RESEARCH PAPER

EFFECT OF INTRATHECAL DEXMEDETOMIDINE AS AN ADJUVANT TO HYPERBARIC ROPIVACAINE FOR SPINAL ANAESTHESIA IN VAGINAL HYSTERECTOMY: A PROSPECTIVE DOUBLE-BLIND RANDOMIZED CONTROLLED TRIAL

Authors: Dr Jyoti Sankhla[1], Dr Sonam Patel[2], Dr Pratibha Chanderiya[3], Dr Devendra Verma[4], Dr Basant Dindor[5], Dr Chandraveer Singh Rao[6], Dr Jatin Prajapati[7]

Affiliations: [1] Senior Resident, Department of Anaesthesiology and Critical Care Medicine, RVRS Medical College, Bhilwara, Rajasthan, India.
[2,3] Post Graduate Student, Department of Anaesthesiology and Critical Care Medicine, RNT Medical College, Udaipur, Rajasthan, India.
[4] Senior Professor, Department of Anaesthesiology and Critical Care Medicine, RNT Medical College, Udaipur, Rajasthan, India.
[5] Professor, Department of Anaesthesiology and Critical Care Medicine, RNT Medical College, Udaipur, Rajasthan, India.
[6] Senior Resident, Department of Orthopaedics, RNT Medical College, Udaipur, Rajasthan, India.
[7] Senior Resident, Department of Community Medicine, World College of Medical Sciences and Research, Jhajjar, Haryana, India. (ORCID: https://orcid.org/0009-0004-7298-4499)

Corresponding Author: Dr Jyoti Sankhla
Address: Department of Anaesthesiology and Critical Care Medicine, RVRS Medical College, Bhilwara, Rajasthan, India. PIN-311001
Email ID: jyoti041095@gmail.com

ABSTRACT

Background: Spinal anaesthesia is the preferred anaesthetic technique for vaginal hysterectomy because it provides effective sensory and motor blockade with rapid recovery. Although hyperbaric ropivacaine offers favourable safety and reduced cardiotoxicity compared with bupivacaine, its relatively shorter duration of analgesia limits its clinical utility. Dexmedetomidine, a highly selective α_2-adrenergic agonist, has emerged as a promising intrathecal adjuvant capable of enhancing spinal block characteristics and prolonging postoperative analgesia.

Methods: This prospective, double-blind, randomized controlled trial was conducted in the Department of Anaesthesiology, R.N.T. Medical College, Udaipur, after institutional ethics approval and CTRI registration. Sixty-six ASA physical status I–II women aged 40–60 years scheduled for elective vaginal hysterectomy were randomized equally into two groups. Group RD received 3.5 mL of 0.75% hyperbaric ropivacaine with 5 µg dexmedetomidine, whereas Group RS received 3.5 mL of 0.75% hyperbaric ropivacaine alone. The primary outcome was the duration of postoperative analgesia. Secondary outcomes included onset and duration of sensory and motor blockade, peak sensory level, haemodynamic variables, success of spinal anaesthesia, and perioperative adverse events.

Results: Baseline demographic characteristics and haemodynamic parameters were comparable between groups. Group RD demonstrated a significantly shorter time to achieve T6 sensory block (6.72 ±0.97 vs. 9.15 ±1.12 minutes; p=0.0001) and peak sensory block (8.96 ±1.15 vs. 11.12 ±1.79 minutes; p=0.0001). The duration of sensory block (250.30 ±26.15 vs. 202.12 ±21.32 minutes; p=0.0001) and postoperative analgesia (216.67 ±16.52 vs. 149.40 ±10.37 minutes; p=0.0001) were significantly prolonged in Group RD. Motor block duration did not differ significantly (186.36 ±15.97 vs. 180.90 ±16.84 minutes; p=0.182). All patients achieved successful spinal anaesthesia. Intraoperative and postoperative haemodynamic parameters remained stable, and the incidence of bradycardia, hypotension, nausea and vomiting, and shivering was comparable between groups.

Conclusion: Intrathecal dexmedetomidine (5 µg) is an effective adjuvant to 0.75% hyperbaric ropivacaine for spinal anaesthesia during vaginal hysterectomy. It significantly improves sensory block characteristics and prolongs postoperative analgesia without adversely affecting haemodynamic stability, motor recovery, or perioperative safety.

