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Original Article

Efficacy of ultrasound guided sphenopalatine ganglion block in management of emergence agitation after sinoscopic nasal surgery: a randomized double-blind controlled study

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ABSTRACT

Background: Nasal surgery has a reported high incidence of agitation during emergence from general anesthesia. Emergence Agitation (EA) increases the risk of surgical site bleeding, falling off the operating table, removal of catheters and intravenous lines, and self-extubation. This study investigated the role of nerve block in EA.
Objectives: This study evaluated the effect of ultrasound-guided sphenopalatine ganglion block (SPGB) on EA after sinoscopic nasal surgery. The primary outcome was the incidence of EA. Secondary outcomes included the quality of the surgical field, bleeding volume, inhalational anesthesia, MAC, VAS in the PACU, postoperative analgesia duration, and total 24 -h opioid consumption.
Patients and methods: This double-blind, randomized controlled study enrolled 120 patients, of whom 110 completed the study. They were randomly allocated into two equal groups: G1, which received general anesthesia and a bilateral sphenopalatine ganglion block (SPBG) with 5 mL lidocaine 2% on each side, and G2 (control), which received general anesthesia and a bilateral sphenopalatine saline injection of 5 mL on each side.
Results: A significant decrease in the incidence of EA was found in G1 compared to G2 (20% *vs.* 64%). Intraoperative bleeding volume was significantly lower, and surgical field quality was significantly higher in G1 compared to G2. Pain severity was significantly lower in G1 in the PACU, and 24 h postoperative opioid consumption was significantly reduced compared to G2. Additionally, postoperative analgesia duration was significantly longer in G1 than in G2 (9 h *vs.* 3 h).
Conclusion: SPGB effectively reduced EA incidence, severity, and duration after sinoscopic nasal surgery. Furthermore, SPGB reduced intraoperative bleeding, improved surgical field quality, prolonged postoperative analgesia, and reduced 24 -h opioid consumption after sinoscopic nasal surgery.
Registration: National Clinical Trial Registry, NCT04168879.

Introduction

Emergence Agitation (EA) is an acute confusion state that develops in the early phase of anesthesia recovery and is characterized by disorientation, hallucination, restlessness, and purposeless aggressive movement [1]. The occurrence of EA increases the risk of surgical site bleeding, falling off the operating table, removal of catheters and intravenous lines, and self-extubation. This may lead to further complications such as desaturation and aspiration of blood. Thus, continuous monitoring, additional medications, and physical restraint may be required [2,3]. Nasal surgery has a reported high incidence of agitation during emergence from general anesthesia, with an incidence as high as 55.4%. The exact mechanism is unknown. Possible nasal surgery-related predisposing factors include nasal congestion and awake extubation, usually performed due to airway contamination with blood and a nasal pack [4]. Inhalational anesthetics, especially sevoflurane and desflurane, are major risk factors for EA. The incidence of EA under sevoflurane anesthesia has been reported to

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be as high as 66% [5]. Moreover, postoperative pain is reported as a major risk factor for EA. However, EA is still reported in pain-free interventions and occurs regardless of the severity of pain. These reports demonstrated that EA and postoperative pain are separate clinical phenomena [1].

The sphenopalatine ganglion (SPG) is the largest parasympathetic ganglion of the head and neck found in the pterygopalatine fossa. It receives sensory, sympathetic, and parasympathetic fibers. Traditional blind techniques of SPG blocks (SPGB) have been reported to decrease postoperative bleeding and pain after endoscopic sinus surgery [6]. Most studies have concentrated on the effects of SPGB on intraoperative hemodynamics, intraoperative bleeding, and anesthetic and analgesic consumption.

This study aimed to evaluate the efficacy of ultrasound-guided sphenopalatine ganglion block on the incidence of EA after functional endoscopic sinus surgery (FESS) nasal surgery.

Patients and methods

This prospective, randomized, double-blind, controlled study was conducted at the Ear, Nose, and Throat (ENT) surgery theatre of Assiut University Hospitals. The study was approved by the Institutional Review Board (IRB) of the Faculty of Medicine, Assiut University, in October 2021 (NO.17101544) and registered as a clinical trial in November 2019 (NCT04168879).

