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Original Article

Cost-effectiveness and efficacy of scalp block for elective supratentorial craniotomy in resource-limited settings: A randomized controlled trial

Chanatthee Kitsiripant[1], Aunchitha Boonyamarn[1], Maliwan Oofuvong[1], Sumidtra Prathep[1], Anukoon Kaewborisutsakul[2]

[1]Department of Anesthesiology, Faculty of Medicine, Prince of Songkla University, [2]Department of Surgery, Neurological Surgery Unit, Faculty of Medicine, Prince of Songkla University, Hat Yai, Thailand.

E-mail: *Chanatthee Kitsiripant - chanat.k@gmail.com; Aunchitha Boonyamarn - aunchitha.boon@gmail.com; Maliwan Oofuvong - oomaliwa@gmail.com; Sumidtra Prathep - prathepsumidtra@gmail.com; Anukoon Kaewborisutsakul - anukoonkaew@gmail.com

***Corresponding author:**
Chanatthee Kitsiripant, Department of Anesthesiology, Faculty of Medicine, Prince of Songkla University, Hat Yai, Thailand.

chanat.k@gmail.com

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ABSTRACT

Background: Remifentanil is favored for neurosurgical pain management, but its utilization in low- and middle-income countries (LMICs) is limited. Scalp block techniques are effective in LMICs, but cost-effectiveness is uncertain. This study compares costs and perioperative outcomes of scalp block versus fentanyl infusion in patients undergoing elective supratentorial craniotomy.

Methods: A prospective double-blind randomized controlled trial was conducted with 36 patients aged 18–65 years undergoing elective supratentorial craniotomy. Patients were randomly assigned to receive either scalp block with 0.5% bupivacaine (Group S) or fentanyl infusion (Group F), with normal saline placebo administered in both groups. The primary endpoint was the anesthetic costs, with secondary endpoints including perioperative opioid consumption, intraoperative hemodynamic changes, and perioperative complications.

Results: The cost of fentanyl was significantly lower than that of local anesthetics (3.31 [3.31, 3.75] vs. 4.27 [4.27, 4.27] United States dollars, $P < 0.001$). However, the overall anesthetic cost did not differ significantly between groups. Group F demonstrated a significant reduction in mean arterial pressure immediately and 5 min after pin insertion compared to Group S (75.8 [13.9] vs. 92.5 [16.9] mmHg, $P = 0.003$ and 67.7 [6.4] vs. 78.5 [10.7] mmHg, $P < 0.001$, respectively).

Conclusion: Fentanyl infusion presents cost advantages over scalp block in LMIC settings. However, prudent opioid use is imperative. This study underscores the need for ongoing research to optimize neurosurgical pain management and evaluate long-term safety implications.

Keywords: Cost, Craniotomy, Efficacy, Fentanyl, Low- and middle-income countries (LMICs)

INTRODUCTION

Low- and middle-income countries (LMICs) encounter several challenges due to shortages of medical supplies, equipment, and medications, which can compromise the quality of care and limit patient treatment options. Anesthesiologists should prioritize cost-effective practices, considering factors such as anesthesia duration and choice of anesthetic agents. Utilizing techniques that promote early recovery, superior pain control, and fewer complications can reduce the need for excessive anesthesia-related medications, ultimately lowering costs.

Remifentanil, despite its suitability for neuroanesthesia, may be inaccessible in LMICs due to its high cost. Various methods exist for managing nociceptive stimuli during neurosurgery, balancing the risk of high-dose opioids causing hypotension and delayed recovery with the consequences of inadequate pain management leading to adverse outcomes.[5]

In resource-limited settings, scalp block techniques requiring minimal resources are favored for their ability to mitigate hemodynamic response,[2,3,6,9,12,15] reduce opioid consumption,[1-4,11,13,15] and facilitate rapid recovery.[12,15] However, previous studies primarily focused on comparing scalp block with local anesthetic infiltration or evaluating different local anesthetics, with limited evidence on the cost-effectiveness of these techniques. In LMICs where remifentanil may be unavailable, fentanyl stands as the primary choice for neurosurgical procedures. Fentanyl infusion provides continuous analgesia throughout the operation, ensuring sustained suppression of sympathetic activation and hemodynamic fluctuations induced by nociceptive stimuli. Consequently, this study aimed to compare the costs and perioperative outcomes of scalp block versus fentanyl infusion in patients who underwent elective craniotomy for supratentorial tumor removal.