Keywords: Dexmedetomidine; Hyperbaric ropivacaine; Spinal anaesthesia; Vaginal hysterectomy; Intrathecal adjuvant; Postoperative analgesia
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INTRODUCTION

Spinal anaesthesia, also known as subarachnoid block (SAB), is considered the gold standard anaesthetic technique for lower abdominal and infraumbilical surgeries, including vaginal hysterectomy, because it provides rapid onset, reliable sensory and motor blockade, excellent muscle relaxation, and effective perioperative analgesia. Compared with general anaesthesia, spinal anaesthesia offers several advantages such as avoidance of airway manipulation, reduced postoperative respiratory depression, nausea and vomiting, improved patient and surgeon satisfaction, and early postoperative recovery. These benefits have established spinal anaesthesia as the preferred regional anaesthetic technique for gynaecological procedures requiring profound intraoperative anaesthesia and effective postoperative pain control. The quality and duration of spinal anaesthesia, however, are largely dependent on the choice of intrathecal local anaesthetic and the use of suitable adjuvants that can prolong analgesia without increasing adverse effects.

Hyperbaric bupivacaine has long been the most commonly used intrathecal local anaesthetic because of its rapid onset and prolonged duration of action. Bupivacaine is a racemic mixture containing equal proportions of S- and R-enantiomers.[1] Although it provides dense sensory and motor blockade, its R-enantiomer has been associated with significant cardiovascular and central nervous system toxicity following inadvertent intravascular administration.[2] Serious complications including refractory ventricular arrhythmias and cardiac depression have encouraged the search for safer alternatives possessing comparable anaesthetic efficacy but lower systemic toxicity.

Ropivacaine, a long-acting amino-amide local anaesthetic, is the pure S(-)-enantiomer structurally related to bupivacaine and was developed to improve the safety profile of regional anaesthesia. Due to its lower lipid solubility, ropivacaine demonstrates greater sensory-motor differentiation by producing less intense motor blockade while preserving effective sensory anaesthesia. It has a significantly lower potential for cardiotoxicity and neurotoxicity compared with bupivacaine and has therefore gained widespread acceptance for neuraxial and peripheral nerve blockade.[3] Furthermore, its relatively shorter duration of motor blockade facilitates early postoperative mobilization, making it particularly suitable for enhanced recovery protocols. However, the shorter duration of sensory blockade and postoperative analgesia associated with intrathecal ropivacaine frequently necessitates the addition of adjuvant drugs to improve block characteristics and prolong analgesic duration.

Various intrathecal adjuvants, including opioids and α_2-adrenergic agonists, have been investigated to enhance the efficacy of local anaesthetics. Among these, fentanyl has been extensively used because of its rapid onset, high potency, and favourable analgesic properties.[4] Nevertheless, opioid-related adverse effects such as nausea, vomiting, pruritus, urinary retention, and respiratory depression have prompted increasing interest in non-opioid adjuvants.[5] Dexmedetomidine, a highly selective centrally acting α_2-adrenergic receptor agonist with an affinity nearly eight times greater than clonidine, has emerged as a promising intrathecal adjuvant because of its analgesic, sedative, and sympatholytic properties.[4] By producing hyperpolarization of nerve tissues and inhibiting nociceptive transmission at the spinal cord level, dexmedetomidine prolongs sensory and motor blockade, enhances postoperative analgesia, maintains haemodynamic stability, and reduces perioperative analgesic requirements without significant respiratory depression.

Although several studies have demonstrated the beneficial effects of dexmedetomidine as an intrathecal adjuvant, limited evidence is available regarding its efficacy when combined with hyperbaric ropivacaine for vaginal hysterectomy. Therefore, the present prospective double-blind randomized controlled study was undertaken to compare the clinical efficacy of intrathecal hyperbaric ropivacaine alone and hyperbaric ropivacaine combined with 5 µg dexmedetomidine in patients undergoing vaginal hysterectomy. The primary objective was to compare the duration of postoperative analgesia, while secondary objectives included comparison of the onset and duration of sensory and motor blockade, intraoperative haemodynamic stability, and perioperative adverse effects.

