06	<0.001	8.00±0.82	4.00±0.82	0.046
Diabetic neuropathy	8.33±0.71	3.89±1.36	0.007	8.55±0.51	4.13±1.15	<0.001
Frozen shoulder	8.76±0.49	2.53±1.06	<0.001	–	–	–
Gonarthrosis	8.37±0.62	4.03±0.96	<0.001	8.63±0.52	4.88±0.99	0.010
Psoriatic arthritis	7.77±0.71	3.15±1.29	<0.001	8.00±0.71	3.00±0.71	0.039
Spondylosis	8.53±0.51	3.88±1.05	<0.001	8.50±0.52	4.67±0.99	0.002
Fibromyalgia	8.12±0.78	3.24±1.09	<0.001	8.00	3.00	–*
Carpal tunnel syndrome	8.00±0.58	3.00±0.82	0.016	8.20±0.79	3.50±0.97	0.004
Reflex sympathetic dystrophy	8.89±0.33	2.11±1.45	0.007	8.00	2.00	–*
Restless leg syndrome	8.25±0.50	3.50±1.00	0.066	–	–	–
Coxarthrosis	8.50±0.71	3.50±2.12	–*	8.00	4.00	–*
Postherpetic neuralgia	9.00±0.00	3.50±2.12	–*	9.00	3.00	–*
Hemiplegia	9.00±0.00	2.50±0.71	–*	–	–	–

$P<0.05$, significant difference. VAS: Visual Analog Scale, Before VAS: VAS score at baseline, After VAS: VAS score at 6 months after treatment, reflex sympathetic dystrophy: complex regional pain syndrome. *: *P* value not calculated due to insufficient patients

Table 3: The indications for use and average doses of gabapentinoids.

Indications	Pregabalin (mg)		Gabapentin (mg)	
	Mean dose	Recommended dose	Mean dose	Recommended dose
Lumbar disc herniation	97.45±74.52 50 (50–300)	150–600	1051.06±457.85 900 (300–2400)	900–3600
Cervical disc herniation	77.50±61.72 50 (50–300)	150–600	960.0±448.45 900 (300–2400)	900–3600
Spondylolisthesis	72.97±44.64 50 (25–225)	–	1000.0±489.90 900 (600–1600)	–
Diabetic neuropathy	166.67±108.97 150 (50–300)	150–300	1035.48±563.65 1200 (200–2400)	1200–3600
Frozen shoulder	65.79±35.08 50 (50–150)	300–600	1200	900–3600
Gonarthrosis	80.83±61.48 50 (50–300)	300–600	862.50±518.07 750 (300–1800)	900–3600
Psoriatic arthritis	75.0±61.24 50 (25–300)	–	1260.0±684.11 1200 (600–2400)	–
Spondylosis	67.65±35.09 50 (50–150)	150–600	966.67±483.05 850 (300–1800)	900–3600
Fibromyalgia	151.47±95.39 150 (50–300)	300–450	300	900–2400
Carpal tunnel syndrome	78.57±48.80 50 (50–150)	300–600	1080.0±404.97 1200 (300–1800)	900–3600
Reflex sympathetic dystrophy	91.67±66.14 50 (50–225)	300–600	600	900–3600
Restless leg syndrome	43.75±12.50 50 (25–50)	150–450	–	900–3600
Coxarthrosis	75.0±35.36 75 (50–100)	300–600	600	900–3600
Postherpetic neuralgia	100.0±70.71 100 (50–150)	300–600	1200	900–1800
Hemiplegia	225.0±106.07 225 (150–300)	300–600	–	900–3600

Recommended dose: These are the doses recommended by the FDA (Food and Drug Administration), mg: Miligram, reflex sympathetic dystrophy: complex regional pain syndrome

DPN, spinal cord injury-associated neuropathic pain, and FM for pregabalin), gabapentin and pregabalin are widely prescribed off-label for a variety of other pain syndromes.[2] Therefore, we evaluated the gabapentinoid utilization and doses in musculoskeletal and nervous system painful conditions. We found that the indication for gabapentinoid utilization was predominantly associated with neuropathic pain and gabapentinoid doses were below the recommended amounts.