MATERIALS AND METHODS

This prospective randomized double-blind controlled trial received approval from the Institutional Ethics Committee (approval number 64–335–8–1) and was registered with the Thai Clinical Trials Registry (approval number 20210602005). A total of 36 patients aged 18–65 years, classified as American Society of Anesthesiologists (ASA) physical status I to III, scheduled for elective supratentorial craniotomy, participated in the study. Written informed consent was obtained from all patients. Exclusion criteria encompassed patients with Glasgow Coma Score <13, bifrontal craniotomy, hypertension, malignant arrhythmias, cardiac disease, chronic pain, cerebrovascular disease, allergy to local anesthetic drugs, coagulopathy, scalp infection, or pregnancy.

Randomization and blinding

Randomization was conducted using a computer-generated randomization and sealed envelope system, assigning patients to either Group S or Group F. In Group S, each patient underwent a scalp block with 20 mL of 0.5% bupivacaine, targeting branches such as the supraorbital, supratrochlear, zygomaticotemporal, auriculotemporal, greater occipital, and lesser occipital nerves using a landmark technique. The dosage of bupivacaine was calculated not to exceed 3 mg/kg of the patient's body weight. Normal saline was administered 10 min before pin insertion, followed by a continuous infusion of normal saline throughout the surgery to serve as a placebo for fentanyl. In Group F, each patient received a scalp block with 20 mL of normal saline placebo, followed by a single bolus of 2 μg/kg fentanyl administered 10 min before pin insertion. This was followed by a continuous infusion of 1 μg/kg/h of fentanyl until the completion of the operation [Figure 1]. The study drugs were prepared by the hospital pharmacy and presented by a nurse who was not involved in patient management. All attending anesthesiologists, surgeons, patients, and outcome assessors were blinded to intervention allocation.

Study protocol

On arrival at the operating theatre, ASA standard monitoring procedures were initiated, including electrocardiography, non-invasive blood pressure, and pulse oximetry. Pre-oxygenation with 100% oxygen at a flow rate of 6 L/min was administered to all patients for 5 min. Anesthesia maintenance after intubation utilized a mixture of 50% oxygen in the air and sevoflurane up to an end-tidal concentration of 2.0%. Subsequent monitoring included end-tidal carbon dioxide level, rectal temperature, and invasive blood pressure, with mean arterial pressure (MAP) recorded through arterial blood pressure monitoring.

The study interventions followed the allocated group protocol. Scalp block was performed 20 min before pin insertion, followed by a single bolus and continuous infusion of the study drug. All patients were observed in the intensive care unit (ICU) postoperatively. Baseline characteristics, including age, sex, body mass index, tumor location and size, heart rate (HR), and MAP before induction, were recorded and continuously monitored and recorded at various time points after pin insertion (0, 5, 10, and 15 min), at skin incision, dural incision, dural closure, and skin closure. The first rescue dose of fentanyl (0.5–1 μg/kg) was administered if the HR increased by more than 10 bpm or MAP increased by more than 20% from baseline. Data on the time to first rescue fentanyl dose, intraoperative rescue fentanyl consumption, vasopressor requirement, anesthesia duration, cost, and estimated blood loss were documented. Postoperatively, other recorded parameters such as time to first rescue fentanyl, fentanyl consumption within 24 h, pain score using the Behavioral Pain Scale, Richmond Agitation–Sedation Scale (RASS) score at 0, 4, 8, 12, and 24 h postoperatively, and the incidence of postoperative nausea and vomiting (PONV) were also recorded.