METHODOLOGY

This prospective, double-blind, randomized controlled study was conducted in the Department of Anaesthesiology at Pannadhaya Mahila Chikitsalya, R.N.T. Medical College, Udaipur, Rajasthan, after obtaining approval from the Institutional Ethics Committee (Approval No. RNT/ACAD./IEC/2024/328; dated 28 June 2024) and registration with the Clinical Trial Registry–India (CTRI/2024/09/074085; registered on 19 September 2024). Written informed consent was obtained from all participants before enrolment. The study included women scheduled to undergo elective vaginal hysterectomy under spinal anaesthesia.

The sample size was calculated using a superiority trial design for comparison of two independent means with equal allocation, considering the duration of postoperative analgesia as the primary outcome. The calculation was based on the study by Bayer et al. [6],

assuming a standard deviation of 34.60 minutes, a one-sided α error of 5% (Z = 1.65), 90% power (β = 10%; Z = 1.28), an expected mean difference of 90 minutes, and a superiority margin (δ) of 10 minutes. The calculated minimum sample size was approximately four participants per group. However, to satisfy the assumptions of the Central Limit Theorem and improve the reliability of parametric statistical analysis, a minimum sample size of 30 participants per group was considered. After accounting for an anticipated 10% dropout rate, 33 participants were enrolled in each group, resulting in a total sample size of 66 patients.

Women aged 40–60 years, belonging to the American Society of Anesthesiologists (ASA) physical status I or II, weighing between 40 and 80 kg, with a height greater than 140 cm, and scheduled for elective vaginal hysterectomy under spinal anaesthesia were included in the study. Patients who refused consent, had contraindications to regional anaesthesia, significant coexisting systemic illnesses such as hypertension, diabetes mellitus, renal impairment, severe hepatic disease, rheumatoid arthritis, coagulation disorders, thyroid disease, psychiatric illness, severe anaemia, malnutrition, morbid obesity, fused spine, or a known allergy to amide local anaesthetics or dexmedetomidine were excluded from the study.

Eligible patients were randomly allocated into two equal groups using a computer-generated randomization sequence with sealed envelope allocation. Group RS received 3.5 mL of 0.75% hyperbaric ropivacaine alone, whereas Group RD received 3.5 mL of 0.75% hyperbaric ropivacaine combined with 5 µg dexmedetomidine hydrochloride. The study drugs were prepared by an anaesthesiologist who was not involved in postoperative data collection. To preserve the baricity of the solution, the final volume in the dexmedetomidine group was maintained at 3.55 mL without dilution using normal saline. The study followed a double-blind design in which the patients, operating surgeon, postoperative nursing staff, and the observer responsible for outcome assessment were blinded to group allocation.

All patients underwent a detailed pre-anaesthetic evaluation and were kept fasting overnight before surgery. After arrival in the operating room, an 18/20-gauge intravenous cannula was secured, and patients were preloaded with Ringer's lactate solution (10 mL/kg). Standard intraoperative monitoring, including electrocardiography, non-invasive blood pressure, pulse oximetry, and heart rate, was instituted, and baseline vital parameters were recorded. Under strict aseptic precautions, spinal anaesthesia was administered in the left lateral position at the L3–L4 or L4–L5 intervertebral space using a 25-gauge Quincke spinal needle. Following confirmation of free cerebrospinal fluid flow, the study drug was injected intrathecally according to the assigned group, after which the patient was immediately placed supine and administered supplemental oxygen at 5 L/min through a venti mask.

Sensory block was assessed using loss of pinprick sensation with a 24-gauge hypodermic needle along the mid-clavicular line. Assessments were initiated three minutes after intrathecal injection and repeated every two minutes until 15 minutes. The onset of sensory block was defined as the time from intrathecal injection to loss of pinprick sensation at the T6 dermatome. The highest sensory level attained, time to achieve peak sensory block, duration of sensory block (regression to S1 dermatome), and duration of postoperative analgesia (time to first rescue analgesia) were recorded. Motor blockade was evaluated using the modified Bromage scale, and the onset, maximum Bromage score, and duration of motor blockade until complete recovery (Bromage score 0) were documented. Surgery was commenced only after achieving a sensory level of T6 and a Bromage score of at least 2. Cases requiring conversion to general anaesthesia because of inadequate block were considered failures.