Adult patients aged 18–55 years with ASA physical status I and II, scheduled for elective external nasal surgery, were eligible for enrollment in the study. Patients were excluded if they refused to consent, had a history of overt inflammatory diseases or coagulation profile abnormalities, or required emergency nasal explorations. A total of 120 patients were eligible for enrollment, patient enrollment began in November 2021. 110 patients completed the study, they were randomly allocated in a 1:1 ratio into two groups: Group I (SPG) received general anesthesia and a bilateral SPGB with 5 mL lidocaine 2% on each side, and Group 2 (control) received general anesthesia and a bilateral sphenopalatine saline injection of 5 mL on each side. Lidocaine was used as it was the only amide local anesthetic available at the time of the study. The study medications (saline or lidocaine) were prepared in our clinical trial pharmacy and sent to the operating theatre in the morning in identical sterile vials labeled with the research medication, patient's name, and patient's number. The block was performed by an expert anesthesia consultant in ultrasound-guided regional anesthesia. The anesthetist responsible for the block, the data collector, and the patients were blinded to the nature of the medications used.

The primary outcome measure was the incidence of EA, which was assessed using the Richmond Agitation-Sedation Scale (RASS) score [7]. Emergence was defined as the time from the closure of inhalational anesthesia to the extubation [8]. The secondary outcomes included intraoperative hemodynamics, quality of the surgical field, bleeding volume, inhalational anesthesia, MAC, VAS in the PACU (mild pain = 0–3; moderate pain = 4–6; and severe pain = 7–10), postoperative analgesia duration, and total 24-h opioid consumption.

General anesthesia was induced with 2 mg/kg propofol, 2 μg/kg fentanyl, 1 mg/kg lidocaine, and 0.15 mg/kg cisatracurium after 3 min of 100% O_2 preoxygenation. Anesthesia was maintained with mechanical ventilation (8 mL/kg tidal volume, ventilation rate 12) in 50% O_2/air, sevoflurane inhalation (adjusted to keep BIS between 40 and 60), and muscle relaxant. For preemptive analgesia, 60 mg ketorolac was administered via IV infusion 30 min before anesthesia induction. For postoperative nausea and vomiting (PONV) prevention, 8 mg intravenous dexamethasone was given at anesthesia induction, and 8 mg intravenous ondansetron was given 30 min before the end of surgery. Hemodynamics, bleeding volume, and quality of the operative field were recorded intraoperatively at 20, 40, 60, and 80 min (or end of surgery). The Boezaart grading score (0–5) was used for the evaluation of the operative field by the surgeon (0 = no bleeding; 1 = slight bleeding, no suctioning required; 2 = slight bleeding, occasional suctioning required; 3 = slight bleeding, frequent suctioning required, bleeding threatens the surgical field a few seconds after suction is removed; 4 = moderate bleeding, frequent suctioning required, bleeding threatens the surgical field directly after suction is removed; and 5 = severe bleeding, constant suctioning required, bleeding appears faster than can be removed by suction, surgical field severely threatened, and surgery usually not possible) [9]. The suction chamber method was adopted to estimate blood loss after eliminating the normal saline volume used for washing blood accumulated in the suction. The sponges used were weighted and the blood weight was converted into milliliters using the following equation: the amount of blood in mL = (mass of used sponges + - fresh gauze – the weight of all sponges before surgery)/1.05. Intraoperative hypertension or tachycardia was recognized as a 20% elevation in blood pressure or heart rate (HR) from baseline despite adequate anesthesia depth and muscle relaxation. It was treated with esmolol 10 mg increments. Hypotension was treated by administering a bolus of crystalloids and ephedrine increments (12 mg per dose). Bradycardia (<50 bpm) was treated with 0.005 mg/kg atropine.

At the end of the surgery, neuromuscular blockade was reversed by atropine 0.015 mg/kg and neostigmine 0.04 mg/kg, given after a train-of-four ratio of 0.9. Sevoflurane was turned off, and mechanical ventilation was converted to manual ventilation with 100% O_2 at 8 L/min. Extubation was performed only when patients began to breathe spontaneously with a tidal volume $\geq$ 5 mL/kg, maintained head elevation for 5 seconds, and obeyed verbal commands with a BIS value of 70.

