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Original Article

Efficacy of ultrasound guided superior laryngeal nerve block on sedation for delayed extubation in maxillofacial surgery with free flap reconstruction

Xiao-Dong Wang, Yi Zhou†, Zi-Jian Guo, Liang Jiao, Fang Han, Xu-Dong Yang*

Department of Anesthesiology, Peking University School and Hospital of Stomatology, Beijing, PR China

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ABSTRACT

Objective: Superior laryngeal nerve block (SLNB) is a regional anesthesia technique for addressing airway response. However, SLNB on the efficacy of sedation in patients with delayed extubation is unknown, particularly for maxillofacial surgery (MS). The aim of the study was to assess whether ultrasound guided (UG) SLNB reduces the incidence of moderate to severe cough for delayed extubation in MS with free flap reconstruction.

Methods: 60 patients were randomly assigned to the GEA group (control group) and the SLNB group (UG-SLNB postoperatively, study group). During the initial two postoperative hours, the incidence of moderate and severe cough, agitation, and the number of patients requiring rescue propofol and flurbiprofen were recorded. Additionally, the time spent under the target level of sedation, postoperative hemodynamics, and the total does of propofol during the postoperative 24 h were recorded.

Results: The data showed the SLNB group had a significantly lower incidence of moderate to severe cough and agitation ($p < 0.05$), and a longer sedation time ($p < 0.05$). The number of patients required rescue propofol and flurbiprofen, as well as the hemodynamic changes, were significantly different between the two groups ($p < 0.05$).

Conclusion: The use of UG-SLNB is associated with reduced incidence of postoperative cough. Moreover, SLNB can enhance the efficacy of postoperative sedation with need of fewer agents postoperatively.

Clinical Trial Registration: ChiCTR2000039982

1. Introduction

Perforator-based free flaps have been increasingly used in the repair and reconstruction in maxillofacial surgery (MS), which comprised a resection phase and a reconstruction phase. Due to the involvement of the upper airway and some vital structures, delayed nasotracheal extubation is often used [1,2], furthermore, appropriate sedation is needed to maintain the designated position of the head and neck to ensure adequate blood supply to the flap. Nevertheless, violent agitation and sympathetic stimulation are common during the early postoperative period in patients with delayed extubation [3,4]. Uncontrolled stress may lead to serious consequences, such as bleeding and free flap crisis [5,6]. Thus, suitable methods are required for sedation of the patients. Some surveys have reported that opioids and sedatives may be useful during the early postoperative period [7–9]; however, their use may be associated with adverse effects [10,11].

Stress can be inhibited by suppression of the laryngeal reflex, which is predominantly mediated by the internal branch of the superior laryngeal nerve (SLN) [12]. The use of UG-SLNB during laryngeal surgery is associated with reduced cardiovascular responses and less frequent postoperative tachycardia, sore throat, and cough [13]. In recent years, UG-SLNB has also been used for other surgeries and treatments, such as conscious endotracheal intubation and treatment of neurogenic cough [14,15]. However, to our knowledge, it has not been used for MS with free flap reconstruction to maintain sedation in cases of delayed extubation.

In this prospective randomized study, we assessed the efficacy of sedation by UG-SLNB in patients with delayed extubation after MS with free flap reconstruction.

2. Methods

2.1. Study designed and radomization

This single-center, prospective, double-blind, randomized trial was performed between December 2020 and March 2022. The study

* Corresponding authors. Department of Anesthesiology, Peking University School and Hospital of Stomatology, 22# Zhongguancun South Avenue, Beijing 100081, China.
E-mail address: kqyangxudong@163.com (X.-D. Yang).
† Co-first author: Yi Zhou.

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was approved by the Peking University Hospital of Stomatology Ethics Committee (PKUSSIRB-202,056,095) and registered with the Chinese Clinical Trial Registry (ChiCTR2000039982). Written informed consent was obtained from the participants. We included patients aged 18–65 years of both sexes who had an American Society of Anesthesiologists physical status of I or II and underwent overnight endotracheal extubation. We excluded patients with lymph node dissection, uncontrolled hypertension, postoperative cognitive dysfunction, arrhythmia, tracheotomy, and flap crisis surgery.