Haemodynamic parameters, including systolic blood pressure, diastolic blood pressure, heart rate, and peripheral oxygen saturation, were recorded every three minutes during the first 15 minutes following spinal anaesthesia and subsequently every five minutes until completion of surgery. Hypotension, defined as systolic blood pressure <90 mmHg or a fall greater than 20% from baseline, was treated with intravenous mephentermine (6 mg). Bradycardia, defined as heart rate <60 beats/min, was treated with intravenous atropine (0.4 mg). Intraoperative nausea and vomiting were managed with intravenous ondansetron (4 mg), while other adverse events such as shivering and headache were recorded and managed appropriately. Clinical efficacy of spinal anaesthesia was categorized as completely successful (no supplementation required), partially successful (requiring ketamine, propofol, or fentanyl supplementation), or failed (conversion to general anaesthesia). Postoperatively, intravenous tramadol (2 mg/kg) was administered as rescue analgesia on patient demand, and the time to first rescue analgesia was considered the duration of postoperative analgesia.

Statistical analysis was performed using IBM SPSS Statistics version 20.0. Continuous variables were expressed as mean ±standard deviation or median with interquartile range, as appropriate, while categorical variables were presented as frequencies and percentages. Intergroup comparisons of continuous variables were performed using the unpaired Student's *t*-test, and categorical variables were analysed using the Chi-square test or Fisher's exact test, wherever applicable. A two-sided p value <0.05 was considered statistically significant.

RESULTS

A total of 66 patients undergoing elective vaginal hysterectomy were enrolled and randomized equally into Group RD (0.75% hyperbaric ropivacaine with 5 µg dexmedetomidine; *n*=33) and Group RS (0.75% hyperbaric ropivacaine alone; *n*=33). All randomized patients completed the study and were included in the final analysis. Baseline demographic characteristics and preoperative haemodynamic parameters were recorded before administration of spinal anaesthesia. No statistically significant differences were observed between the two groups for any baseline variable.

Table 1. Baseline demographic and clinical characteristics of the study participants

Variable	Group RD (n=33)	Group RS (n=33)	*p*-value
Age (years)	51.42 ± 4.09	51.78 ± 4.16	0.970
Weight (kg)	56.63 ± 3.67	55.91 ± 4.20	0.460
Height (cm)	155.18 ± 2.98	155.93 ± 2.89	0.300
Baseline SBP (mmHg)	123.97 ± 5.79	122.50 ± 5.60	0.290
Baseline DBP (mmHg)	82.33 ± 6.16	80.55 ± 6.09	0.240
Baseline MAP (mmHg)	96.21 ± 5.26	94.33 ± 4.78	0.130
Baseline Heart Rate (beats/min)	83.90 ± 6.98	85.61 ± 6.13	0.290

Data are presented as mean ±SD.

Sensory and motor block characteristics following spinal anaesthesia are summarized in Table 2. The onset and extent of sensory blockade and the development of motor blockade were assessed in both groups.

Table 2. Sensory and motor block characteristics

Variable	Group RD (n=33)	Group RS (n=33)	*p*-value
Time to T6 sensory block (min)	6.72 ± 0.97	9.15 ± 1.12	0.0001
Time to peak sensory block (min)	8.96 ± 1.15	11.12 ± 1.79	0.0001
Peak sensory block (Median, Range)	T4 (T3–T6)	T5 (T3–T6)	0.028
Time to maximum Bromage score (min)	9.15 ± 1.43	9.72 ± 1.44	0.108
Maximum Bromage score 2	5 (15.2%)	9 (27.3%)	0.228
Maximum Bromage score 3	28 (84.8%)	24 (72.7%)	

Continuous variables are presented as mean ±SD and categorical variables as n (%).

The peak sensory block level, duration of sensory and motor blockade, duration of postoperative analgesia, and overall outcome of spinal anaesthesia are presented in Table 3.

Table 3. Peak sensory block level, duration of block and clinical efficacy

Variable	Group RD (n=33)	Group RS (n=33)	*p*-value
Peak sensory block level			
T3	5 (15.2%)	2 (6.1%)	>0.05
T4	15 (45.5%)	9 (27.3%)	
T5	6 (18.2%)	9 (27.3%)	
T6	7 (21.2%)	13 (39.4%)	
Total duration of sensory block (min)	250.30 ± 26.15	202.12 ± 21.32	0.0001
Total duration of motor block (min)	186.36 ± 15.97	180.90 ± 16.84	0.182
Duration of analgesia (min)	216.67 ± 16.52	149.40 ± 10.37	0.0001
Completely successful spinal anaesthesia	33 (100%)	33 (100%)	1.000
Partially successful spinal anaesthesia	0	0	

Data are presented as mean ±SD or n (%).