The level of agitation was assessed using the RASS from the closure of inhalational anesthesia up to 30 min after extubation. EA was defined as RASS $\geq$ 1; dangerous agitation was RASS = 3 or 4. During emergence and in the PACU, coughing was evaluated using the following four-point scale: 0 = no cough, 1 = single cough (no persistence in the single cough episode), 2 = persistent cough episode lasting <5 seconds, and 3 = persistent cough episode lasting ≥5 seconds or bucking.

In the PACU and postoperative unit, patients were monitored for hemodynamics and complications, including the duration of EA, PONV, coughing, and bleeding. Patients were documented to have PONV if they reported any episode of nausea, retching, or vomiting during the first 24 h postoperative. The time of the first analgesic request was recorded, and VAS was reported. Rescue analgesia was prescribed as intravenous 1 g paracetamol if VAS < 4 and 50 mg meperidine if VAS $\geq$ 4. Additionally, 24 -h opioid consumption was measured. Patients were discharged from the PACU based on an Aldrete recovery score ≥9.

SPGB was performed with the suprazygomatic approach, after the stabilization of general anesthesia with real-time ultrasound guidance. A linear ultrasound transducer (6−12HZ) (GE-Logiq P7) was placed just inferior to the zygomatic arch; then, the transducer was angled 45 ° in a cephalic direction until the acoustic shadow of the maxilla was recognized anteriorly and the acoustic shadow of the mandibular coronoid process overlying the pterygoid process of the greater wing of the sphenoid bone recognized posteriorly (Fig.1). After sterilization of the zygoma and suprazygomatic area, a Pajunk single-shot nerve block echogenic needle was introduced out-of-plane behind the orbital rim suprazygomatic in a perpendicular manner and advanced 1 cm to bypass the zygoma. The internal maxillary artery was identified by the Doppler technique to avoid vascular injury. The needle was then advanced 10 °