Random numbers generated using the SAS 8.0 software were used to randomly assign the participants (1:1) to the SLNB group (postoperative UG-SLNB) or GEA group (no UG-SLNB; control group). The participant assignment codes were stored in sealed envelopes. Before the surgery, the envelopes were provided to the anesthesiologist in charge of administering the UG-SLNB by a researcher who was not involved in patient care. Free flap reconstruction was performed by the same surgical team. Patients, surgeons, the attending anesthesiologist, and nurses who conducted the postoperative follow-up were blinded to the group allocation. The anesthesiologist who administered the UG-SLNB was not involved in the postoperative follow-up.

2.2. General anesthesia and UG-SLNB

General anesthesia was induced using midazolam (0.05 mg/kg), 1% propofol (1.5–2.5 mg/kg), sufentanil (0.15–0.2 mg/kg), and rocuronium (0.6 mg/kg) in both groups. To maintain bispectral index values of 40–60, general anesthesia was maintained using a continuous infusion of propofol (2–6 mg/kg/min) and remifentanil (0.1–0.2 μg/kg/min) combined with 1–2% inhalant sevoflurane. In addition, sufentanil (single doses of 5 μg) was administered intermittently when the heart rate or blood pressure exceeded 30% of the baseline value, whereas rocuronium (single doses of 10 mg) was administered when train of four monitoring showed more than two muscle twitches.

Sufentanil (5 μg), tropisetron (5 mg), and dexmedetomidine by continuous infusion of 0.2–0.7 μg/kg/h were administered intravenously 30 min before the end of surgery; meanwhile, both sevoflurane and remifentanil were stopped. The patients received patient-controlled intravenous analgesia (PCIA), which included 1–1.5 μg/kg of sufentanil and 10 mg of tropisetron. The PCIA pump was installed with a background infusion rate of 2 mL/h. The average analgesia time was set as 48 h.

Patients were transferred to the post-anesthesia care unit (PACU) with the endotracheal tube in place when they started breathing spontaneously (train of four > 0.9). In the PACU, dexmedetomidine was administered by continuous infusion of 0.2–0.7 μg/kg/h for sedation. Patients with visual analogue scale (VAS) >3 of flurbiprofen (50 mg) was administered in the PACU. On the morning after the surgery, patients were extubated according to the local extubation protocol, which included assessments of the consciousness, respiration, gag reflex, and swallowing, in the PACU before discharge.

Postoperatively, bilateral UG-SLNB was performed in the PACU. Ultrasound images were obtained using an ultrasound unit (M9; Mindray, Shenzhen, China) and an 8–12-MHz linear array probe. In the BSN group, patients were placed in the supine position. After skin disinfection, the ultrasound probe was covered with a sterile sheath and positioned above the hyoid bone. The probe was moved to the left greater cornu of the hyoid bone. Then, a 22-gage, 50-mm needle (Stimuplex, Braun) was inserted along the medial aspect of the probe using in-plane imaging and advanced from the lateral to medial aspect toward the greater cornu of the hyoid (Fig 1). A total of 2 mL of 0.2% ropivacaine was slowly injected on each side. The spread of each local anesthesia was confirmed by visual inspection.

2.3. Study measurements and outcomes

The postoperative cough (POC), sore throat *(POST)*, and hoarseness *(POH)* were measured by the 4 grade scales (Table 1). All patients with POC grade >1 in the PACU were considered to experience moderate to severe cough. Postoperative sedation was evaluated using the sedation agitation scale (SAS) scores, whereby scores of 1 and 7 correspond to unarousable and dangerous agitation, respectively (Table 2). The target level of sedation was set at a SAS score of 3–5. If the patients exhibited agitation (SAS score > 5) and a rescue bolus of propofol (0.5–1 mg/kg) was given as needed, but the agitation was not eliminated, a continuous infusion of propofol (20 mg/mL) was administered and titrated to reach an SAS of 3. The primary outcome was the incidence of moderate to severe POC during the initial two postoperative hours. The secondary outcomes were the assessment of patients exhibiting agitation (SAS > 5) during the initial two postoperative hours, hemodynamic parameters at five postoperative points time (5, 15, 30, 60, and 120 mins), the duration of the target level of sedation, the total does of rescue propofol and flurbiprofen in PACU, and the adverse events (hemodynamic and other events) during the initial two postoperative hours. The hemodynamic adverse events include hypotension (systolic BP < 90 mm Hg), hypertension (systolic BP > 180 mm Hg), bradycardia (HR < 50/min), and tachycardia (HR > 120/min). The other adverse events included vomiting, headache, respiratory depression, and abnormal bleeding. The