Outcomes

The primary outcome assessed the anesthetic costs. Secondary outcomes included time to the first rescue fentanyl administration, total rescue fentanyl consumption,

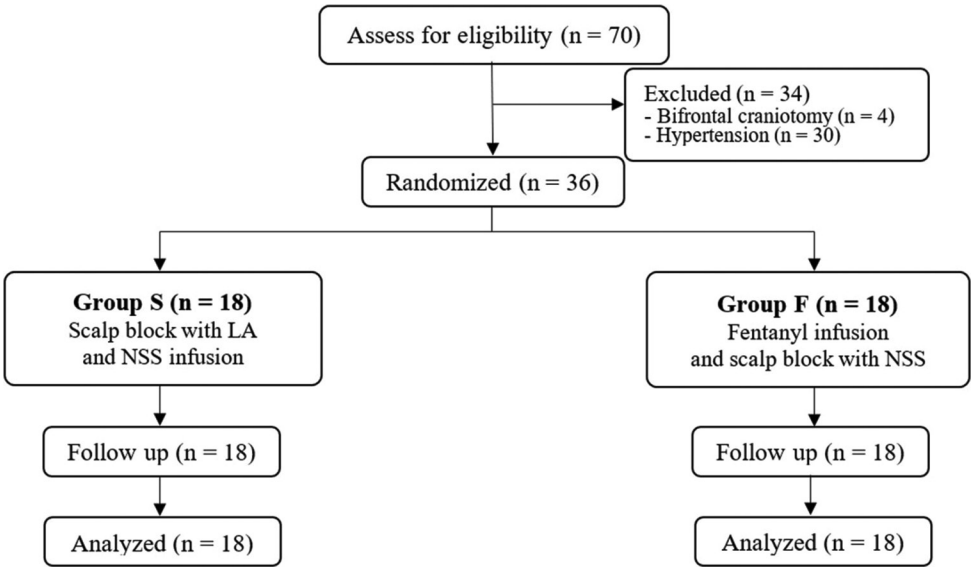

Figure 1: CONSORT flow diagram showing patient recruitment in the study. LA: Local anesthetic, NSS: Normal saline solution.

intraoperative hemodynamic parameters, time to extubation, pain score, RASS score, and perioperative complications such as intraoperative vasopressor requirement and PONV.

Sample size calculation

The sample size per group was determined using two independent means with a two-tailed significance level of 0.05 and a power of 0.8, considering previous data on primary and secondary outcomes.[2,3] Sixteen patients per group we initially calculated as the maximum required sample size. Anticipating a dropout rate of 10%, the final overall target sample size was set at 36 patients.

Statistical analysis

The data were analyzed using R version 2.13.0 (R Foundation for Statistical Computing, Vienna, Austria). Categorical variables were presented as numbers, while continuous variables were analyzed by *t*-test or Wilcoxon rank-sum test. Categorical variables were compared using Fisher's exact or Pearson's Chi-squared test. The Shapiro–Wilk test was used to check the normality of the data. Statistical significance was determined at $P < 0.05$.

RESULTS

Seventy patients were initially assessed for eligibility. Ultimately, 36 patients completed the study and were randomized (18 patients for each group), with their data included in the final analysis. Thirty-four patients were excluded from the study due to not meeting the inclusion criteria [Figure 1]. Patient characteristics and intraoperative data were not significantly different between the two groups [Table 1].

As shown in Table 2, the cost of administration of a single bolus of intravenous fentanyl at 2 μg/kg followed by a continuous infusion of 1 μg/kg/h in Group F was significantly lower compared to the cost of local anesthetics for the scalp block in Group S (3.31 [3.31, 3.37] vs 4.27 [4.27, 4.27] United States dollar [USD], $P < 0.001$). However, the total anesthetic cost was not significantly different between groups.

The time to first rescue fentanyl administration and total rescue fentanyl consumption during both intraoperative and postoperative periods did not exhibit significant differences between the groups. In Group S, four patients (22.2%) did not require postoperative rescue fentanyl, whereas all patients in Group F required it in the first 24 hours postoperatively. While the time to extubation did not differ significantly, Group S showed an earlier extubation time of 4 h compared to Group F ($P = 0.310$). Concerning perioperative complications such as vasopressor requirement and PONV, Group S demonstrated a lower incidence compared to Group F, though these differences were not statistically significant ($P = 0.215$ and $P = 0.732$, respectively) [Table 3].

Most patients were calm during ICU admission. Neither agitation nor oversedation was observed. The pain scores assessed using the Behavioral Pain Scale and RASS in the first 24 hours postoperatively were also not significantly different between the two groups [Table 4].

Group F had a significantly lower MAP immediately and 5 min after pin insertion (75.8 [13.9] and 67.7 [6.4] mmHg, respectively) compared to Group S (92.5 [16.9] and 78.5 [10.7] mmHg; $P = 0.003$ and $P < 0.001$, respectively).

