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Evaluating the perioperative analgesic effect of ultrasound-guided trigeminal nerve block in adult patients undergoing maxillofacial surgery under general anesthesia: A randomized controlled study

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ABSTRACT

Background: Although ultrasound-guided nerve blocks have lately been used to control pain, there is not much evidence assessing the outcome of trigeminal nerve block (TNB) in maxillofacial surgery. This study sought to evaluate the safety and efficacy of analgesia with an ultrasound-guided trigeminal nerve block (USGTNB) in patients undergoing unilateral maxillofacial surgery under general anesthesia.

Methods: This single-blinded, parallel-group, randomized clinical trial included 50 adult patients who had American Society of Anesthesiologists physical status I or II and were prepared for elective unilateral maxillofacial procedure under general anesthesia. The patients were randomized into two groups. In the intervention (TNB) group, 25 patients received USGTNB using 5 ml of bupivacaine 0.25%, while in the control group, 25 patients received only general anesthesia. Total intraoperative fentanyl consumption was the primary outcome. The secondary outcomes were the intraoperative hemodynamic parameters besides the postoperative pain, total opioid consumption, complications, and patient satisfaction.

Results: Compared to general anesthesia, USGTNB significantly reduced the intraoperative fentanyl consumption (2.38 ± 0.62 vs 0.36 ± 0.55, $p < 0.001$), and the intraoperative heart rate and mean arterial blood pressure at 1, 2, and 3 h ($p < 0.001$), the numerical rating score during the 24 postoperative hours ($p < 0.001$), and the postoperative nalbuphine consumption (11.60 ± 4.72 vs 1.92 ± 3.28, $p < 0.001$). USGTNB had a better safety profile and showed better patient satisfaction compared to general anesthesia alone (8.04 ± 0.89 vs 5.84 ± 0.90, $p < 0.001$).

Conclusion: USGTNB can provide an effective, safe approach for controlling pain in adult patients undergoing maxillofacial surgery.

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1. Introduction

Maxillofacial surgeries include a wide range of procedures from straightforward tooth extractions to intricate reconstructive and free flap surgeries. These surgeries are challenged by the complicated anatomy and limited surgical space. Furthermore, pain and bleeding are common encounters during maxillofacial surgery [1]. Postoperative pain raises both the hospital costs and length of stay. Additionally, it affects sleep and lowers the quality of life [2]. There are numerous treatments for postoperative pain including opioid and nonopioid medications as well as oral, intravenous, and regional anesthetics [3]. The adverse effects of opioids include postoperative nausea/vomiting and respiratory depression that make it difficult to extubate patients, particularly in maxillofacial surgeries involving mouth closure by intermaxillary fixation [4]. Another challenge in maxillofacial surgery is significant bleeding. Blood loss can usually be managed using head-up positioning, injecting adrenaline-containing local anesthetic, and avoiding hypertension [5,6].

Recently, a multimodal strategy was put forth to lessen the negative effects of opioids [7]. Fluoroscopy-guided blocks are considered the standard treatment of pain in the head and neck surgery. As a substitute, operations guided by computed tomography are beneficial but costly and radiation risky. Recently, the use of ultrasonography for perioperative pain management has grown significantly. Ultrasonography offers good soft tissue and vascular visualization together with real-time needle placement [8].

Ultrasound-guided trigeminal nerve blocks (USGTNB) have been developed for the management of trigeminal neuralgia [9]. The trigeminal nerve can be indirectly blocked by injection through the pterygopalatine fossa, which includes the sphenopalatine ganglion. The parasympathetic and sympathetic activities of this ganglion are mediated by the superficial and deep petrosal nerves, respectively. The orbit, nose, buccal

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mucosa, and palate carry the sensory functions of the sphenopalatine ganglion [10]. Maxillofacial procedures can benefit from nerve blockades as they improve postoperative analgesia, lower opioid usage, and have fewer adverse effects [11]. Furthermore, USGTNB can prevent injury to blood vessels, particularly the maxillary artery. Recently, a few reports have brought up the possibility of using USGTNB for postoperative analgesia in craniofacial surgery [12,13]. The aim of this study was to assess the efficacy and safety of perioperative USGTNB for pain control in patients undergoing unilateral maxillofacial surgery under general anesthesia.