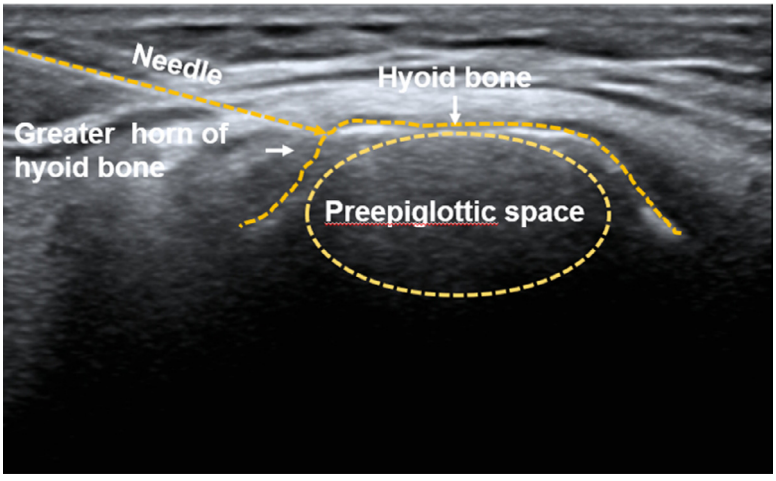

Fig 1. The ultrasound image about the path of injection of ultrasound-guided bilateral superior laryngeal nerve block.

Table 1
Grade of severity of postoperative cough, sore throat and hoarseness of voice.

Grading	Severity of cough	Severity of sore throat	Severity of hoarseness
Grade 0	No cough	No sore throat	None
Grade 1	Light or single cough	Mild sore throat (complains of sore throat only upon inquiry)	Noted by the patient
Grade 2	More than one episode of unsustained (65 s) coughing	Moderate sore throat (complains of sore throat on his/her own)	Obvious to the observer
Grade 3	Sustained (65 s) and repetitive cough with head lift	Severe sore throat (severe pain associated with marked change in voice)	aphonia

Table 2
Sedation Agitation Scale.

Score	Characteristics	Example of Patients' Behavior
1	unarousable	Minimal or no response to noxious stimuli, does not communicate or follow commands
2	Very sedated	Arouses to physical stimuli but does not communicate or follow commands, may move spontaneously
3	sedated	Difficult to arouse, awakens to verbal stimuli or gentle shaking but drifts off again, follows simple commands
4	Calm and cooperative	Calm, awakens easily; follows commands
5	Agitated	Anxious or mildly agitated, attempting to sit up, calms down to verbal instructions
6	Very agitated	Does not calm, despite frequent verbal reminding of limits; requires physical restraints, biting endotracheal tube
7	Dangerously agitated	Pulling at endotracheal tube, trying to remove catheters, climbing over bed rail, striking at staff, thrashing side to side

moderate to severe POH and POST (grades 2 and 3) were recorded at 24 h postoperatively as the other adverse events.

2.4. Statistical analysis

Sample size was calculated based on a previous study. The incidence of moderate to severe POC was 0 in the study group, compared to 45% in the control group. Therefore, in this study 80% power was considered [13]. To detect differences, it was necessary to include 26 patients per group with an α risk of 2.5% and a beta risk of 20% in a two-tailed comparison. The ratio of sample size between the study and control groups was 1:1. We enrolled 30 patients in each group to compensate for about 10% dropouts during the study period.

