

Effect of Preoperative Preconditioning of Patients with External Nasal Compression for Different Time Intervals on Emergence Agitation After Nasal Surgeries: A Randomised Controlled Trial

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ABSTRACT

Introduction: Emergence agitation is a commonly experienced phenomenon in the waking period of general anaesthesia, which can adversely affect the recovery of patients in the postoperative period. Patients undergoing nasal surgeries under general anaesthesia, involving postoperative nasal packing, tend to have a higher rate of emergence agitation after extubation. Non pharmacological methods like nasal clips, can be safe and cost-effective alternatives to pharmacological agents for controlling emergence agitation.

Aim: To evaluate the efficacy of preoperatively applying nasal clips for various durations in patients scheduled for nasal surgeries under general anaesthesia, which require nasal packing in the postoperative period, in reducing emergence agitation after extubation.

Materials and Methods: The present randomised controlled trial was conducted at department of Anaesthesia, Shrimati Bhikhiben Kanjibhai Shah Medical Institute and Research Centre (SBKS MIRC) in Piparia, Vadodara, Gujarat, India. A total of 75 patients with ASA I and II, aged 18-65 years, posted for elective nasal surgeries under general anaesthesia with postoperative bilateral nasal packing, were randomly divided into three groups. Group A (25 patients) wore nasal clips for 30 minutes preoperatively, Group B (25 patients) wore the clip for 40 minutes preoperatively, and Group C (25 patients)

served as the control group without nasal clips. At the time of extubation, the emergence agitation score, ability to cough, time to verbal response, respiratory rate, incidences of desaturation, laryngospasm, or any other complications were observed and noted by an anaesthetist who was unaware of the application of nasal clips preoperatively. All data statistically analysis were performed using Statistical Package for Social Sciences (SPSS) for Windows (version 21.0; IBM Corporation).

Results: All three groups were comparable ($p > 0.05$) in terms of demographic profile, type and duration of surgery, and baseline haemodynamic parameters like Heart Rate (HR), Mean Arterial Pressure (MAP), Oxygen Saturation (SpO_2), and baseline Electrocardiography (ECG). Emergence agitation was significantly lower in Group A and B as compared to Group C (p -value=0.02). On comparing Groups A and B, Group B had a significantly lower incidence of emergence agitation (p -value=0.02). There were two cases of dangerous emergence agitation in the control group and one case in Group A while no cases were reported in Group B. Other parameters at extubation were comparable among all groups. Patient satisfaction was significantly higher in Groups A and B in comparison to Group C.

Conclusion: The present study suggests that preoperative preconditioning with nasal clips for 40 minutes in patients undergoing elective nasal surgeries can be a useful and safe method to reduce postoperative emergence agitation.

Keywords: Emergence delirium, Extubation, General anaesthesia, Recovery period

INTRODUCTION

Emergence agitation is a commonly encountered adverse phenomenon in the waking period of general anaesthesia. It is described as a short-term state of confusion that occurs immediately after arousal from general anaesthesia and lasts for approximately 15-30 minutes. Clinically, patients are perceived as 'waking' from anaesthesia but with disorientation, hallucinations, hypersensitivity to external stimuli, restlessness, and hyperactivity [1]. It can also be described as a passive process with the gradual return of consciousness after discontinuing the administration of anaesthetic and adjuvant agents at the end of the surgical procedure [2]. It is very satisfactory for an anaesthetist and the patient if this process of emergence from anaesthesia is smooth and pleasant. Unfortunately, it can be associated with undesirable complications like vigorous coughing, haemodynamic changes, and even mental status changes in the form of cognitive impairment [3]. It has been reported that the incidence of emergence agitation at the time of recovery from general anaesthesia is approximately 19 percent in adult patients [3].