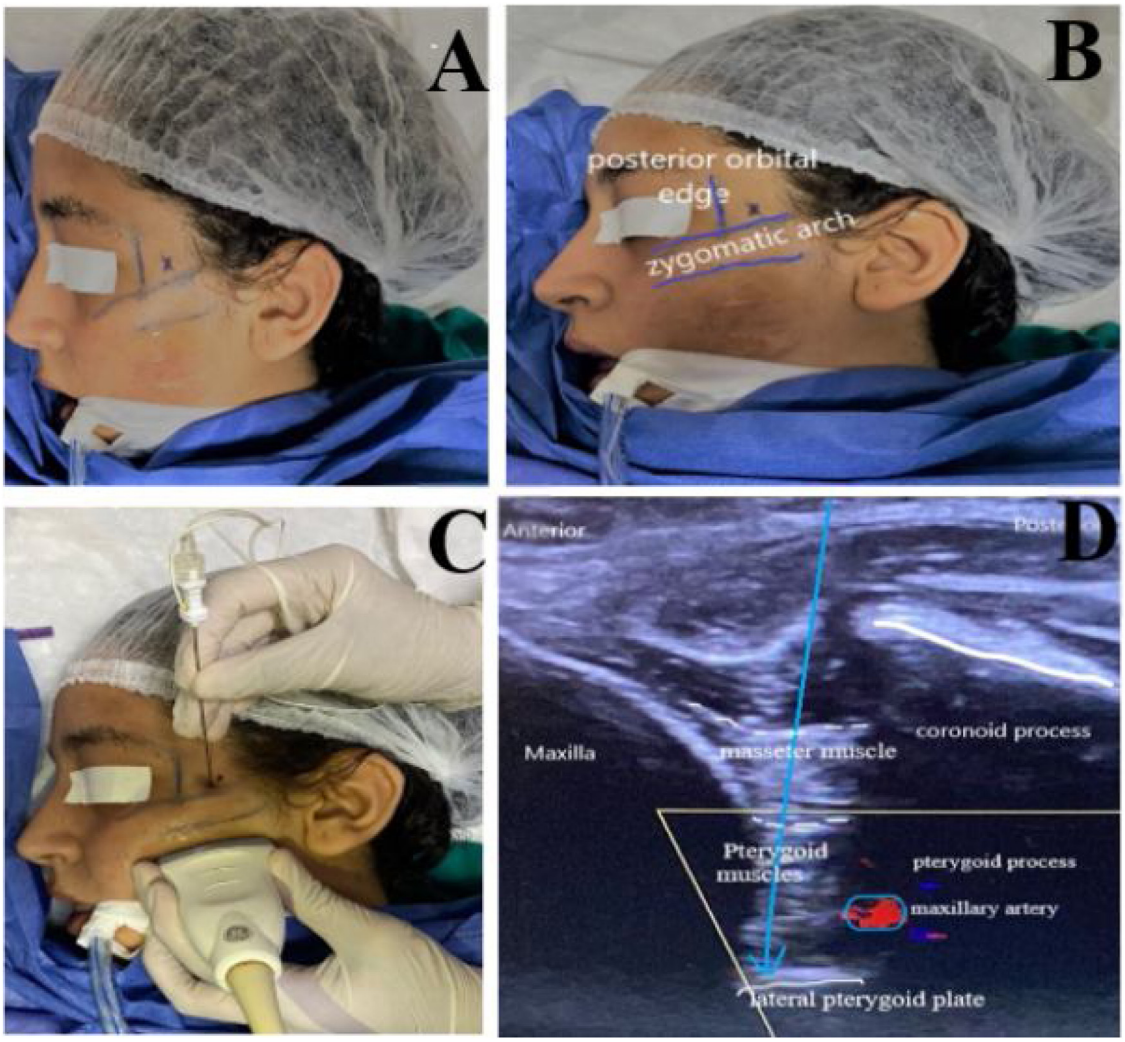

Fig. 1. (A and B) Anatomical landmark: posterior orbital rim and zygomatic arch. (C) The entry point is about 1 cm posterior to the posterior orbital rim and superior to the zygomatic arch. A linear transducer was placed infra zygomatic and angled 45 ° in the cephalic direction. (D) The sonoanatomy of the pterygopalatine fossa (PPF) lies deep to the pterygoid muscles between the maxilla anteriorly and the pterygoid process posterior and deep to the coronoid process of the mandible. Blue arrow: Needle trajectory about 10 ° anterior and 45 ° caudal in out-of-plane approach, arrowhead indicates the site of the needle tip in PPF. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article).

anterior and 45 ° caudal, 3–5 cm into the sphenopalatine fossa through the pterygomaxillary fissure, deep to the masseter and pterygoid muscles. The needle hub was left open to atmospheric pressure for 15 seconds to exclude inadvertent intravascular placement of the needle tip, and then 5 mL lidocaine 2% local anesthetic were injected. This approach is safe because anatomical structures prevent needle placement in an unsafe position without first passing through the bone [10].

The sample size was calculated based on the incidence of EA, according to the results of Kim *et al.* [4]. In this study, the incidence of EA after nasal surgery was 52%. A total of 108 patients (54 in each group) were required to detect a 50% difference between the study groups, with an α error of 0.05 and 80% power at 95% confidence. We decided to enroll 120 patients to compensate for dropouts. Data were analyzed using IBM-SPSS 24.0 (IBM-SPSS Inc., Chicago, IL, USA). The normality of continuous variables was evaluated using the Kolmogorov–Smirnov test. Chi-square/Fisher's exact/Monte Carlo exact test was used to compare the distribution of frequencies among different groups. Parametric data were analyzed by an independent sample t-test. Nonparametric data were analyzed using the Mann-Whitney test (Boezaart score, RASS score). Data were expressed as a number, percentage, and mean ± SD. Repeated-measure analysis with Bonferroni correction was used to analyze repeated measures (bleeding volume, MAP, and HR). A *P*-value < 0.05 was considered statistically significant. Absolute risk reduction (ARR) was calculated using the formula: incidence in the control group – incidence in the SPGB group. The number needed to treat (NNT) was calculated as 1/ARR.

Results

Out of 120 patients, 110 completed the study (Fig. 2, flow chart). Patients were randomly allocated in a 1:1 ratio into G1 (SPGB group) and G2 (control group). No statistical differences were found in demographic data, surgery duration, and ASA status between the study groups (Table 1). No statistical differences were found in baseline mean blood pressure (MBP) and HR between the studied groups. However, a significant decrease in MBP and HR was observed from 10 min post-block until the end of surgery (Fig. 3).