Statistical analysis was performed using IBM SPSS STATISTICS 25 software (SPSS Inc., Chicago, IL, USA). The values are expressed as mean ± SE, median values (interquartile range), numbers, and percentages. Continuous variables with normal distribution were analyzed using the unpaired *t*-test. Categorical variables were analyzed using the continuity correction χ^2 test or Fisher's exact test. The repetitive measure variables were analyzed using the repetitive measure analysis of variance test.

3. Results

3.1. Subject characteristics

We excluded three patients (two from the GEA group and one from the SLNB group) excluded from the study because of postoperative bleeding and postoperative free flap swelling. Therefore, data from 60 patients were analyzed (Fig 2). The demographic and surgical variables were not significantly different between the groups. The tumor location and supplied free flap were not significantly different between the groups (Table 3). No complications were caused by UG-SLNB. No flap crisis was happened during hospitalization.

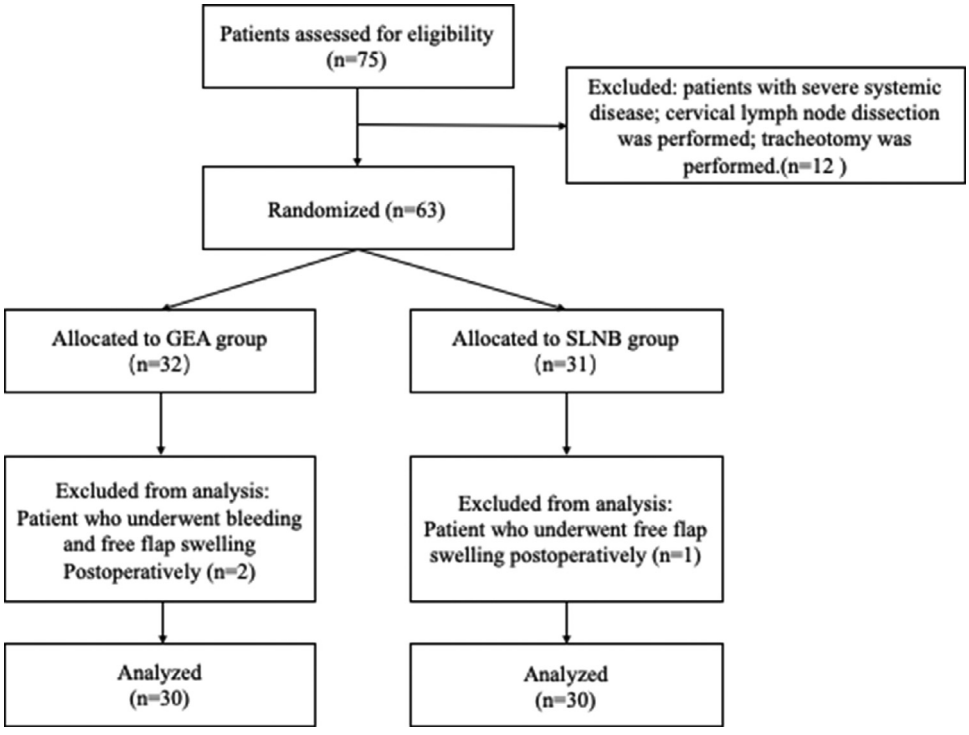

Fig 2. Flow diagram of patients through the trial.

Table 3
Comparison of patient demographics, surgical data and types of free flap.

	GEA Group (n = 30)	SLNB Group (n = 30)	P value
Patient demographics			
Age, years	45.6 ± 13.5	49.6 ± 12.5	0.229
Sex (male/female)	15/15	14/16	0.796
Weight (kg)	63.2 ± 9.8	66.5 ± 14.1	0.301
Height (cm)	166.0 ± 8.9	165.8 ± 6.9	0.949
Surgical data			
Duration of surgery (min)	277.7 ± 89.7	298.3 ± 93.7	0.386
Fluid (ml)	2076.7 ± 305.9	2116.7 ± 395.7	0.663
Total propofol (mg)	1723.3 ± 730.5	1673.3 ± 670.0	0.783
Total sufentanil (μg)	35.3 ± 11.7	32.5 ± 16.1	0.438
Total dexmedetomidine (μg)	308±92.9	228±49.1	0.009
Surgical sites, n (%)			0.655
Maxillary	7(23.3%)	10(33.3%)	
Mandibular	17(56.7%)	18(66.7%)	
Others	6(20.0%)	2(6.7%)	
Flap types, n (%)			0.069
Radial forearm	3(10.0%)	1(3.3%)	
Anterolateral thigh	4(13.3%)	13(43.3%)	
Fibula	11(36.7%)	8(26.7%)	
Others	12(40.0%)	8(26.7%)	
Flap survival during hospitalization	30(100.0%)	30(100.0%)	0.999