A systematic review and meta-analysis found that gabapentinoids were ineffective in reducing pain or disability in low back pain or lumbar radicular pain compared to placebo.[6] The Cochrane database systematic review found that: (a) gabapentin could provide good pain relief in PHN and DPN rather than other types of neuropathic pain compared with placebo,[7] (b) pregabalin is effective in PHN, DPN, and mixed or unclassified post-traumatic neuropathic pain but not in human immunodeficiency virus neuropathy, and there was insufficient evidence for its effectiveness in central neuropathic pain,[8] (c) there was insufficient evidence to support or refute the claim that gabapentin reduces pain in FM,[9] (d) pregabalin produced a greater reduction in pain intensity in patients with FM.[10] A systematic review found that gabapentinoids seem to be effective and safe for the management of osteoarthritis pain.[11] A meta-analysis found that gabapentin and pregabalin were effective in treating RLS, with no difference between the treatments.[12] A report by Goodman and Brett noted that the potential benefits of off-label gabapentinoid use are uncertain and that guidelines tend to overestimate gabapentinoid effectiveness.[2] Although there is limited evidence to support off-label use of gabapentinoids for most painful clinical conditions, gabapentinoids may be significantly beneficial in a variety of chronic painful conditions. The results of our study also supported this position.

We could find no data regarding the use of gabapentinoids for pain management in PsA and frozen shoulder in previous