A significant reduction in the incidence of EA, the primary outcome of the study, was noted in the SPGB group compared to the control group (20% *vs.* 64%), with an absolute risk reduction (ARR) = 0.44 (44%) and number needed to treat (NNT) = 2.3 (Fig. 4 and Table 2).

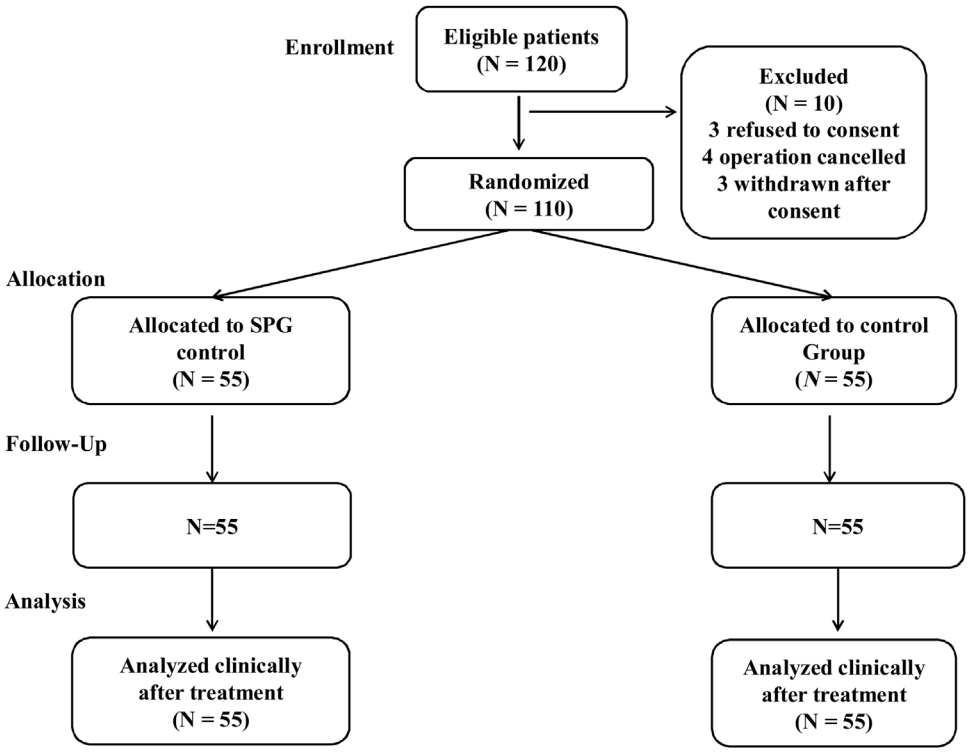

Fig. 2. Study flow chart.

Table 1
Patient demographic data and surgery duration in both groups.

	SPG group (N = 54)	Control group (N = 54)
Age (Years)	40 ± 9	42 ± 8
Sex		
Female	31 (43%)	26 (44%)
Male	23 (57%)	28 (56%)
BMI (kg/m^2)	27 ± 2	27.3 ± 2.5
ASA		
I	31 (57%)	30 (56%)
II	23 (43%)	24 (44%)
Surgery duration (min)	67 ± 5	68 ± 4
Mean MAC to BIS 40–50	1.8 ± 0.3*	2.7 ± 0.5
Extubation time (min)	9 ± 2	10 ± 1.7

Mean ± SD. Independent sample t-test for numerical data and chi-square for categorical data.
* $P < 0.001$.

The severity of EA was lower in the SPGB group; no cases of dangerous agitation (RASS = +3 or +4) occurred in the SPGB group, while 4 were observed in the control group. An agitated state (RASS + 2) was found in 4 cases in the SPGB group versus 17 in the control group, and a restless state (RASS + 1) was found in 7 cases in the SPGB group *versus* 14 in the control group (Fig. 4 and Table 2).

