

# Comparison of respiratory events following proseal laryngeal mask airway removal in children undergoing total intravenous anesthesia with propofol and sevoflurane: A randomized parallel group trial

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Respiratory events are a frequent occurrence in pediatric anesthesia, and despite advancements in pediatric anesthesia, they remain a leading cause of perioperative morbidity and mortality.<sup>[1,2]</sup> Commonly encountered respiratory adverse events (RAEs) include bronchospasm, laryngospasm, persistent coughing, oxygen desaturation, airway obstruction, and stridor.<sup>[3]</sup>

The use of a laryngeal mask airway (LMA) results in less laryngeal stimulation and therefore a lower incidence of RAEs as compared to endotracheal intubation.<sup>[4,5]</sup> Airway events during and after LMA removal depend upon the type of anesthesia and surgical procedure, plane of anesthesia at time of device removal, and a positive preoperative respiratory history.<sup>[6-8]</sup> The reported incidence of RAEs after LMA removal in literature is variable, and it is unclear whether the choice of anesthesia affects the incidence of RAEs during emergence from general anesthesia (GA). Several studies in

## Abstract

**Objectives:** This study aims to compare the incidence of respiratory adverse events following removal of ProSeal laryngeal mask airway (PLMA) after total intravenous anesthesia (TIVA) with propofol and inhalational anesthesia with sevoflurane in healthy children undergoing lower limb, lower abdominal, or genitourinary surgery under general anesthesia with caudal analgesia.

**Patients and methods:** This randomized, parallel-group, double-blind trial was conducted with children with American Society of Anesthesiologists physical status Class I or II between August 01, 2023, and September 30, 2024. Children were randomly allocated to the TP group (TIVA with propofol) to receive induction and maintenance with total intravenous anesthesia with propofol or the IS group (inhalation with sevoflurane) to receive induction and maintenance of anesthesia with sevoflurane. The primary outcome was the incidence of any respiratory event (coughing, biting of device/teeth clenching, oxygen desaturation, breath holding, laryngospasm, bronchospasm, or upper airway obstruction) during emergence from anesthesia and PLMA removal. Secondary outcomes were prevalence of individual respiratory events, airway hyperreactivity scores, emergence times, incidence of emergence agitation, duration of postanesthesia care unit stay, postoperative nausea and vomiting, hemodynamic parameters, and peripheral oxygen saturation during emergence.

**Results:** A total of 86 children (70 males, 16 females; mean age:  $4.265 \pm 2.23$  years; range, 6 months to 7 years) were enrolled in the study, with 43 in both groups. A respiratory event occurred in 15 patients in the IS group (34.8%) and four patients in the TP group (9.30%;  $p=0.004$ ). There was no difference in the occurrence of individual events. Airway hyperreactivity scores were higher in the IS group ( $p=0.032$ ). Emergence time was quicker and emergence agitation and excessive salivation were more common in the IS group. Time to postanesthesia care unit discharge, postoperative nausea and vomiting and, hemodynamic parameters before and after PLMA removal were comparable.

**Conclusion:** The incidence and severity of adverse respiratory events during emergence from anesthesia was more frequent in the sevoflurane group.

**Keywords:** Pediatric anesthesia, propofol, respiratory adverse effects, sevoflurane.

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children have evaluated anesthesia techniques to minimize RAEs in children with underlying upper respiratory tract infection (URTI); however, there are limited studies in healthy children undergoing elective surgery.