Serial haemodynamic parameters were monitored throughout the intraoperative and postoperative periods. Baseline, end-of-surgery, and final postoperative observations are summarized below.

Table 4. Intraoperative and postoperative haemodynamic parameters

Parameter	Time point	Group RD	Group RS	*p*-value
Heart rate (beats/min)	Baseline	85.96±8.86	86.82±7.55	0.67
	End of surgery	83.21 ± 6.75	84.45 ± 7.42	0.480
	360 min postoperative	84.75 ± 5.09	85.39 ± 3.52	0.550
Systolic blood pressure (mmHg)	Baseline	121.39±7.47	120.36±7.10	0.56
	End of surgery	120.55 ± 5.23	120.73 ± 7.84	0.910
	360 min postoperative	118.27 ± 2.18	120.00 ± 3.77	0.026

Diastolic blood pressure (mmHg)	Baseline	80.03±5.44	78.06±3.66	0.08
	End of surgery	81.27 ± 7.14	83.18 ± 9.57	0.360
	360 min postoperative	85.36 ± 4.94	86.27 ± 3.09	0.330
Mean arterial pressure (mmHg)	Baseline	94.48 ± 4.42	92.09 ± 3.68	0.019
	End of surgery	94.57 ± 4.84	95.39 ± 8.18	0.600
	360 min postoperative	96.39 ± 3.23	97.48 ± 2.37	0.123

Data are presented as mean ±SD.

Perioperative adverse events recorded during the study period are shown in Table 5. Bradycardia, hypotension, nausea and vomiting, and shivering were documented in both groups.

Table 5. Perioperative adverse events

Adverse event	**Group RD (n=33)**	**Group RS (n=33)**	***p*-value**
Bradycardia	7 (21.2%)	5 (15.2%)	0.919
Hypotension	6 (18.2%)	5 (15.2%)	
Nausea and vomiting	4 (12.1%)	5 (15.2%)	
Shivering	3 (9.1%)	2 (6.1%)	

Data are presented as n (%).

DISCUSSION

The present prospective double-blind randomized controlled study evaluated the effect of adding 5 µg intrathecal dexmedetomidine to 0.75% hyperbaric ropivacaine for spinal anaesthesia in patients undergoing vaginal hysterectomy. The principal findings demonstrated that dexmedetomidine significantly hastened the onset of sensory blockade, reduced the time to achieve peak sensory block, prolonged the duration of sensory blockade and postoperative analgesia, while maintaining a similar duration of motor blockade, haemodynamic profile, and incidence of adverse events compared with hyperbaric ropivacaine alone. All patients achieved successful spinal anaesthesia without requiring supplementation or conversion to general anaesthesia.

The demographic characteristics of patients in both study groups were comparable, with no statistically significant differences in age, weight, height, or baseline haemodynamic parameters. Similar baseline characteristics have been reported in previous randomized studies evaluating intrathecal dexmedetomidine with ropivacaine, thereby minimizing confounding factors and ensuring valid comparison of block characteristics and clinical outcomes.[6,7]

The addition of dexmedetomidine significantly accelerated the onset of sensory blockade and shortened the time required to achieve peak sensory level. Patients receiving dexmedetomidine attained the T6 sensory level approximately 2.4 minutes earlier than those receiving ropivacaine alone and also achieved a higher median sensory level. These findings are consistent with those reported by Bayer et al.[6], who observed earlier onset of sensory block and faster attainment of peak sensory level with dexmedetomidine compared with fentanyl as an intrathecal adjuvant during vaginal hysterectomy. Similar observations were also reported by Saxena et al.[8] and Hong Bi et al.[9], who demonstrated that intrathecal dexmedetomidine significantly hastened sensory block onset and improved cephalad spread of anaesthesia. The enhanced block characteristics may be attributed to the synergistic interaction between dexmedetomidine and local anaesthetics at the spinal dorsal horn, resulting in inhibition of nociceptive neurotransmission and augmentation of sensory blockade.[4]