A calm and alert state (RASS 0) was observed in 6 cases in the SPGB group *versus* 17 cases in the control group. A drowsy state (RASS -1) was found in 15 cases *versus* 4 in the SPGB and control group, respectively. Light sedation state (RASS -2) was reported in 11 cases in the SPGB group, while none was reported in the control group. Moderate sedation state (RASS -3) was found in 10 cases in the SPGB group only. Only 1 case of deep sedation state (RASS -4) occurred in the SPGB group. No case of unarousable state (RASS -5) was reported in both groups. A significant reduction in the duration of EA was found in the SPGB group compared to the

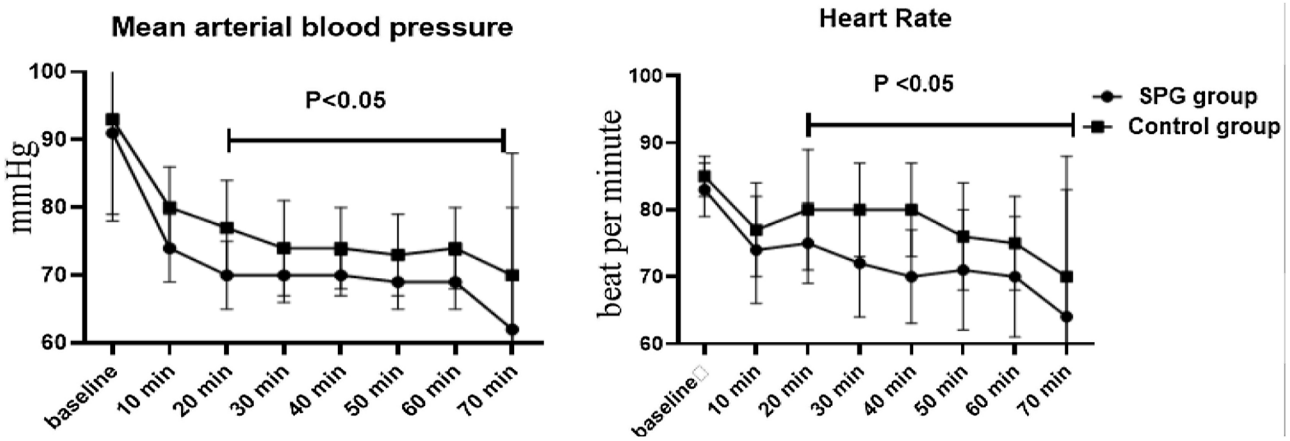

Fig. 3. Mean blood pressure and heart rate between study groups.

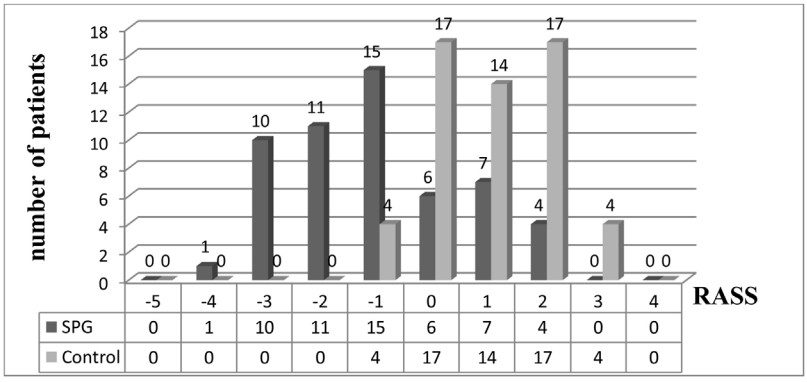

Fig. 4. RASS between the study groups.

Table 2
PACU data.

	SPG group (N = 55)	Control group (N = 55)	*P*-value
% of EA	20% (11)	64 (35%)	<0.001
Dangerous EA	0	4 (7%)	
ARR	0.44		
NNT	2.3		
Duration of EA (min)	9 ± 3	12 ± 4	0.01
VAS in PACU	1.9 ± 0.7	2.2 ± 1	0.4
Number	10 (18%)	32 (58%)	
Median	0	1	
No pain	45	23	<0.001
Mild (1–3)	10	27	
Moderate (4–6)	0	5	
Severe (7–10)	0	0	
EA with pain	8	27	<0.001
EA without pain	3	9	0.05
pain without EA	2	4	0.7
PONV	3 (6%)	12 (22%)	0.01
Cough	5 (9%)	17 (31%)	
Grade 1	4	9	0.02
Grade 2	1	7	
Grade 3	0	2	
PACU stay (min)	17 ± 8	16 ± 7.5	0.3

Mean ± SD. Independent sample t-test for parametric data, Mann–Whitney for non-parametric data, and chi-square for categorical data.

control group, 9 ± 3 min versus 12 ± 4 min in both groups, respectively. (Table 2).