2. Methods

2.1. Ethical considerations

The study was conducted after the approval by the Ethics Committee of the Faculty of Medicine, Suez Canal University, Egypt. This trial was recorded at the ClinicalTrials.gov (Trial ID: NCT05567497). Each participant gave written informed permission after being informed of the study's goals and methods. The information of each participant was kept private.

2.2. Study design, setting, and date

This single-blinded, parallel-group, randomized clinical trial was performed at the Suez Canal University Hospital, Egypt, between November 2022 and March 2023.

2.3. Eligibility criteria

The present study included 50 adult patients aged 21- to 60-year-old of both sexes who had American Society of Anesthesiologists (ASA) physical status I or II and underwent elective unilateral maxillofacial surgery under general anesthesia.

We excluded patients who were necessitating postoperative ventilation from the start since it was difficult to assess respiratory depression and postoperative pain. Patients with a history of allergy to the used prescriptions and those with coagulopathy, polytrauma, fracture base of the skull, or infection at the puncture site were also excluded.

2.4. Randomization, allocation concealment, and blinding

Fifty adult patients were randomly divided into 25 patients per group. The trigeminal nerve block group (TNB group) underwent USGTNB. The control group received general anesthesia only. Using the procedure of sequentially numbered, opaque, sealed envelopes, randomization, and allocation concealment were carried out [14]. We prepared a total of 50 opaque, small envelopes. Each envelope contained the allocation paper, marked as "Treatment A" ($n = 25$) or "Treatment B" ($n = 25$) and a sheet of single-sided carbon paper over the allocation paper. We combined all the envelopes (the two sets) and shuffled them thoroughly. Then, we marked a number on the front of each envelope sequentially from 1 to 50 and placed them into a plastic container ready for use. The allocation was concealed from the study subjects.

2.5. Interventions

2.5.1. Preoperative management

Each patient underwent a comprehensive history and examination, including a close examination at the area that will be punctured for the local anesthetic injection. Routine preoperative investigations were done including complete blood count, prothrombin time, partial tissue thromboplastin time, international normalized ratio, and random blood sugar. The day before the surgery, fasting instructions were explained to the patients. Also, the numerical rating scale (NRS) was demonstrated. The NRS ranges from 0 to 10 with variable degrees of ascending pain in between [15].

2.5.2. Intraoperative management

Upon arrival in the operating room, the heart rate (HR), non-invasive blood pressure, oxygen saturation, respiratory rate, and temperature were monitored basically. A 20-gauge or wider intravenous line was secured. For induction of general anesthesia, fentanyl (2 µg/kg), propofol (2 mg/kg), and rocuronium (0.6 mg/kg) were administered intravenously (IV) to all participants in both groups. Oral endotracheal intubation was performed. Then, the lungs were mechanically ventilated with Datex-Ohmeda® GE ventilator machine. Anesthesia was maintained with sevoflurane at low flow (1 liter oxygen/minute). Sevoflurane MAC was adjusted between 2% and 3%. The patients' ventilation parameters (tidal volume and respiratory rate) were adjusted to maintain an end-tidal carbon dioxide level between 35 and 40 mmHg, and rocuronium (0.15 mg/kg) boluses were given every 30 min till the end of surgery. Fentanyl (1 µg/kg) bolus doses were given again if the mean arterial pressure (MAP) and/or heart rate (HR) increased by 20% from the preoperative baseline, and the total intraoperative fentanyl top ups were recorded.

2.5.3. Trigeminal nerve block

Following intubation, the blocks were performed in an aseptic setting with the patients being observed with a fitted oxygen face mask. The block was performed on the same side of the surgery. The side of the patient's face that needed to be blocked was on the upper side while they lay supine. The high-frequency, linear array

transducer (Sonosite M-Turbo ® US machine, 7–12 MHz) was positioned longitudinally on the side of the face slightly below the zygomatic bone, above the mandibular notch, and in front of the mandibular condyle. The probe's angle was cephalad, pointing in the direction of the pterygopalatine fossa. To reach the foramen rotundum, the local anesthetic could be injected deeply into the superior head of the lateral pterygoid muscle along the pterygomaxillary fissure. The zygomatic bone, lateral pterygoid muscle, lateral pterygoid plate, maxillary bone, and maxillary artery were identified in the pterygopalatine fossa using US and color power Doppler US. A 22-G, 5 cm insulated echogenic needle was inserted out of plane above the zygomatic bone (suprazygomatic approach) and introduced in a lateral to medial and posterior to anterior direction in the pterygopalatine fossa. The patient's mouth was kept open with an oral airway to prevent the coronoid process from creating an auditory shadow. The probe was slightly elevated in a superior direction. A negative aspiration was followed by the administration of 5 mL of 0.25% bupivacaine.