Table 1: Patient characteristics and intraoperative data.

Parameters	Group S (*n*=18)	Group F (*n*=18)	*P*-value
Sex, *n* (%)			0.264
Male	7 (38.9)	3 (16.7)	
Female	11 (61.1)	15 (83.3)	
Age (years)	45.8 (13.2)	43.9 (8.8)	0.627
Weight (kg)	60.5 (9.3)	63.3 (14.1)	0.485
Height (cm)	160.9 (12.7)	157.4 (8)	0.321
BMI (kg/m^2)	23.4 (3.6)	25.4 (5)	0.175
ASA classification, *n* (%)			0.724
I	0	0	
II	5 (27.8)	7 (38.9)	
III	13 (72.2)	11 (61.1)	
Tumor size (cm)	4.6 (2.2)	4.7 (1.7)	0.838
Duration of operation (min), median (IQR)	287.5 (235, 382.5)	297.5 (210, 381.2)	0.987
Duration of anesthesia (min), median (IQR)	347.5 (321.2, 417.5)	360 (270, 455)	0.752
Estimate blood loss (ml), median (IQR)	750 (350, 1200)	500 (362.5, 887.5)	0.383

Data presented as mean (standard deviation) unless otherwise indicated. BMI: Body Mass Index, ASA: American Society of Anesthesiologists, IQR: Interquartile range, Group S: Scalp block, Group F: Fentanyl.

Table 2: Cost of interventional drugs, other drugs, and anesthetic service.

Cost	Group S (*n*=18)	Group F (*n*=18)	*P*-value
Interventional drugs cost (USD)	4.27 (4.27, 4.27)	3.31 (3.31, 3.75)	<0.001
Other drugs cost (USD)	32.13 (26.92, 35.38)	30.32 (23.61, 34.61)	0.311
Service cost (USD)	449.69 (380.29, 516.71)	482.47 (441.97, 574.22)	0.399
Total cost (USD)	486.37 (423, 560.03)	516.89 (467.65, 607.84)	0.624

Data presented as median (interquartile range). USD: United States dollar, Group S: Scalp block, Group F: Fentanyl

Table 3: Rescue fentanyl, time to extubation, and perioperative complications.

Parameters	Group S (*n*=18)	Group F (*n*=18)	*P*-value
Time to first rescue fentanyl			
Intraoperative period (min)	97.5 (56.2, 138.8)	60 (57.5, 72.5)	0.494
Postoperative period (h)	1.3 (0.8, 2.9)	1.5 (0.6, 2)	0.970
Rescue fentanyl consumption			
Intraoperative period (μg)	75 (50, 125)	50 (25, 87.5)	0.344
Postoperative 24 h (μg)	165 (127.5, 232.5)	150 (90, 180)	0.410
Postoperative fentanyl requirement, *n* (%)	14 (77.8)	18 (100)	0.104
Time to extubation (h)	11.2 (0.4, 17.4)	15.8 (3.6, 18)	0.310
Perioperative complications			
Intraoperative vasopressor requirement, *n* (%)	9 (60)	13 (86.7)	0.215
PONV, *n* (%)	6 (33.3)	8 (44.4)	0.732

Data presented as median (interquartile range) unless otherwise indicated. PONV: Postoperative nausea and vomiting. Group S: Scalp Block, Group F: Fentanyl

Although there was no significant difference between groups, the MAP in Group F remained relatively stable from 10 min after pin insertion until skin closure, while Group S displayed more variation from baseline. The HR in Group F was lower than that in Group S, though this difference was also not significant [Figure 2].

DISCUSSION

Anesthesia care in LMICs faces significant challenges, including inadequate infrastructure, lack of trained personnel, limited access to medications and equipment, and financial constraints. Khan *et al.*[7] highlight the critical

Table 4: Postoperative pain score and RASS in the first 24 h.