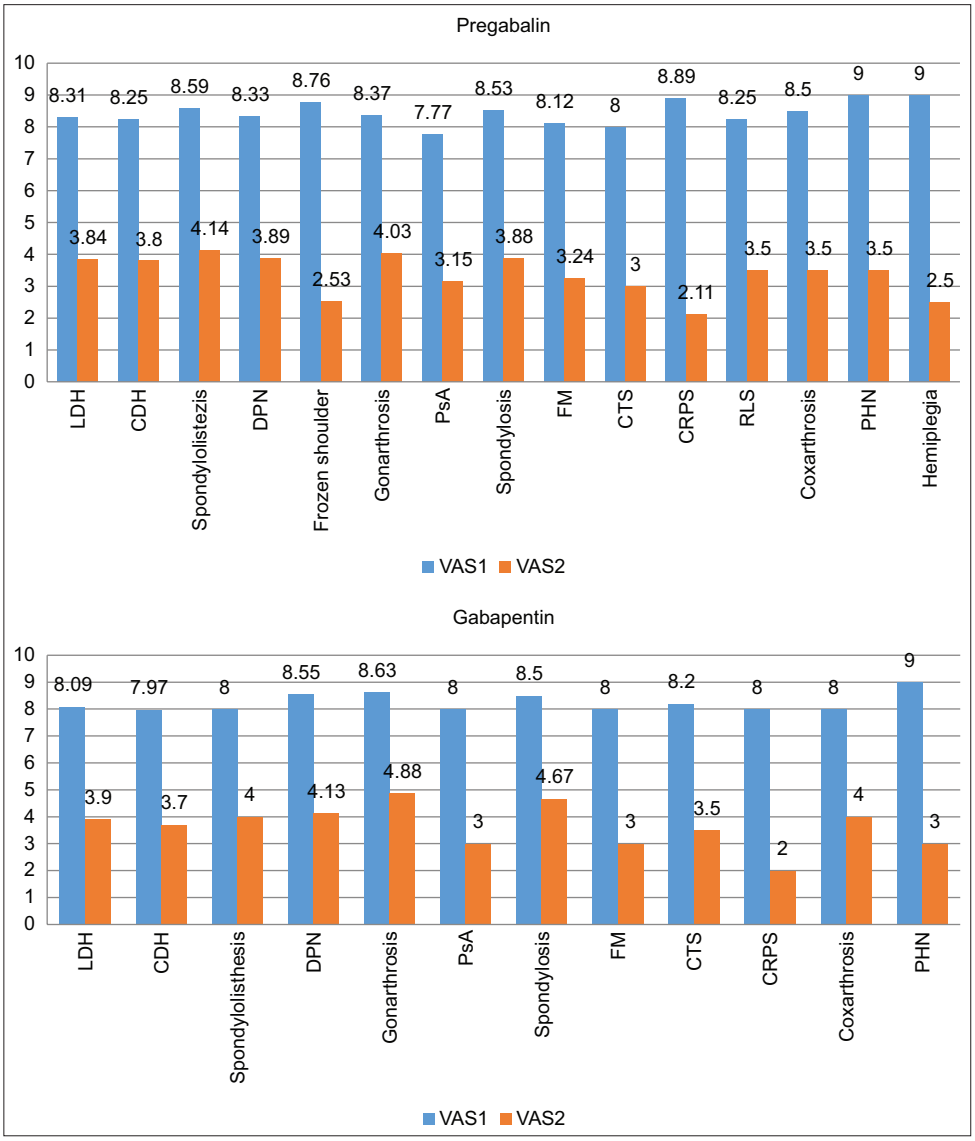

Figure 2: The median changes of Visual Analog Scale (VAS) scores before (VAS1) and after (VAS2) treatment for pregabalin and gabapentin. LDH: Lumbar disc herniation; CDH: Cervical disc herniation; DPN: Diabetic peripheral neuropathy; PsA: Psoriatic arthritis; FM: Fibromyalgia; CTS: Carpal tunnel syndrome; CRPS: Complex regional pain syndrome; RLS: Restless le syndrome; PHN: Postherpetic neuralgia

data. A common comorbidity in PsA is FM, characterized by chronic widespread pain, fatigue, and poor functional status, with a reported prevalence ranging from 10% to 27%.[13] Abnormal central pain responses due to underlying inflammation, just like neuropathic-like pain, play a role in the development of FM in patients with PsA.[14] Frozen shoulder or adhesive capsulitis is a condition that causes progressive stiffness, pain, limited motion, and functional impairment in the shoulder due to excessive scar tissue or adhesions in the glenohumeral joint. It has been suggested that persistent nociception in the early stages of a frozen shoulder may lead to peripheral and later long-term central sensitization and increased activity of the sympathetic nervous system. Central sensitization, as in many other arthritic and rheumatic conditions, may compromise response to treatment.[15] Therefore, we preferred gabapentinoids as a treatment option because the sensitization in the pain process contributed in both cases, thus, gabapentinoids may be an effective tool in the treatment of both conditions. However, further research is needed in this regard.

Külekçioğlu *et al*. investigated the gabapentinoid utilization rates in inpatients with musculoskeletal disorders and reviewed the conditions, doses, and durations of utilization. They identified gabapentinoid use in 27.9% of patients (14.2%

gabapentin and 13.7% pregabalin). They determined that gabapentinoids were predominantly used for neuropathic pain indication and were used in lower than recommended doses.[1] The results of our study were consistent with this study. Therefore, we think that treatment should be started at low doses and increased according to the response of the patient.

Pain can be categorized as nociceptive, inflammatory, or neuropathic. Both inflammatory and neuropathic pain are mediated by peripheral and central mechanisms. When inflammation and tissue or nerve damage occur, neuropeptides released from nociceptive neurons activate the immune system, causing the release of various cytokines, which contribute to peripheral sensitization by increasing sensory neuron excitability.[16] Gabapentinoids have also been shown to have anti-inflammatory properties through their effects on cytokine levels extra their antinociceptive effects.[17,18] Given the ability of gabapentinoids to modulate pain pathways and inflammatory processes, it is conceivable that these drugs could be used in the treatment of a wide variety of conditions, from neuropathic pain to chronic inflammatory diseases. Future studies are needed in this direction.

There was a female gender predominance in our study. Hormonal influences, genetic predispositions, and psychosocial stress factors may contribute to the higher frequency of chronic pain in women.[19] Women are more prone than men to generalized hyperalgesia from recurrent visceral pain.[20] This may explain why women are more likely to experience chronic pain than men.

The study has some limitations such as a small sample size, being a single-center and retrospective study, the lack of a control group, the absence of inpatients, the lack of quality of life measures, and the absence of long-term follow-up. However, this study provides useful information about the versatile uses of gabapentinoids in treating a range of painful conditions.

CONCLUSION

Originally developed as anticonvulsants, gabapentin, and pregabalin are increasingly used in the treatment of various types of pain, including neuropathic and musculoskeletal pain. Although gabapentinoids raise concerns about addiction, it should not be overlooked that gabapentinoids are useful in the treatment of chronic painful conditions when used in the correct indications and doses.

Ethical approval

The research/study approved by the Institutional Review Board at Bezmialem Vakif University, number 2024/40, dated January 31, 2024.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial ıntelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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