While its pathogenesis remains unclear, a higher incidence has been seen in Ear, Nose, Throat (ENT) surgeries, possibly due to a sense of suffocation during emergence from anaesthesia when intranasal packing is used postoperatively [2,3]. This may have adverse outcomes in the form of nasal sinus bleed, self-removal of catheters (drains, urinary catheter, Ryle's tube, etc.), sudden increase in heart rate and blood pressure (which may precipitate myocardial ischaemia, cerebrovascular bleed), self-extubation (dangerous in difficult airway patients), aspiration of collected blood in the nasopharynx, and even negative pressure pulmonary edema (if the patient tries to forcibly inspire through a closed nasal airway). To control this, additional use of medications or physical restraints may be necessary [3-5]. Nasal packing used after nasal surgery causes a significant increase in airflow resistance, leading to acute breathing difficulty in patients who predominantly breathe through their noses. Patients who are acclimatised to mouth breathing due to chronic nasal blockage caused by nasal pathologies like rhinosinuitis, nasal septum deviation, nasal polyps, and inferior turbinate hypertrophy,

may experience less discomfort and emergence due to nasal blockage caused by nasal packing [6].

This observation led the authors to use a non pharmacological method in the form of nasal clips in the preoperative period to reduce postoperative emergence. The application of nasal clips simulates nasal obstruction and helps patients acclimatise to mouth breathing in the preoperative and postoperative periods [7]. Good empathetic patient counselling, along with this technique, helps alleviate anxiety and apprehension in patients about surgery and anaesthesia. Nasal surgeries involve airway sharing between the surgeon and anaesthetist and are usually contaminated with blood, which requires awake extubation to maintain intact reflexes and prevent aspiration. However, this may intensify emergence agitation [2,8]. Various studies have been conducted in adults to decrease emergence agitation using pharmacological agents like dexmedetomidine, opioids, inhalational agents, propofol, remifentanyl, etc. [3,4]. However, there are very few studies using non pharmacological methods to reduce emergence agitation in such cases [1,7].

In the present study, patients were preconditioned with external nasal compression using nasal clips (commonly used in swimming) to induce acute nasal obstruction in the preoperative period for variable durations to reduce the incidence of postoperative emergence agitation.

MATERIALS AND METHODS

The present randomised controlled study was conducted at Department of Anaesthesia, Shrimati Bhikhiben Kanjibhai Shah Medical Institute and Research Centre (SBKS MIRC) in Piparia, Vadodara, Gujarat, India. The trial protocol was registered in Clinical Trials Registry India (CTRI) (CTRI/2021/12/038512) and approved by the Institutional Ethical Committee (SVIEC/ON/MEDI/RP/21033). The study was conducted over a period of six months from December 2021 to August 2022, and written informed consent was obtained from all participants. Additional consent was obtained from one patient for photography of the application of the nasal clip, ensuring confidentiality and anonymity. The study aimed to evaluate patients undergoing various nasal surgeries, including rhinoplasty, septoplasty, septorhinoplasty, turbinoplasty, and functional endoscopic sinus surgery, under general anaesthesia with bilateral nasal packing in the postoperative period.

Sample size calculation: The sample size was calculated using Process Automation Software System (PASS) 15 (NVSS-National Vital Statistics System). Based on a pilot study and previous research [7], twenty patients per group showed to detect a 40 percent decrease in the incidence of emergence agitation, with a significance level of 0.05 and 80 percent power.

Inclusion criteria: To account for potential dropouts (patient refusal or surgery cancellation for any reason), 25 patients were included in each group.

Therefore, a total of 75 patients with ASA I and II, aged 18-65 years, posted for elective nasal surgeries under general anaesthesia with postoperative bilateral nasal packing (done by Otolaryngorhinology surgeons after nasal surgery), were randomly allocated into three groups (n=25 in each group) using a computer-generated method.

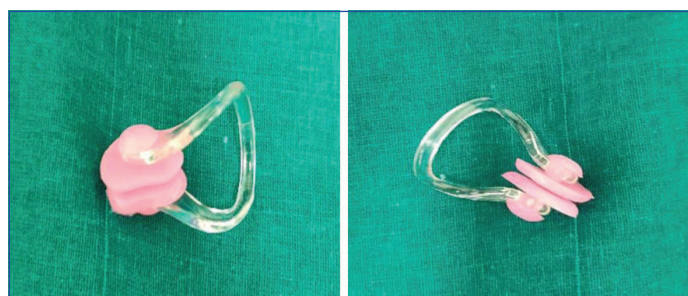
Exclusion criteria: Patients below 18 years or above 65 years, those refusing to participate, those with ASA III or higher, hepatic, renal, cardiac, or respiratory co-morbidities, bleeding disorders or coagulopathies, a history of smoking, Body Mass Index (BMI) ≥ 30 kg/m², or a history of snoring and obstructive sleep apnea were excluded from the study. Patients in whom laryngoscopy and intubation duration was prolonged (>3 minutes), multiple attempts were required, or trauma was caused to the airway were also excluded.