2.5.4. Postoperative management

For all patients, 1 g of paracetamol was administered intravenously (IV) every 8 h for 48 h. The post-operative nalbuphine top ups, oxygen saturation, HR, MAP, and the NRS were recorded every 6 h for the first 24 h. Any patient presenting with NRS more than three was given IV nalbuphine (0.07 mg/kg) as a rescue analgesic. The total analgesic consumption and patient satisfaction score were recorded for the first 24 h (1, not satisfied; 10, highly satisfied). Adverse effects including nausea, vomiting, persistent paresthesia, and respiratory depression were noted and treated in accordance with customary protocols.

2.6. Outcomes

The primary outcome was the total intraoperative fentanyl consumption. The secondary outcomes included the intraoperative hemodynamic parameters as well as the postoperative pain, total opioid consumption, complications, and patient satisfaction.

2.7. Sample size

Wang et al. [13] reported that the total dose of intraoperative fentanyl would be reduced in the UGTNG group to 17 µg (corresponding to a mean dose of fentanyl in the control group of 30 g, with a standard deviation of 9.7). To provide 90% power for independent populations and a unilateral α of 0.05, an estimated 25 patients per group would be needed. In the current study, a sample size calculation resulted in 23 participants per group. To account for the loss from following up, we added 10%. Thus, in the end, the total sample size was 50 patients.

2.8. Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (IBM SPSS Statistics) for Windows, version 26 (IBM Corp., Armonk, NY, USA). All numerical variables followed normal distribution, and values were expressed as means and standard deviations (SD). The two groups were compared using unpaired t-test. For categorical data, the variables were summarized as frequencies (count and percentage). Pearson's Chi-square test for independence was used to examine the association between two categorical variables. The ANOVA test was used to evaluate repeated measures of continuous variables. A p-value of <0.05 is the threshold for significance.

3. Results

Fifty-three patients were recruited, one patient refused to participate, and two patients were disqualified because of coagulation issues. Fifty patients were randomly allocated into two groups (25 patients each) (Figure 1).

Table 1 demonstrates no statistically significant differences between the two groups regarding age, sex, ASA physical status, and length or type of surgery.

We found no statistical differences between both groups in the HR at the baseline and during skin incision. The HR values at 1, 2, and 3 h were significantly higher in the control group. The block group had significantly lower HR compared to their baseline values. We found no major differences in the MAP between both groups at the baseline and during skin incision. The MAP values at 1, 2, and 3 h were significantly higher in the control group. Both the block and control groups had significantly lower MAP compared to their baseline values. The total fentanyl consumption was significantly lower in the TNB group than the control group (Table 2).

Table 3 reveals that the patients who underwent TNB experienced less postoperative pain and had lower NRS than the control group. The block group had significantly lowered NRS values at 6, 12, 18, and 24 h compared to the 30 min values (30 min after emergence from the anaesthesia). All patients in the control group needed nalbuphine in comparison to only seven patients (28%) in the TNB group. The total postoperative nalbuphine consumption was considerably reduced in the TNB group compared to the control group ($P < 0.001$).

Only postoperative headache was significantly lower in the TNB group ($p = 0.047$). Two patients in TNB group had paresthesia, and none of the patients in both groups had respiratory depression with no