Propofol and sevoflurane are commonly used for induction and maintenance of anesthesia in children. Propofol is a profound bronchodilator and found to be superior to sevoflurane in suppressing laryngeal reflex responses.<sup>[9]</sup> Its rapid recovery profile and minimal accumulation, even after prolonged infusions, make it highly effective for the induction and maintenance of GA. Total intravenous anesthesia (TIVA) with propofol results in reduced postoperative nausea and vomiting (PONV), a lower incidence of emergence delirium, and minimized environmental pollution. Sevoflurane anesthesia has the advantages of a mild, nonirritating odor for induction, rapid onset and recovery, and a favorable cardiovascular profile.<sup>[10]</sup>

Some earlier studies suggest that intravenous induction with propofol provides protection against respiratory complications; however, it is associated with prolonged emergence times.<sup>[7,11-13]</sup> Inhalational induction may be necessary in younger and uncooperative patients and those with needle phobia or difficult intravenous access. Thus, while the choice of anesthesia induction depends on certain patient factors, the anesthesiologist can select the method of anesthesia maintenance. It appears logical to assume that RAEs at induction will depend on the induction technique, whereas RAEs at emergence will depend more on the technique of maintenance of anesthesia. This study aimed to compare the incidence of RAEs following removal of a ProSeal LMA (PLMA; Teleflex Medical, Morrisville, NC, USA) after TIVA with propofol and inhalational anesthesia with sevoflurane in healthy children undergoing lower limb, lower abdominal, or genitourinary surgery under GA with caudal analgesia. The hypothesis of our study was that the incidence of RAEs during emergence and after PLMA removal would be lower in children receiving TIVA with propofol compared to children receiving inhalational anesthesia with sevoflurane for the maintenance of anesthesia.

## PATIENTS AND METHODS

This randomized, parallel-group, double-blind trial was conducted with children with American

Society of Anesthesiologists (ASA) physical status Class I or II who underwent elective lower limb, lower abdominal, and genitourinary surgeries, with an anticipated duration <120 min, under GA. The study was conducted at Maulana Azad Medical College, Department of Anesthesiology between August 1, 2023, and September 30, 2024. We excluded patients having active or recent (<2 weeks) URTI, cardiac or respiratory disease, obesity, obstructive sleep apnea, nasal obstruction, tonsillar or adenoid hypertrophy, neurological disorders, conditions predisposing to pulmonary aspiration such as hiatus hernia or intestinal obstruction, anticipated difficult airway, and children requiring endotracheal intubation. Written informed consent was obtained from the parents/legal guardians of all patients participating in the trial. The study protocol was approved by the Maulana Azad Medical College and Associated Hospitals, Ethics Committee (Date: 15.05.2023, No: F.1/IEC/MAMC/MD/MS/96/02/2023/98). The trial was prospectively registered under the Clinical Trials Registry of India (CTRI/2023/07/055369) on July 19, 2023. The trial adhered to the principles of the Declaration of Helsinki. This manuscript adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized controlled trials.

Patients were randomly allocated in a 1:1 ratio to one of the two study groups: the TP group (TIVA with propofol) and the IS group (Inhalation with sevoflurane). Sequence generation was done by a computer-generated random number table and allocation into groups by opening a sealed opaque envelope immediately before surgery. Patients or their caregivers were asked to pick an envelope on the day of the surgery by the investigator.

The primary outcome was the incidence of any respiratory event (coughing, biting of PLMA/teeth clenching, oxygen desaturation, breath holding, laryngospasm, bronchospasm, and upper airway obstruction) during emergence from anesthesia and removal of the PLMA. The secondary outcomes were the prevalence of individual respiratory events, airway hyperreactivity scores, emergence times, emergence agitation scores, incidence of emergence delirium, duration of postanesthesia care unit (PACU) stay, PONV, and hemodynamic parameters [systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate (HR)],

and peripheral oxygen saturation (SpO<sub>2</sub>) during emergence.

The research investigation team member collecting data at the end of surgery was not involved in the conduct of anesthesia and was blinded to the patient's group allocation. The propofol infusion pump and screen showing end-tidal sevoflurane values were concealed. Additionally, patients and their caregivers were blinded to the group allocation.

A thorough preanesthetic check-up, including detailed history and physical examination, was done, and appropriate investigations were ordered. Patients were kept fasting as per ASA guidelines and received premedication with oral midazolam 0.5 mg/kg 30 min before surgery. Eutectic mixture of local anesthetic cream was applied on the dorsum of both hands 2 h before the anticipated start of surgery, and an intravenous cannula was secured with the child in the parent's lap before shifting to the operation room.