Study Procedure

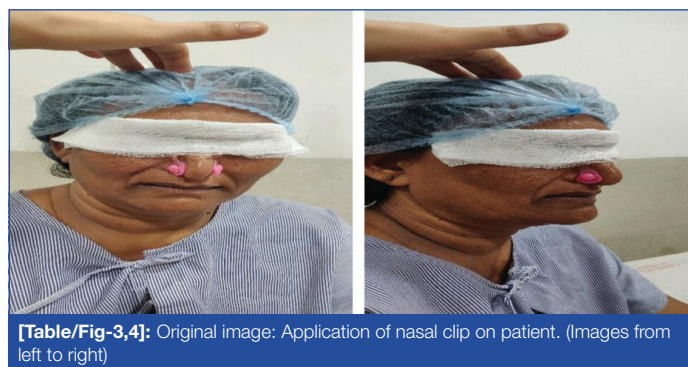
Patients who met the inclusion criteria were divided into the following groups:

- Group A (25 patients): Nasal compression for 30 minutes before induction of anaesthesia.
- Group B (25 patients): Nasal compression for 40 minutes before induction of anaesthesia.
- Group C (25 patients): No nasal compression before induction of anaesthesia.

A preanaesthetic checkup was done on the day of surgery, and baseline haemodynamic parameters were noted. After obtaining written informed consent and providing proper counselling, the patient's nose was closed with a plastic nasal clip commonly used for swimming [Table/Fig-1-4]. All patients were instructed to breathe through their mouth and were observed by an anaesthesiologist in the recovery room who did not participate in data collection.



[Table/Fig-1,2]: Original image: Nasal clip used in swimming. (Images from left to right)



[Table/Fig-3,4]: Original image: Application of nasal clip on patient. (Images from left to right)

In the operating theatre, multipara monitors were applied, and baseline respiratory rate, pulse rate, Non Invasive Blood Pressure (NIBP), Oxygen Saturation (SpO₂), and Electrocardiography (ECG) were recorded. An intravenous line was secured using an 18 G intravenous cannula, and intravenous fluids were started. Anaesthesia was administered by an expert anaesthesiologist who did not participate in data collection. Patients were premedicated with intravenous injection of glycopyrrolate 0.004 mg/kg and midazolam 0.025 mg/kg. General anaesthesia was induced with Injection nalbuphine (0.1 mg/kg) and propofol (2.0-2.5 mg/kg), and tracheal intubation was facilitated with injection succinylcholine (2 mg/kg). The endotracheal tube was fixed after confirming bilateral equal air entry by auscultation and capnography. Oropharyngeal packing was performed and then surgical positioning was given. Bilateral air entry equality was reconfirmed after positioning.

Anaesthesia was maintained with a mixture of oxygen and nitrous oxide (50:50), isoflurane (1-1.5%), and an intravenous infusion of Injection Atracurium with a loading dose of 0.5 mg/kg followed by a maintenance dose of 0.1 mg/kg/hr. Volume-controlled mode was used with ventilatory settings of a tidal volume of 6-8 mL/kg and a respiratory rate of 12-14/min to maintain an End-Tidal Carbon Dioxide (ETCO₂) level between 30-35 mmHg. All patients received Injection ondansetron 4 mg and injection paracetamol one gram intravenously approximately 15 minutes before the end of surgery. Standard monitoring, including electrocardiography, Non Invasive Blood Pressure (NIBP), Oxygen Saturation (SpO₂), and capnometry, was maintained throughout the procedure. Towards the end of the surgery, isoflurane was tapered and infusion of injection atracurium

was stopped. The oropharyngeal pack was removed, and oral suction was carried out. After confirming spontaneous efforts of the patient, muscle relaxant reversal was done with injection neostigmine 50 micrograms/kg and injection glycopyrrolate 10 micrograms/kg intravenously.