The duration of sensory blockade and postoperative analgesia were significantly prolonged in the dexmedetomidine group. Sensory blockade lasted approximately 48 minutes longer, while the duration of analgesia increased by more than one hour compared with ropivacaine alone. These findings corroborate the observations of Gupta et al.[10], who reported significant prolongation of sensory regression and postoperative analgesia following addition of dexmedetomidine to intrathecal ropivacaine. Likewise, Bayer et al.[6] demonstrated longer analgesic duration with dexmedetomidine than fentanyl, whereas Hong Bi et al.[9] and Shahid et al.[11] also reported prolonged postoperative analgesia with intrathecal dexmedetomidine. The prolonged analgesic effect is explained by activation of presynaptic and postsynaptic α_2-adrenergic receptors within the dorsal horn, resulting in suppression of substance P release and hyperpolarization of spinal interneurons.[4]

Although motor blockade was marginally longer in the dexmedetomidine group, the difference did not reach statistical significance. Similar findings have been described by Naithani et al.[7], who observed comparable motor block characteristics between different doses of intrathecal dexmedetomidine, and by Bayer et al.[6], who reported only a modest increase in motor block duration despite significantly prolonged analgesia. Preservation of motor recovery while extending sensory blockade is advantageous in facilitating postoperative mobilization and recovery.
Haemodynamic variables remained stable throughout the intraoperative and postoperative periods in both groups. Serial measurements of heart rate, systolic blood pressure, diastolic blood pressure, and mean arterial

pressure did not reveal clinically important differences between groups. Furthermore, the incidences of bradycardia, hypotension, nausea and vomiting, and shivering were low and statistically similar. These observations are in agreement with Gupta et al.[10], Bayer et al.[6], and Farokhmehr et al.[12], who also reported acceptable haemodynamic stability and a favourable safety profile with low-dose intrathecal dexmedetomidine. Although Naithani et al.[7] observed greater hypotension with higher doses of dexmedetomidine, the present study suggests that a 5 µg dose provides effective analgesic augmentation without increasing perioperative complications.

The present findings indicate that intrathecal dexmedetomidine is an effective adjuvant to hyperbaric ropivacaine for vaginal hysterectomy, providing superior sensory block characteristics and prolonged postoperative analgesia while maintaining a high success rate of spinal anaesthesia and an acceptable safety profile. These results are consistent with the available literature and support the use of low-dose dexmedetomidine as a valuable adjunct in spinal anaesthesia for gynaecological surgery.

The present study has several limitations. It was conducted at a single tertiary-care centre with a relatively small sample size, limiting generalizability. Only one dose of dexmedetomidine was evaluated, and long-term postoperative outcomes were not assessed. Future multicentre trials with larger populations comparing different dexmedetomidine doses are warranted.

CONCLUSION

The addition of 5 µg intrathecal dexmedetomidine to 0.75% hyperbaric ropivacaine significantly enhanced the quality of spinal anaesthesia in patients undergoing vaginal hysterectomy. Dexmedetomidine accelerated the onset of sensory blockade, reduced the time to achieve peak sensory level, and significantly prolonged the duration of sensory blockade and postoperative analgesia compared with hyperbaric ropivacaine alone. Although motor block duration was slightly longer in the dexmedetomidine group, the difference was not statistically significant. Both groups demonstrated a 100% success rate of spinal anaesthesia, with stable intraoperative and postoperative haemodynamic parameters and a comparable incidence of adverse events. These findings suggest that low-dose intrathecal dexmedetomidine is an effective and safe adjuvant to hyperbaric ropivacaine, providing prolonged postoperative analgesia without increasing perioperative complications. These findings support the use of 5 µg intrathecal dexmedetomidine as an effective adjuvant to hyperbaric ropivacaine during vaginal hysterectomy.

DECLARATIONS

Ethics approval and consent to participate: The study was approved by the Institutional Ethics Committee, R.N.T. Medical College, Udaipur (Approval No. RNT/ACAD./IEC/2024/328). Written informed consent was obtained from all participants.

Trial registration: Clinical Trial Registry–India (CTRI/2024/09/074085).

Availability of data and materials: The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

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Conflict of Interest: The authors declare that they have no competing interests.

Authors' Contributions: All authors contributed to the study conception, data collection, statistical analysis, manuscript preparation, critical revision, and approved the final manuscript.

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