In the operation room, standard monitors, including pulse oximeter, electrocardiography and noninvasive blood pressure, were attached and continuously monitored. Baseline values of noninvasive blood pressure, SpO<sub>2</sub>, and HR were noted. Monitoring of bispectral index (BIS) was also instituted.

In the TP group, GA was induced with intravenous fentanyl 2 mcg/kg, followed by propofol infusion using a target-controlled infusion pump (Agilia SP TIVA; Fresenius Kabi, Bad Homburg, Germany) with the Paedfusor pharmacokinetic model with initial plasma target set at 4 to 6 mcg/mL. In the IS group, GA was induced with intravenous fentanyl 2 mcg/kg, followed by inhalation of 6 L of oxygen and sevoflurane. Patients in both groups then received intravenous vecuronium for muscle relaxation, after which a PLMA was inserted. No more than two attempts at PLMA insertion were allowed. The number of insertion attempts were recorded. Patients were put on mechanical ventilation using pressure control mode. Ventilatory parameters were adjusted to achieve normocapnia. All children in both the groups were then placed in the lateral position and given caudal analgesia with 0.75 mL/kg of 0.25% bupivacaine.

In the TP group, GA was maintained with TIVA using a target-controlled infusion pump (Agilia SP TIVA) with the Paedfusor pharmacokinetic model to maintain BIS values between 40 and 60. In the IS group, GA was maintained with 2 to 4% sevoflurane titrated to maintain BIS between 40 and 60 throughout surgery. During surgery, if there was a rise in the HR or blood pressure of  $\geq 20\%$ , the child was given 0.5 mcg/kg fentanyl after ensuring an adequate BIS value. Patients in both groups received dexamethasone 0.15 mg/kg and ondansetron 0.1 mg/kg for prevention of PONV.

Towards the end of the surgery, propofol and sevoflurane were discontinued, and neuromuscular blockade was reversed. In both groups, the PLMA was removed after gentle oropharyngeal suctioning once patients were judged to be fully awake. The following criteria were achieved before PLMA removal: end-tidal sevoflurane  $< 0.2\%$  in the IS group, spontaneous tidal volume  $> 5$  mL/kg, age-appropriate respiratory rate without breath holding, SpO<sub>2</sub>  $> 95\%$ , facial grimace, eye opening and conjugate gaze, and purposeful movements.<sup>[14]</sup>

We noted the occurrence of any RAE during and after PLMA removal. These included coughing, PLMA biting or teeth clenching, oxygen desaturation (SaO<sub>2</sub>  $< 95\%$ ), breath holding (apnea  $> 5$  sec), laryngospasm (defined as respiratory efforts without airflow despite jaw thrust and chin lift and requiring assisted positive pressure ventilation), bronchospasm or any upper airway obstruction (requiring jaw thrust and chin lift). A child was considered positive for airway adverse events if any one of the above events occurred.

We calculated an airway hyperreactivity score for each patient. The airway hyperreactivity score was used to quantify the severity of airway reactivity during emergence from anesthesia. It was based on three parameters: coughing or bucking, breath-holding, and oxygen desaturation. Each parameter was graded on a scale from 0 to 4 depending on severity. Coughing and bucking was scored as 0 if there was none, 1 if occasional, 2 if frequent, 3 if continuous, and 4 if there was laryngospasm. Breath-holding was scored as 0 if there was none, 1 for breath holding for  $< 15$  sec, 2 for breath holding for 15 to 30 sec, 3 if breath