Following these steps, inhalational agents were turned-off (defined as 'time 0' in the emergence process) [7] and switched to 100% oxygen. At this time, patients were not disturbed but were asked to open their eyes through continual verbal orders. Other types of stimulation were prevented. Extubation was performed when patients exhibited adequate spontaneous tidal volume and were able to respond to verbal orders. Emergence was observed from 'time 0' until the patient's discharge from the operation theatre to the Post Anaesthesia Care Unit (PACU). Agitation level during emergence period was evaluated using the Riker Sedation-Agitation Scale (RSAS), off [Table/Fig-5] [7,9] and the maximum agitation score for each patient was recorded. If the score was 5 or higher, incremental doses of 0.5-1 mg midazolam were administered until the patient became calm (score of 4 or less), and the total dose of midazolam was recorded. The ability to cough during emergence was assessed using a four-point numerical scale [10]:

0=no cough.

1=single cough.

2=persistent cough lasting less than 5 seconds.

3=persistent cough lasting ≥ 5 seconds or bucking.

Duration from 'time 0' to first verbal response and extubation was recorded.

Score	Category description
7	Dangerous agitation: Pulling-off the tracheal tube, trying to remove catheters, climbing over bedrail, or striking the staff
6	Very agitated: Requiring restrain and frequent verbal reminding of limits
5	Agitated: Anxious or mildly agitated, attempting to sit up and calms down on verbal instructions
4	Calm, co-operative: Calm and follows commands
3	Sedated: Difficult to arouse but awakens to verbal stimuli or gentle shaking but drifts off again; follows simple commands
2	Very sedated: Arouse to physical stimuli but does not communicate or follow commands; may move spontaneously
1	Unarousable: Minimal or no response to noxious stimuli; does not communicate or follow commands

[Table/Fig-5]: Riker sedation-agitation scale [7,9].

Emergence agitation (according to the RSAS) was assessed at extubation and then every five minutes for the first 15 minutes, and then every 15 minutes thereafter until discharge from the PACU. In severe cases of emergence agitation, physical restraint and intermittent doses of 1 milligram of midazolam were given based on the decision of the attending anaesthesiologist.

Twenty-four hours after surgery, patient satisfaction with recovery was assessed using a four-point numerical rating scale [7].

3=very satisfied.

2=satisfied.

1=neutral.

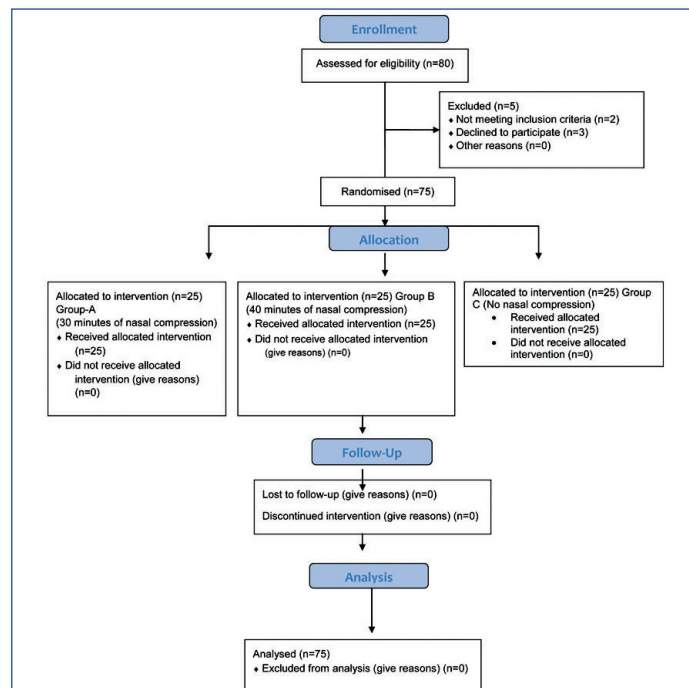
0=unsatisfied.