In the SPGB group, 8 cases of EA reported mild pain in PACU (VAS 1-3), and 2 cases reported no pain despite the presence of EA. In the control group, 27 cases with EA reported pain in PACU, while 9 cases reported no pain (Table 2). The mean intraoperative sevoflurane MAC required to maintain BIS between 40–50 was significantly lower in the SPGB group compared to the control group, 1.8 ± 0.3 *versus* 2.7 ± 0.5 min respectively (Table 1). Extubation time did not significantly differ between the 2 groups (Table 1).

The quality of the surgical field, evaluated by the Boezaart score, was significantly better in the SPGB group throughout the operation compared to the control group (Fig. 5). Intraoperative blood loss was consistently lower in the SPGB group compared to the control group (Fig. 5). Total intraoperative blood loss was significantly lower in the SPGB group (71 ± 17 mL) than in control group (123 ± 24 mL) (Fig. 5 and Table 3).

In PACU, 10 cases (18%) in the SPGB group reported mild pain, while 32 cases (58%) in the control group reported pain (27 mild and 5 moderate) (Table 2). A significant reduction in the incidence of PONV and cough severity was observed in the SPGB group compared to the control group (Table 2). The duration of PACU stay was similar between the groups (17 ± 8 min *vs.* 16 ± 7.5 min) (Table 2). The duration of analgesia (time to first analgesic request) was longer in the SPGB group compared to the control group (9 h *vs.* 3 h) (Table 3). Total postoperative meperidine consumption was significantly lower in the SPGB group (89 ± 39 mg) compared to the control group (171 ± 27 mg) (Table 3).

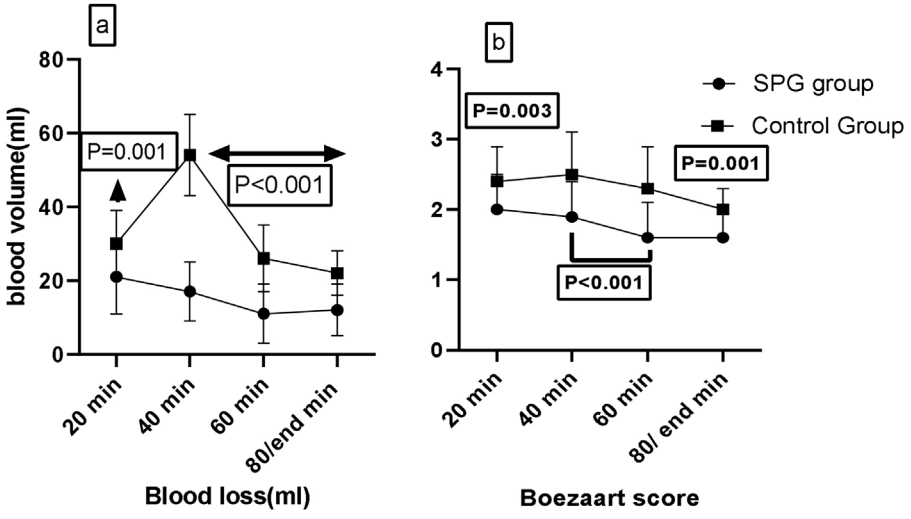

Fig. 5. (a) Blood loss (ml). (b) Boezaart score.

Table 3
Postoperative analgesia and 24-h analgesic consumption in both groups.

	SPG group (N = 54)	Control group (N = 54)	*P*-Value
Blood Loss (mL)	71 ± 17	123 ± 24	<0.001
Time to first analgesic requirement (h)	9 ± 2	3 ± 0.7	<0.001
24-h meperidine consumption (mg)	89 ± 39	171 ± 27	<0.001

Mean ± SD. Independent sample t-test for parametric data, Mann–-Whitney for non-parametric data.