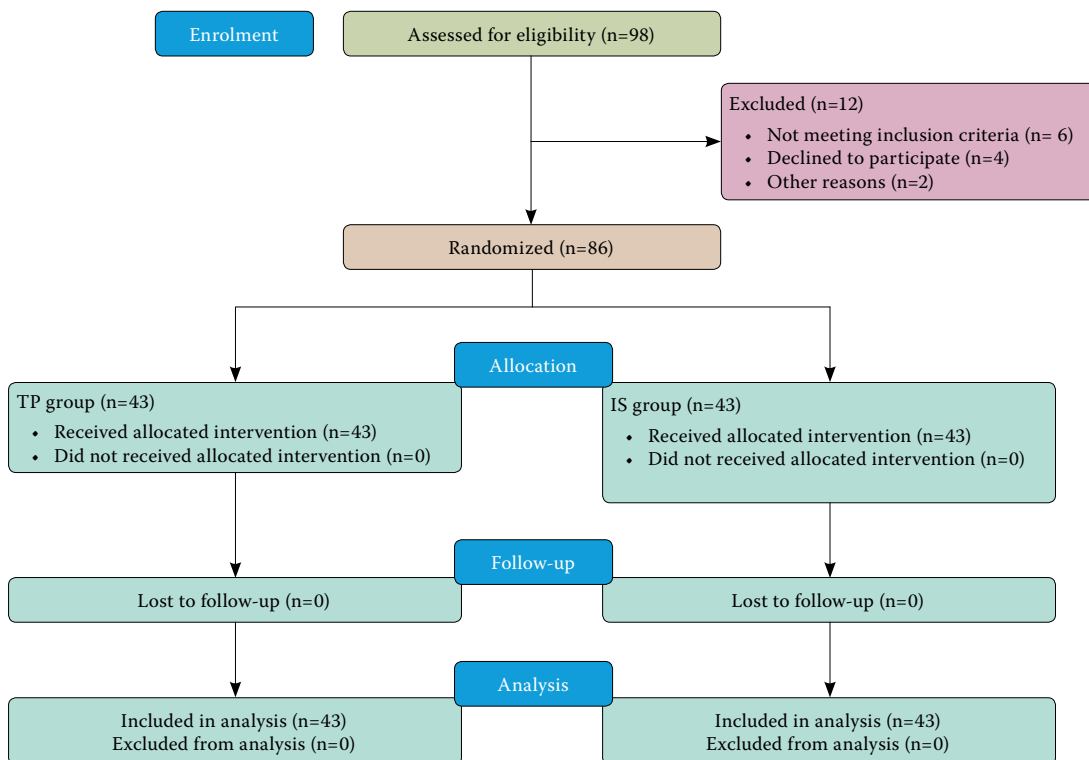
holding for >30 sec, and 4 if positive pressure ventilation was required. Oxygen desaturation was scored as 0 if there were normal oxygen levels with  $\text{SpO}_2 \geq 98\%$ , 1 if the  $\text{SpO}_2$  was 94 to 97%, 2 if the  $\text{SpO}_2$  was 90 to 94% >10 sec, 3 if the  $\text{SpO}_2$  was <90% for >10 sec, and 4 if the  $\text{SpO}_2$  was <85% for >10 sec. The total score was the sum of these components, and a value of 0 indicated no airway hyperreactivity, 1–3 mild, 4–8 moderate, and 9–12 severe hyperreactivity.<sup>[5]</sup>

Emergence time was calculated as time from discontinuation of propofol or sevoflurane until PLMA removal. Emergence agitation was graded using a 4-point agitation scale<sup>[15]</sup> as follows: (i) calm; (ii) not calm but easily consolable; (iii) not easily calmed, restless, or moderately agitated; (iv) combative, disoriented, or excited. For statistical purposes, Grades 1 and 2 were considered nonproblematic behavior, and Grades 3 or 4 were considered delirium. The observed delirium was not treated with any drug.

The duration of PACU stay was assessed as time taken to achieve a modified Aldrete

score  $\geq 9$ .<sup>[16]</sup> This score evaluated five parameters: activity, respiration, circulation, consciousness, and oxygen saturation, each scored from 0 to 2. For activity, a score of 2 was given if the patient was able to move all four extremities, 1 if the patient was able to move two extremities, and 0 if the patient was unable to move. For respiration, normal deep breathing and coughing was scored as 2, dyspnea or shallow breathing as 1, and apnea as 0. For circulation, blood pressure within 20% of preanesthesia level was given a score of 2, within 20 to 49% a score of 1, and a variation >50% a score of 0. For consciousness, 2 was given if the patient was fully awake, 1 for a patient who was arousable on calling, and 0 for an unresponsive patient. For oxygen saturation, maintaining  $\text{SpO}_2 > 92\%$  on room air was scored as 2, requiring supplemental oxygen to keep  $\text{SpO}_2 > 90\%$  as 1, and oxygen saturation <90% even with oxygen as 0.