The primary outcome of the present study was the reduction in emergence agitation after extubation, defined as an RSAS score of at least five immediately after extubation. The secondary outcomes were the need for rescue sedatives and the occurrence of immediate postoperative complications such as desaturation ($SpO_2 \leq 90\%$), laryngospasm, and postoperative nausea and vomiting.

STATISTICAL ANALYSIS

Continuous parametric data were presented as mean \pm SD, and categorical data were presented as the number of patients. Analysis

of Variance (ANOVA) was used to compare the three groups for quantitative parametric data. The Kruskal-Wallis test was used for the analysis of quantitative non parametric data. The Chi-square (χ^2) test was used to compare qualitative data. Continuous parametric data were presented as mean \pm SD, non parametric data as median (interquartile range), and categorical data were presented as the number of patients. The p-values less than 0.05 were considered significant, and p-values <0.001 were considered highly significant. All data manipulations and statistical analysis were performed using SPSS for Windows (version 21.0; IBM Corporation). The Consolidated Standards of Reporting Trials (CONSORT) diagram given [Table/Fig-6].



[Table/Fig-6]: CONSORT flow diagram.

RESULTS

Out of the 80 patients initially selected for the study, two patients had a Body Mass Index (BMI) greater than 30 kg/m², and three patients declined to participate, so they were excluded from the study. Therefore, a total of 75 patients participated in the study, and all were able to complete the study without any dropouts [Table/Fig-6]. All three groups were comparable ($p>0.05$) in terms of demographic profile, type and duration of surgery, and baseline haemodynamic parameters like HR, MAP, SpO_2 and baseline ECG [Table/Fig-7], Mean Arterial Pressure (MAP), Oxygen Saturation (SpO_2), and baseline Electrocardiogram (ECG) findings [Table/Fig-7].

Variables	Group A (30 min)	Group B (40 min)	Group C (control)	p-value
Age (years)	28.6 \pm 3.2	29.2 \pm 2.4	28.7 \pm 3.5	0.761
BMI (kg/m ²)	24.6 \pm 3.6	24.5 \pm 2.8	25.2 \pm 2.1	0.654
Gender (M/F)	11/14	13/12	14/11	0.688
Duration of surgery (minutes)	74.65 \pm 7.4	75.3 \pm 2.3	74.72 \pm 7.7	0.862
Baseline Mean Arterial Pressure (MAP) (mmHg)	87.44 \pm 4.41	87.28 \pm 4.38	86.88 \pm 2.71	0.87
Baseline Heart Rate (HR) (beats per minute)	86.36 \pm 4.40	85.84 \pm 4.69	86.68 \pm 2.80	0.76
Oxygen saturation (SpO_2) (%)	99 \pm 1.04	99.12 \pm 0.92	99.24 \pm 0.77	0.65
Electrocardiogram (ECG) (Rate (beats per minute) and rhythm)	86.36 \pm 4.40 Sinus rhythm	85.84 \pm 4.69 Sinus rhythm	86.68 \pm 2.80 Sinus rhythm	0.76

[Table/Fig-7]: Patients characteristics and baseline parameters (mean \pm SD). Analysis of variance was used as statistical test. $p<0.05^*$ statistically significant

The time to verbal response, time to extubation, respiratory rate at extubation, and grade of cough were comparable ($p>0.05$) among all groups [Table/Fig-8]. There was one case of desaturation in Group A (nasal compression for 30 minutes) for a short duration after extubation, which was treated and resolved by administering 100% oxygen for a few minutes. Group C (control group) had one case of laryngospasm due to persistent trickling bleeding from the nasopharynx after extubation, which was resolved by proper oxygenation, suctioning, and nebulisation.