Values are shown as means ± SD, numbers of patients (n), and percentages (%).
No significant differences were observed between the two groups. SD = standard difference; GEA = general anesthesia; SLNB = ultrasound-guided bilateral superior laryngeal nerve block.

3.2. Efficacy of sedation

Table 4 presents data regarding the efficacy of sedation. Patients in the SLNB group had a significantly lower incidence of moderate to severe POC than in the GEA group during the initial two postoperative hours (5 [16.7%] vs. 15 [50%], respectively; p = 0.013). The duration of target level of sedation was significantly longer in the SLNB group than in the GEA group (69.6 ± 18.9 min vs 43.6 ± 23.0 min, respectively; p = 0.000). The incidence of agitation was significantly lower in the SLNB group than in the GEA group (3 [10%] vs. 10 [33.3%], respectively; p = 0.028). No patient in either group required a continuous propofol infusion; no significant difference was noted in the total propofol doses between the groups, whereas a significantly lower proportion of patients required rescue propofol bolus in the SLNB group than in the GEA group (2 [6.67%] vs. 10 [33.3%], respectively; p = 0.01). Additionally, the number of patients who required flurbiprofen were significantly less frequent in the SLNB group than in the GEA group (4 [13.3%] vs. 12 [40%], respectively; p = 0.02).

Table 4
Comparison of efficacy of sedation.

	GEA Group (n = 30)	SLNB Group (n = 30)	P value
Patients with moderate to severe POC (n [%])	15[50%]	5[16,7%]	0.013
Percentage of time under target level of sedation	43.6 ± 23.0	69.6 ± 18.9	0.000
Agitation (SAS >5) (n [%])	10[33.3%]	3[10%]	0.028
Patients requiring rescue propofol (n [%])	10[33.3%]	2[6.7%]	0.01
Patients requiring rescue flurbiprofen (n [%])	12[40%]	4[13.3%]	0.02
Total does of propofol	80[52.5,97.5]	50[40,50]	0.145

Values are shown as means ± SD, median (interquartile range), numbers of patients (n), and percentages (%).
GEA = general anesthesia; SLNB = ultrasound-guided bilateral superior laryngeal nerve block; SAS = sedation agitation score.

3.3. Hemodynamic parameters

Compared to the GEA group, the fluctuations of heart rate (HR) and mean arterial pressure (MAP) were less significant in the SLNB group. The HR was significantly lower in the SLNB group than in the GEA group at 30 min postoperatively (72.3 ± 12.0 vs. 80.5 ± 14.6, respectively; p = 0.02) and 1 hour postoperatively (67.6 ± 9.9 vs. 77.3 ± 12.3, respectively; p = 0.001) (Fig 3). The MAP remained stable during the initial two postoperative hours in the SLNB group, although the MAP was statistically higher, compared to the GEA group at postoperative 5, 15, and 30 min. By contrast, the MAP significantly fluctuated in the GEA group and was significantly increased compared to the SLNB group at 30 min postoperatively (Fig 4).

3.4. Adverse effects

Table 5 presents the adverse effects, including hemodynamic changes and the incidence of moderate-to-severe POH and POST. The incidence of bradycardia and hypotension was not significantly different between the two groups (p > 0.05). There was no patient with tachycardia or hypertension in the SLNB group, while three patients had tachycardia and two had hypertension in the GEA group, with no significant statistical difference (p > 0.05). The incidence of moderate-to-severe POSH was significantly lower in the SLNB group than in the GEA group (19 [63.3%] vs. 11 [36.7%], respectively; p = 0.037), while the incidence of moderate-to-severe POH was not significantly different between the groups (10 [33.3%] vs. 8 [26.7%], respectively; p = 0.573).