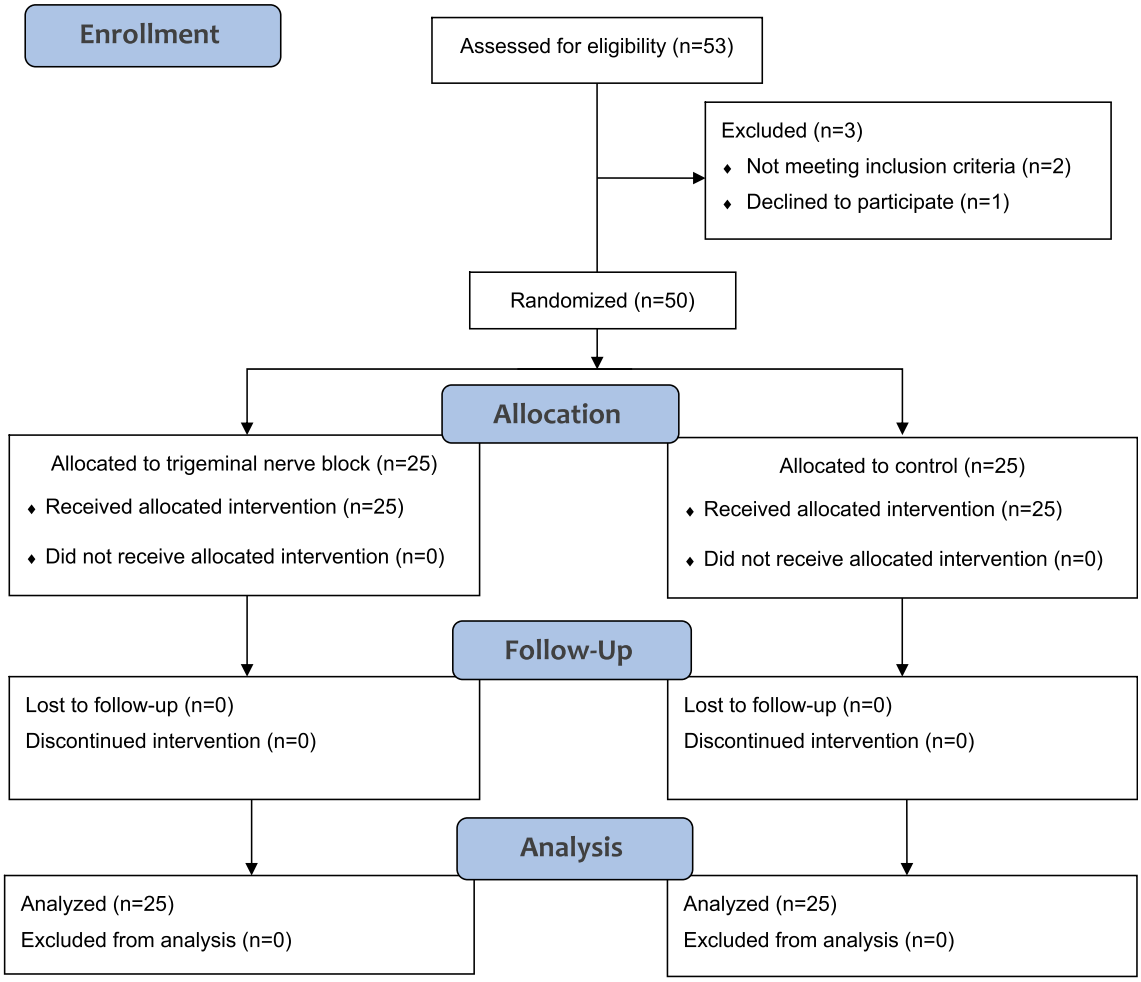

Figure 1. The CONSORT flow diagram of the trial.

Table 1. Demographic and surgical data.

	Control ($n = 25$)	TNB group ($n = 25$)	p-value
Sex, n (%)			
Male	14 (56.0%)	16 (64.0%)	0.564
Female	11 (44.0%)	9 (36.0%)	
Age, Year, Mean ± SD	33.56 ± 10.07	37.28 ± 11.54	0.230
Duration of Surgery, Hour, Mean ± SD	3.25 ± 0.77	2.96 ± 0.69	0.169
Type of Surgery, n (%)			
Maxillary/Mandibular Fracture	23 (92.0%)	24 (96%)	0.342
Mass Excision	2 (8.0%)	1 (4.0%)	
ASA physical status, n (%)			
I	17 (68.0%)	20 (80.0%)	0.324
II	8 (32.0%)	5 (20.0%)	

TNB:trigeminal nerve block; SD: standard deviation; n: numbers; ASA: American Society of Anesthesiologists.

Table 2. Heart rate, mean arterial pressure, and total fentanyl consumption during the intraoperative period.