Variables	Group A (30 min)	Group B (40 min)	Group C (control)	p-value
Time to verbal response from time 0 (minutes)	6.15±1.8	6.14±2.0	6.15±1.7	0.476
Time to extubation from time 0 (minutes)	7.36 ±1.5	7.41±1.3	7.37 ±1.4	0.564
Respiratory rate at extubation (breaths per minute)	18.12±1.3	17.91±2.5	17.98±2.7	0.816
Grade of coughing during emergence (mean value)	1.3	1.2	1.3	0.789
Desaturation (no. of patients)	1	0	0	0.353
Laryngospasm (no. of patients)	0	0	1	0.353

[Table/Fig-8]: Criteria on recovery (mean±SD).

Analysis of variance and χ^2 -test was used as statistical tests. $p<0.05^*$ statistically significant

During and after extubation, patients were considered agitated if their Riker Sedation Score (RSS) was ≥ 5 . Agitation was considered dangerous if the RSS was seven. Emergence agitation was noted at extubation and then every five minutes for the first 15 minutes, and then every 15 minutes thereafter until discharge from the Post Anaesthesia Care Unit (PACU). The emergence agitation score was significantly lower in Group B (40 minutes of nasal compression) throughout the period of extubation until 30 minutes in the PACU. After 30 minutes, the emergence agitation score was comparable in all groups [Table/Fig-9].

Time interval	Group A (30 minutes)	Group B (40 minutes)	Group C (control)	p-value
At extubation	4.16±1.67	4.08±0.6	5±1.19	0.01
5 min	4.08±1.60	3.92±0.4	4.96±1.17	0.0049
10 min	3.96±1.45	3.88±0.33	4.92±1.11	0.0014
15 min	3.88±1.36	3.88±0.33	4.8±1	0.0015
30 min	3.56±1.08	3.88±0.33	4.36±0.75	0.0024
45 min	4	4	4	NS
1 h	4	4	4	NS
1 h 15 min	4	4	4	NS
1 h 30 min	4	4	4	NS

[Table/Fig-9]: Emergence agitation score (mean±SD).

Analysis of variance (ANOVA) was used as statistical tests. $p<0.05^*$ statistically significant

The overall incidence of emergence agitation was significantly lower in Group B ($p=0.02$) compared to the other groups. When comparing Group A and B, Group B had a significantly lower incidence of emergence agitation. There were two cases of dangerous emergence agitation in the control group and one case in Group A, while no cases were observed in Group B. Patient satisfaction was significantly higher in Group A and B compared to Group C ($p=0.02$). The consumption of midazolam was significantly lower in Group B ($p=0.005$) [Table/Fig-10].

Variables	Group A (30 min)	Group B (40 min)	Group C (control)	p-value
Emergence agitation (no. of patients with RSAS ≥ 5)	10	4	18	0.02
Dangerous emergence agitation (no. of patients with RSAS=7)	1	0	2	
Midazolam consumption (mg)	1.4±0.9	0	2.3±1.3	0.005
Patient satisfaction score (mean)	1.5	3.1	1	0.02

[Table/Fig-10]: Emergence agitation and patient satisfaction.

Kruskal-Wallis test and Analysis of variance (ANOVA) was used as statistical tests. $p<0.05^*$ statistically significant

DISCUSSION

Emergence agitation is a postanesthetic phenomenon that occurs during the early phase of general anaesthesia recovery. It is characterised by agitation, confusion, disorientation, and possible violent behaviour [1]. This phenomenon not only poses risks to surgical outcomes and increases the rate of postoperative complications but also leads to a traumatic experience for the patient and decreases patient satisfaction after surgery [3].

Kim HJ et al., conducted a retrospective study to identify factors affecting the incidence of emergence agitation [2]. They found that young age, recent smoking, sevoflurane inhalational anaesthesia, moderate to severe postoperative pain, presence of a tracheal tube, presence of a urinary catheter, and nasal packing in the postoperative period were associated with approximately a 5-fold increase in the incidence of emergence agitation in patients recovering from general anaesthesia. In some cases, severe agitation may require the administration of sedatives or the use of physical restraints. When a patient is recovering from anaesthesia, they are in a light plane of anaesthesia and are partially awake or disoriented/dissociated. In this state, the presence of an endotracheal tube and nasal pack can be significant causes of emergence agitation [2,11].