Time	Group S (*n*=18)		Group F (*n*=18)		*P*-value	
	BPS	RASS	BPS	RASS	BPS	RASS
0 h	3 (3, 3)	−3 (−3, −3)	3 (3, 4)	−3 (−3, −3)	0.456	1
4 h	3 (3, 3.8)	0 (0, 0)	3 (3, 4)	0 (0, 0)	0.296	0.961
8 h	3 (3, 3)	0 (0, 0)	3 (3, 4)	0 (0, 0)	0.264	0.309
12 h	3 (3, 3)	0 (0, 0)	3 (3, 3)	0 (0, 0)	0.155	0.597
24 h	3 (3, 3)	0 (0, 0)	3 (3, 3)	0 (0, 0)	1	1

Data are presented as median (interquartile range) for BPS and RASS. BPS: Behavioral pain scale, RASS: Richmond Agitation-sedation scale, Group S: Scalp Block, Group F: Fentanyl

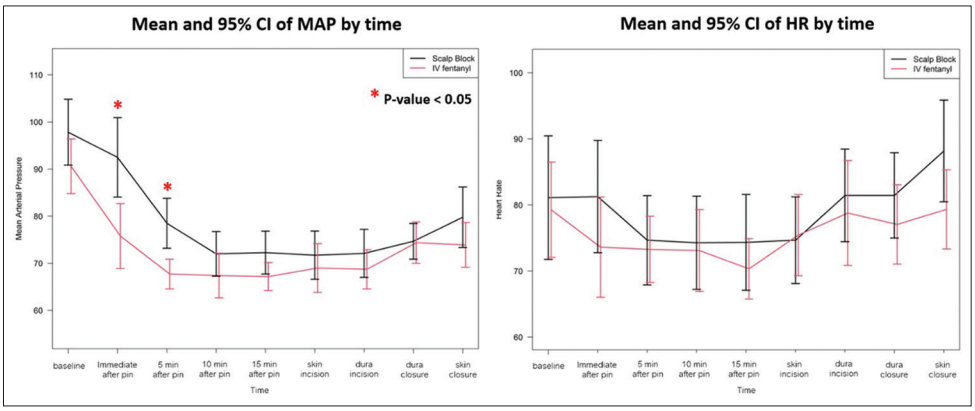

Figure 2: Variation in intraoperative MAP and HR. MAP: Mean arterial pressure, HR: Heart rate, CI: Confidence interval.

shortage of anesthesia providers in LMICs, leading to suboptimal perioperative care and increased mortality rates. Addressing these challenges requires targeted interventions and investments to strengthen anesthesia capacity and infrastructure, ensuring improved access to safe surgical and anesthesia care for underserved populations.

Intravenous opioid administration is essential for maintaining hemodynamic stability during procedures such as craniotomy. However, these surgeries induce significant nociceptive stimuli, necessitating effective analgesia. Given the potential unavailability of remifentanil in certain regions, fentanyl emerges as the preferred choice for neuroanesthesia. A single bolus of intravenous fentanyl followed by continuous infusion has proven efficacy in this context. In addition, scalp block offers an alternative method to manage hemodynamic changes during craniotomy. In this study, 0.5% bupivacaine without adrenaline was used to prevent confounding results resulting from inadvertent intravascular adrenaline exposure.

The cost of local anesthetics for scalp block in Group S was approximately 1 USD less than the cost of fentanyl administration in Group F, although the total anesthetic cost was not significantly different between groups. However, even a modest cost savings can have a notable impact on the healthcare system when applied across multiple cases.

Pain and sedation assessments in neurosurgical patients are challenging because some patients remain intubated and have alterations of consciousness. The behavioral pain scale has been used for measuring patient discomfort and assessing interventions. The RASS can be applied to non-communicative patients to assess the level of sedation.[14] The time to first rescue fentanyl administration and total rescue fentanyl consumption in both the intraoperative and postoperative periods were not significantly different between the groups in this study. In contrast, the previous studies[2,3] found that scalp block decreased the postoperative pain score and the requirement for rescue analgesia and anesthetic agents. These contrasting outcomes could be the result of pain scores that were not significantly different between the groups during the first 24 hours postoperatively in this study. In addition, most patients were calm during ICU admission, leading to RASS scores that did not differ significantly within the first 24 hours postoperatively.