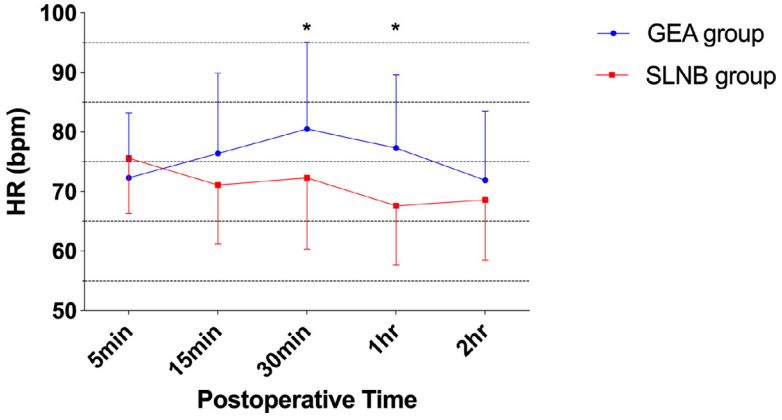

Fig 3. Changes in heart rate in both groups at five measurement points (*P < 0.05 vs GEA Group).

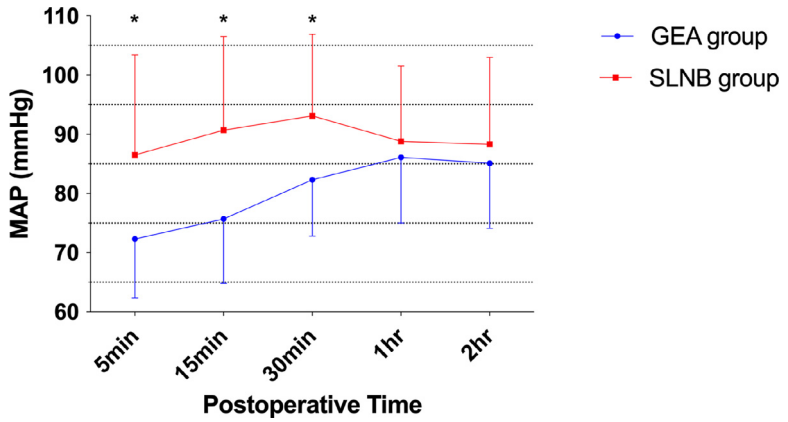

Fig 4. Changes in mean arterial pressure in both groups at five measurement points (*$P < 0.05$ vs GEA Group).

Table 5
Comparison of adverse effect.

	GEA Group ($n = 30$)	SLNB Group ($n = 30$)	P value
Hemodynamic adverse			
Bradycardia (n [%])	1[3.3%]	3[10%]	0.301
Tachycardia (n [%])	3[10%]	0	0.076
Hypotension (n [%])	2[6.7%]	3[10%]	0.640
Hypertension (n [%])	2[6.7%]	0	0.150
Other adverse effects			
POH (n [%])	10[33.3%]	8[26.7%]	0.573
POST (n [%])	19[63.3%]	11[36.7%]	0.037

Values are shown as numbers of patients (n), and percentages (%). GEA = general anesthesia; SLNB = ultrasound-guided bilateral superior laryngeal nerve block; POH = postoperative hoarseness; POST = postoperative sore throat.

4. Discussion

In this prospective, randomized study, despite postoperative continuous infusion of dexmedetomidine for sedation, the incidence of cough was still high in patients with delayed extubation after MS with free flap reconstruction. However, the incidence and severity of cough was reduced, and the efficacy of sedation was enhanced by UG-SLNB.

The mechanical stimulation of larynx can elicit the cough reflex [16]. Therefore, effective suppression of the laryngeal reflex is essential. There are several methods to decrease laryngeal irritation, including topical anesthesia of the laryngotracheal mucosa using lidocaine spray or gel, cricothyroid membrane puncture anesthesia, and use of sedative agents [17–19]. However, these techniques have inconsistent effects [20]. SLNB inhibits the sensory innervation of larynx by blocking the internal branch of the SLN, and it is frequently used as a local nerve block of the upper airway during endoscopic laryngeal surgeries or awake endotracheal intubation [13]. Some studies have suggested that the use of UG-SLNB after general anesthesia resulted in improved recovery, including reduced incidence of postoperative cough, sore throat, and hoarseness of voice [13,21].