Discussion

EA is the most common postoperative neuropsychiatric disorder, referred to as emergence delirium. It is defined as a short-term conscious dissociation state that accompanies recovery from general anesthesia, with an incidence ranging from 5% to 80% [11]. This prospective, randomized, blind study demonstrated that SPGB could effectively decrease the incidence, severity, and duration of EA following sinoscopic surgery under sevoflurane inhalational anesthesia. Furthermore, SPGB improved surgical field quality, reduced intraoperative blood loss, and decreased the required alveolar concentration to maintain adequate anesthesia levels. SPGB reduced PONV, postoperative cough, prolonged postoperative analgesia, and reduced opioid consumption. Although EA is usually self-limited and does not require medical treatment, agitated behavior can cause severe complications in the PACU, such as tube removal, accidental injuries, or falls. Additionally, EA may increase the risk of long-term complications, such as cognitive dysfunction and behavioral changes, which can lead to a lower quality of life, hospital readmission, and even death [12]. Therefore, implementing strategies to prevent or reduce the incidence of EA is of great clinical importance. Both nasal surgery and sevoflurane inhalational anesthesia are major risk factors for EA. One explanation for the higher incidences of EA with sevoflurane and desflurane is their ability to induce differential recovery rates in brain function due to variations in the clearance rates of inhalational anesthetics from different parts of the central nervous system. The auditory sense and locomotion recover early, while cognitive function recovery is delayed. Moreover, sevoflurane anesthesia elevates lactate and glucose levels in the parietal cortex and induces clinically silent epileptogenic activity that contributes to EA [4]. Frederick *et al.* studied the effect of different concentrations of sevoflurane on EA in pediatric patients and documented a reduction in EA with lower concentrations of sevoflurane [13]. Multiple studies have used regional anesthesia to ameliorate EA with satisfying results, possibly due to postoperative pain block and the reduction of intraoperative inhalational anesthetic consumption [5,14–16]. However, further studies are required to examine how regional analgesia could reduce EA [4].

The SPG is the largest parasympathetic ganglion of the head and neck in the pterygopalatine fossa. It receives sensory, sympathetic, and parasympathetic innervation. The maxillary nerve supplies the sensory fibers of the SPG, while the sympathetic fibers are branches of the deep petrosal nerve. The preganglionic parasympathetic fibers are derived from the facial nerve through the greater petrosal nerve, synapse in the SPGB, and project axons to the nasal mucosa and the lacrimal gland. The SPGB controls the blood flow to the nasal mucosa, making it an exciting site for regional anesthesia in FESS [6].

To the best of our knowledge, this is the first study that focused on the effects of ultrasound-guided SPGB on postoperative EA after sinoscopic nasal surgery. We found a statistically significant reduction in the incidence of EA. Regarding EA in ENT (ear, nose, and throat) surgery, we found one trial conducted by Ibrahim *et al.*, which examined the effect of external nasal nerve block in patients undergoing rhinoplasty. Their results agreed with the findings of the current study, concluding that external nerve block is an effective technique that reduces EA, improves the quality of recovery, and reduces postoperative pain and opioid consumption [17]. Our results align with those of Bhattacharyya *et al.*, who evaluated the effect of bilateral SPGB as an adjuvant to general anesthesia in patients undergoing endoscopic sinus surgery [6]. They found that patients who received SPGB showed statistically significantly better recovery scores, less intraoperative bleeding, better intraoperative hemodynamic stability, lower VAS scores, and longer analgesia duration [6]. Additionally, Kesimci *et al.* studied the effect of intranasal SPGB in FESS and reported that SPGB resulted in prolonged postoperative analgesia, less analgesia consumption, less intraoperative bleeding, better surgical field quality, and higher surgeon and patient satisfaction [14]. The present study is limited by the small sample size which may lead to the overestimation of the drug efficacy. Moreover, we did not examine the effect of SPGB on the long-term risks of EA.

Conclusion

Ultrasound-guided supra-zygomatic sphenopalatine ganglion block (SPGB) is a safe and effective technique for decreasing the incidence of postoperative EA after sinoscopic nasal surgery under sevoflurane anesthesia. Additionally, it provided a bloodless surgical field, prolonged postoperative analgesia, and reduced postoperative opioid consumption.

Conflicts of interest

The authors have no conflicts of interest. No ghost authors.

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