Continuous narcotic infusion carries the risks of respiratory depression and potential addiction. To mitigate these risks, all patients were closely monitored in the ICU, with fentanyl dose carefully titrated and adverse effects closely monitored. A prospective observational study conducted by Stark *et al.*[10] highlighted the infrequency of persistent opioid use post-surgery, particularly in surgeries unrelated to orthopedic

and spinal procedures. In addition, in Thailand, strong opioids are not typically prescribed for non-cancer pain as take-home medication, and strict regulations regulate their usage. Patients at high risk of prolonged opioid use receive specialized care from pain clinics, ensuring comprehensive management and monitoring protocols to mitigate opioid-related risks.

At our institution, some neurosurgeons request that their patients remain intubated overnight in the ICU. Therefore, the time to extubation between the two groups was not significantly different due to the wide range of data distribution. However, Altaf *et al*.[2] reported that scalp block contributed to significantly earlier emergence than fentanyl infusion.

Enhanced recovery after surgery (ERAS) is a perioperative protocol integrating evidence-based interventions to promote functional capacity and facilitate patient recovery. Key components include a preoperative carbohydrate load multimodal opioid-sparing techniques, including pre-emptive analgesia with paracetamol and scalp block, which were used to minimize opioid-related side effects such as respiratory depression, PONV, and the risk of opioid overuse. Despite higher adherence to the ERAS protocol observed in Group S, anticipated outcomes such as lower pain scores, reduced rescue analgesia, and less PONV were not achieved. This discrepancy suggests the potential limitations of relying solely on a single modality, emphasizing the importance of a multimodal approach. Combining scalp block with systemic analgesia, such as paracetamol or non-steroidal anti-inflammatory drugs, and adjuncts like dexmedetomidine infusion, alongside opioids as a rescue dose, may offer superior pain control and minimize adverse effects.[8]

This study observed significantly lower MAP immediately and 5 min after pin insertion in Group F compared to Group S, although without significant differences in HR. A prior randomized controlled trial demonstrated the superior efficacy of scalp block over 4 μg/kg fentanyl in attenuating the hemodynamic response during scalp-pin application in elective craniotomy cases.[3] In the present study, a bolus dose of 2 μg/kg fentanyl followed by an infusion of 1 μg/kg/h effectively attenuated sympathetic activation induced by intense nociceptive stimuli during craniotomies, including scalp-pin holder application, scalp incision, and dura incision. However, another trial revealed superior hemodynamic control with scalp block compared to fentanyl infusion in patients undergoing supratentorial craniotomies.[2] This difference may be attributed to the rapid onset of analgesia with fentanyl infusion, compared to the potentially slower onset of action of local anesthesia administered through scalp block, leading to delayed attenuation of hemodynamic response to surgical stimuli. Notably, patients in Group F exhibited lower MAP and HR resulting in a higher vasopressor requirement compared to Group S. Conversely, Yildiz *et al*.[16] proposed administering an additional dose of 1 μg/kg fentanyl just before skull-pin insertion as a simple and effective option without procedural prolongation.

This study had some limitations. First, the assessment of hemodynamic changes, including tachycardia and hypertension, was employed to evaluate intraoperative opioid administration. However, the utilization of an objective tool for intraoperative pain assessment, such as the Analgesia Nociception Index, could provide more valuable insights when making decisions regarding the administration of rescue fentanyl. Second, the study solely focused on patients scheduled for supratentorial craniotomy. Future studies should encompass a broader range of neurosurgical procedures, including infratentorial craniotomy or craniotomy for aneurysm clipping. Moreover, investigating alternative techniques for multimodal analgesia or opioid-free anesthesia could enhance our understanding of optimal pain management strategies in neurosurgery within resource-limited settings.

CONCLUSION

Intraoperative fentanyl infusion presents a readily available alternative to techniques like scalp block, requiring less expertise. This study demonstrates cost advantages over scalp block, making it a variable option for pain management in craniotomy, especially in resource-limited settings or when scalp block may not be feasible. However, it is crucial to emphasize judicious opioid use to ensure patient safety and prevent overuse. This study underscores the necessity for ongoing research optimizing neurosurgical pain management strategies, particularly in resource-limited settings, and highlights the importance of exploring alternative analgesia approaches and assessing their long-term safety implications.

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Ethical approval

The research/study was approved by the Institutional Review Board at the Faculty of Medicine, Prince of Songkla University, number REC64-335-8-1, dated November 18, 2021.

Declaration of patient consent

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

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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 intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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