In the present study, a non pharmacological method in the form of nasal clips was used to precondition patients with nasal obstruction and simulate the postoperative condition of bilateral nasal packing after nasal surgery. Patients who met the inclusion criteria and provided consent were either made to wear nasal clips for 30 minutes or 40 minutes before anaesthesia induction, and their emergence agitation was compared to a control group without nasal compression. All patients were then assessed for recovery parameters like time to verbal response, time to extubation, and grade of coughing [10]. Emergence agitation was evaluated using the Riker sedation scale [7,9], and any complications like desaturation and laryngospasm were noted. The demographic profile, baseline haemodynamics, and recovery parameters were comparable among all groups [Table/Fig-7,8]. Emergence agitation was significantly reduced in Group B (40 minutes of nasal compression), leading to better patient satisfaction [Table/Fig-9].

Kasem A and Abdelkader A conducted a similar study using external nasal compression with nasal clips to reduce the incidence of emergence agitation. They provided nasal compression for 10 minutes and 30 minutes preoperatively and compared it to a control group without nasal compression [7]. They concluded that there was a significant decrease in the incidence of emergence agitation in the group where nasal clips were applied for 30 minutes preoperatively.

Researchers like Kim SY et al., and Polat R et al., have studied the use of dexmedetomidine infusion to reduce emergence after nasal surgeries [4,5]. Kim SY et al., concluded that there was reduced emergence and improved quality of recovery after nasal surgery under general anaesthesia with intraoperative dexmedetomidine infusion. Meanwhile, Polat R et al., compared dexmedetomidine and remifentanyl infusion to reduce emergence agitation during recovery after nasal surgery and found that both drugs provided a smoother and haemodynamically stable emergence compared to the control group. However, remifentanyl was superior to dexmedetomidine in decreasing the incidence of emergence agitation to 3.3% compared to 20% and 46.5% with the dexmedetomidine group and control group, respectively [5].

Another significant cause of emergence agitation is sevoflurane inhalational anaesthesia [12-15]. Although it provides excellent haemodynamic stability, rapid induction and emergence from general anaesthesia, it is associated with a higher incidence of emergence agitation due to its rapid washout from the circulation

owing to its low blood solubility [12]. Ke JJ et al., observed in their study that emergence agitation after nasal surgery under general anaesthesia can be significantly reduced by using total intravenous anaesthesia rather than inhalational anaesthesia [16].

In the present study, patients underwent general anaesthesia induction with intravenous induction agents and were maintained with isoflurane, which has a higher blood gas coefficient than sevoflurane (sevoflurane=0.65; isoflurane=1.4), causing slower recovery and less emergence [15]. Although in the present study, emergence agitation was significantly reduced in both groups with nasal compression, it was found that nasal compression for a duration of 40 minutes was the optimum duration as it was more effective than 30 minutes and patients were comfortable wearing nasal clips for this duration. It is possible that patients may feel uncomfortable if they were made to wear nasal clips for a longer duration than 40 minutes. Further studies may be required to confirm the optimum duration of nasal compression preoperatively that could help patients acclimate comfortably to mouth breathing postoperatively. Moreover, the effectiveness of nasal compression should also be compared with various pharmacological adjuvants to reduce emergence agitation. Nasal clips may not completely replace a pharmacological agent for reducing emergence delirium, but if combined, they may help reduce the required dose of medication.

Limitation(s)

It was not possible to clearly document and quantify subjective or objective preoperative nasal obstruction in all patients. Additionally, the impact of different nasal packing types and materials on postoperative breathing difficulties could not be evaluated. The present study was performed in ASA I and II patients, and further studies need to be done to evaluate the role and benefits of nasal compression in high-risk patients.

CONCLUSION(S)

Preconditioning patients to breathe orally preoperatively for 40 minutes in elective nasal surgeries with the help of nasal clips can be an easily available, cost-effective, and safe method to reduce emergence agitation after nasal surgery with postoperative nasal packing. It not only reduces the complication rate requirement of sedatives or restraints but also improves patient and doctor satisfaction after surgery.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Feb 28, 2023
- Manual Googling: May 09, 2023
- iThenticate Software: Jun 22, 2023 (12%)

ETYMOLOGY: Author Origin

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