	Control ($n = 25$)	p_0	TNB group ($n = 25$)	p_0	p-value
Heart rate, Beat/min, Mean ± SD					
Baseline	83.44 ± 9.59		9.76 ± 15.13		0.930
Skin incision	81.32 ± 7.63	1.000	81.56 ± 11.36	0.009*	0.930
1 h	85.88 ± 6.81	0.002*	79.24 ± 9.48	0.003*	0.007*
2 h	87.84 ± 6.38	<0.001*	76.48 ± 5.91	<0.001*	<0.001*
3 h	88.48 ± 10.39	<0.001*	77.38 ± 9.86	<0.001*	<0.001*
Mean arterial pressure, mmHg, Mean ± SD					
Baseline	99.16 ± 10.47		101.1 ± 9.94		0.500
Skin incision	85.28 ± 10.32	<0.001*	85.44 ± 1.72	<0.001*	0.957
1 h	86.12 ± 7.86	<0.001*	74.12 ± 5.83	<0.001*	<0.001*
2 h	89.64 ± 11.17	0.017*	81.28 ± 6.56	<0.001*	0.002*
3 h	90.87 ± 10.80	0.014*	81.76 ± 7.11	<0.001*	0.002*
Total intraoperative fentanyl consumption, μ/kg	2.38 ± 0.62		0.36 ± 0.55		<0.001*

TNB:trigeminal nerve block; SD: standard deviation; n: number; p0: *p* value for post hoc test (Bonferroni) for ANOVA with repeated measures for comparing between baseline and each other measurement within each group; *: significant at $p \leq 0.05$.

Table 3. The Numerical Rating Scale and postoperative nalbuphine consumption.

	Control ($n = 25$)	p_0	TNB group ($n = 25$)	p^0	p-value
Numerical rating scale, Mean ± SD					
30 min	3.80 ± 0.96		2.28 ± 0.61		<0.001*
6 h	4.32 ± 0.85	0.049*	1.64 ± 0.76	0.002*	<0.001*
12 h	3.92 ± 0.76	0.561	1.36 ± 0.57	<0.001*	<0.001*
18 h	3.28 ± 0.61	0.054	1.20 ± 0.41	<0.001*	<0.001*
24 h	2.56 ± 0.71	<0.001*	1.04 ± 0.20	<0.001*	<0.001*
Postoperative nalbuphine, mg					
Number of patients	25 (100.0%)		7 (28.0%)		
Mean ± SD	11.60 ± 4.72		1.92 ± 3.28		<0.001*

TNB:trigeminal nerve block; SD: standard deviation; n: number; p0: *p* value for post hoc test (Dunn's) for Friedman test for comparing between 30 min after emergence from the anaesthesia and each other period; *: significant at $p \leq 0.05$.

statistically significant differences. Significantly more patients in the TNB group reported feeling satisfied than those in the control group ($p < 0.001$) (Table 4).

4. Discussion

Ultrasound-guided trigeminal nerve block has not been widely evaluated in maxillofacial surgery. This approach is proposed to achieve pain control by targeting the Gasserian ganglion through the pterygopalatine fossa. This study aimed to assess the safety and efficacy of USGTNB for pain control in adult patients undergoing elective maxillofacial surgeries. Our main findings were that the USGTNB effectively decreased the intraoperative fentanyl as well as the postoperative analgesic consumptions, and it provided better control of the patient hemodynamics. No significant complications were reported from USGTNB with better patient satisfaction.

In this study, TNB markedly reduced the intraoperative fentanyl consumption, postoperative NRS, and nalbuphine consumption. Similarly, Kumar et al. [16] assessed the efficacy of TNB in adult patients scheduled for elective faciomaxillary surgery and reported comparable results. Abdelghafar et al. [17] found that patients undergoing craniofacial cancer surgery who had pterygopalatine fossa block experienced less postoperative pain and consumed less analgesics compared to those who did not receive the block. A recent, randomized, clinical trial [13] assessed the efficacy of USGTNB in patients undergoing orthognathic surgery. The researchers found that TNB did not lessen the visual analogue score at 2 and 4 h postoperatively, but it did so at 6 and 12 h postoperatively. Also, USGTNB significantly reduced the opioid and nicardipine use compared to general anesthesia alone.

The trigeminal nerve mediates both sensory and motor innervation to the maxillofacial region. It is divided into ophthalmic, maxillary, and mandibular branches. The sensory divisions of these branches travel to their cell bodies in the trigeminal or Gasserian ganglion found at the floor of the middle cranial fossa. From the Gasserian ganglion, the sensory nerve fibers synapse with the trigeminal nuclei in the brainstem [18,19]. Nader et al. [9] demonstrated that infusing just 2 mL of contrast dye into the pterygopalatine fossa under fluoroscopy guidance caused a backward flow of contrast into the middle cranial fossa and enabled the observation of the Gasserian ganglion. They attributed the dye's retrograde spread to the small size of the pterygopalatine fossa and its connection to the middle cerebral fossa via the foramen rotundum. The USGTNB via pterygopalatine fossa was carried out in patients who had facial pain by injecting 4 ml of 0.25% bupivacaine [20]. The long acting anesthetic bupivacaine has been used for many years in nerve block procedures. Recent studies [21,22] have used bupivacaine alone to effectively manage trigeminal nerve pain. Nader and Kendall [23] assessed the effectiveness and safety of USGTNB using bupivacaine in patients with facial pain. Within 10 min of injection, 80% of the patients experienced complete sensory analgesia in one side of the face. In addition, the patients did not show any neurological adverse effects from the block after being observed for 6–12 months.