We found that UG-SLNB after MS with free flap reconstruction could facilitate the control of cough due to tube retention and the dose of propofol used to achieve sedation, which may be clinical meaningful. Clinically, MS with free flap reconstruction is mostly accompanied by postoperative airway swelling, which necessitates postoperative tube retention [22]. Therefore, postoperative sedation is required to ensure comfortable and quiet state of the patient [5]. In addition, sedation maintains the designated position of the head and neck to ensure adequate blood supply to the flap [23]. Cariati et al. suggested that maintaining the head position is crucial for postoperative flap survival [24]. Furthermore, the Society of Critical Care Medicine guidelines recommend that the use of a “light sedative” after MS is useful because of postoperative early recovery and assessment of neurological, cognitive, and respiratory functions. By contrast, the use of “deep sedation” is not recommended because it is associated with increased length of stay in the hospital, rate of delirium, and prolonged time to extubation [25]. At present, postoperative sedation in MS mainly relies on the use of sedative agents [9]; however, the ideal sedative state requires the control of cough, which is difficult to accomplish with “light sedation”. Our results suggest a strategy for postoperative “light sedation” with suppression of mild to severe cough and reduced postoperative use of drugs.

Stable hemodynamic parameters are associated with improved recovery as well as the survival of the free flap [26,27]. A retrospective study by John et al. demonstrated that postoperative hemodynamic changes, especially tachycardia, after free flap breast reconstruction resulted in free flap failure. It was presumed that postoperative tachycardia could lead to perfusion-related complications, such as delayed wound healing and thrombosis [6]. In the present study, we found that the HR fluctuated significantly in the postoperative period in the GEA group. Furthermore, the number of patients who developed tachycardia was greater in the GEA group than the SLNB group. Although our study was not designed to evaluate the association between postoperative hemodynamic changes and complications, our results suggested that bilateral UG-SLNB leads to effective attenuation of the HR and MAP response in patients with postoperative tube retention, which may be useful for free flap reconstruction in MS.

Several previous studies have found that postoperative sore throat was common after general anesthesia, especially in MS, which may be due to prolonged intubation, pharyngeal packing, and use of stylet for guiding the tube [28,29]. In the present study, the lower incidence of sore throat at 24 h postoperatively in the SLNB group compared to the GEA group may be attributed to the increased tolerance of the laryngeal mucosa to the endotracheal tube and reduced incidence of postoperative cough, which was consistent with the study by Ahmed et al. [30]. The tolerance of the laryngeal mucosa was evidenced from this study by the reduced need of rescue analgesic agents, prolonged postoperative awakening time, and increased incidence of bradycardia. In contrast to previous studies [13], the incidence of hoarseness of voice was not significantly different between the groups, which may be because the patients were followed up at 24 h postoperatively (i.e., after removal of the endotracheal tube) when the effect of the UG-SLNB had worn off.

The present study had some limitations that should be considered when interpreting the results. First, the SLNB was administered in the submandibular region, where the first surgical incision is usually made. This was because of concerns that the pressure from the

ultrasound probe may block the blood supply to the flap. Second, because the duration of surgery was long, SLNB was administered postoperatively, considering the half-life of ropivacaine of 4 h. In future studies, longer-acting local anesthetics should be used so the SLNB can be administered preoperatively. Third, the study included a relatively small number of patients, which may explain the lack of differences in the safety measures between the groups.

5. Conclusions

SLNB can be administered for delayed extubation after MS with free flap reconstruction. Its use is associated with reduced incidence of postoperative cough. Moreover, SLNB can enhance the efficacy of postoperative sedation with need of fewer agents postoperatively. Future studies should evaluate the combination of SLN block and other sedatives for postoperative sedation and analgesia in MS with delayed extubation.

Declaration of Competing Interest

None of the authors have any financial interests in any of the products, devices, or drugs mentioned in this manuscript.

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