Regarding hemodynamics, the block was associated with significantly lower HR and MAP at 1, 2, and 3 h intraoperatively. Likewise, Wang et al. [13] and Abdelghafar et al. [17] revealed that the hemodynamic parameters were significantly lower in patients who had trigeminal nerve block compared to those in the control group. Several studies [24–26] documented that hemodynamic stability was achieved by

Table 4. Postoperative complications and patient satisfaction.

Variable	Control ($n = 25$)	TNB group ($n = 25$)	p-value
Nausea/vomiting, n (%)	4 (16.0%)	1 (4.0%)	0.349
Headache, n (%)	9 (36.0%)	3 (12.0%)	0.047*
Paraesthesia, n (%)	0 (0.0%)	2 (8.0%)	0.490
Respiratory depression, n (%)	0 (0.0%)	0 (0.0%)	0.490
Patient satisfaction, Mean ± SD	5.84 ± 0.90	8.04 ± 0.89	<0.001*

TNB:trigeminal nerve block; SD: standard deviation; n: numbers; *: significant at $p \leq 0.05$.

sphenopalatine ganglion block in different surgeries, such as Sino nasal surgery and trans-sphenoidal endoscopic hypophysectomy. The appropriate deep anesthesia that was induced in the sphenopalatine ganglion and its associated nerves might be responsible for the hemodynamic effects of trigeminal nerve block. Through the foramen rotundum, the local anesthetic can diffuse to block the Gasserian ganglia, preventing blood pressure elevation that may result from painful stimulation during the surgery.

In contrast to our results, Kumar et al. [16] discovered no appreciable variations between the block and the control groups regarding HR at all time points. Meanwhile, trigeminal nerve block significantly lowered the MAP during extubation. The discrepancies between our findings and those of Kumar et al. could be attributed to the routine administration of regular top ups of fentanyl (0.5 µg/kg) to all the studied patients hourly. In our trial, extra fentanyl doses were not administered on a regular basis to all participants but only when there was a 20% increase in the HR or MAP.

Concerning postoperative complications, headache was significantly reduced among patients with USGTNB. It could be explained by the fact that the sphenopalatine ganglion is the switching station for the headache pathways. The blockage of this ganglion is a particular method for ending primary headaches [10]. In addition, postoperative nausea and vomiting were more reduced with TNB but without statistically significant differences between the groups. Similarly, Abdelghafar et al. [17] and Kumar et al. [16] noticed lower incidences of postoperative complications in patients who underwent trigeminal nerve block but without significant differences from those in the control group. Meanwhile, Wang et al. [13] reported a significantly greater incidence of vomiting in patients undergoing orthognathic procedures under general anesthesia compared to those with USGTNB. Wang et al. attributed this to the patients' significant opioid use while under merely general anesthesia.

The current study found no discernible difference in paresthesia between both groups. There were no reported problems as bleeding, paresthesia, hematoma, or infection brought on by USGTNB via pterygopalatine fossa [13]. The use of ultrasonographic guiding in regional anesthesia enables the practitioners to prevent puncture problems, reveals the important anatomical landmarks, and demonstrates the local anesthetic's dissemination [27]. In our study, the patients' satisfaction was increased with USGTNB more than with general anesthesia alone. Similarly, earlier studies [13,16] reported comparable findings. Overall, reduction of pain and complications by TNB could increase the patients' satisfaction in maxillofacial surgeries.

5. Limitations

This was a single-center study with limited sample size. Neither a device nor an objective method was applied to gauge the onset of the block. Multicenter studies on larger sample size with accurate detection of the onset of the block would be needed.

6. Conclusion

Ultrasound-guided trigeminal nerve block can effectively and safely be used for the control of pain in adult patients undergoing maxillofacial surgeries.

Disclosure statement

The authors note that they have no conflicting interests.

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