We also recorded the blood pressure, HR, and  $\text{SpO}_2$  before and after PLMA removal, excessive salivation, retching, vomiting, and the number of attempts at PLMA insertion.



**Figure 1.** The CONSORT flowchart of subject enrolment.

TP: TIVA with propofol; IS: Inhalation with sevoflurane.

### Statistical analysis

In a previous similar study, the percentage of children with at least one RAE was 10.8% in the TIVA group and 36.2% in the sevoflurane group.<sup>[13]</sup> Taking these values as reference, the sample size was calculated as 43 per group, with a 95% confidence level and 80% power, using G\*Power version 3.1 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany).

Statistical analysis was performed using IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Normality of distribution of each variable was assessed by the Kolmogorov-Smirnov test. Quantitative data were expressed as mean  $\pm$  standard deviation (SD) or median (min-max) with interquartile range. Difference between two groups was tested by Student's t-test or Mann-Whitney U test. Qualitative data was expressed in percentage and difference between the proportions was tested by

the chi-square test or Fisher exact test. The level of statistical significance was set at  $p < 0.05$ .

### RESULTS

Ninety-eight patients were assessed for eligibility. Six patients did not meet inclusion criteria, four refused to participate, and two were at risk for aspiration. Therefore, 86 patients (70 males, 16 females; mean age:  $4.265 \pm 2.23$  years; range, 6 months to 7 years) were enrolled for the trial and randomly divided between the TP group and the IS group, each having 43 patients. No patient was lost to follow-up. The CONSORT flowchart of subject enrollment is shown in Figure 1.

The two groups were comparable with respect to demographic parameters, type of surgical procedures, and duration of anesthesia and surgery. The PLMA was placed successfully in a single attempt in all children in both groups. Thirty-three

**TABLE 1**  
Demographic data in both study groups

| Variables                            | TP group (n=43) |                    | IS group (n=43) |                    | p     |
|--------------------------------------|-----------------|--------------------|-----------------|--------------------|-------|
|                                      | n               | Mean $\pm$ SD      | n               | Mean $\pm$ SD      |       |
| Age (year)                           |                 | 4.07 $\pm$ 2.30    |                 | 4.46 $\pm$ 2.16    | 0.414 |
| Sex                                  |                 |                    |                 |                    | 0.579 |
| Male                                 | 34              |                    | 36              |                    |       |
| Female                               | 9               |                    | 7               |                    |       |
| Weight (kg)                          |                 | 17.14 $\pm$ 6.52   |                 | 17.10 $\pm$ 5.78   | 0.978 |
| Height (cm)                          |                 | 102.27 $\pm$ 20.17 |                 | 103.76 $\pm$ 18.23 | 0.721 |
| ASA Class                            |                 |                    |                 |                    | 0.501 |
| I                                    | 39              |                    | 37              |                    |       |
| II                                   | 4               |                    | 6               |                    |       |
| Type of surgery                      |                 |                    |                 |                    | 0.519 |
| Lower abdominal                      | 20              |                    | 25              |                    |       |
| Genitourinary                        | 21              |                    | 17              |                    |       |
| Lower limb                           | 2               |                    | 1               |                    |       |
| Duration of surgery (min)            |                 | 91.14 $\pm$ 25.56  |                 | 86.21 $\pm$ 21.90  | 0.340 |
| Duration of anesthesia (min)         |                 | 109.88 $\pm$ 26.19 |                 | 106.21 $\pm$ 21.82 | 0.482 |
| Number of attempts at PLMA insertion |                 |                    |                 |                    | -     |
| 1                                    | 43              |                    | 43              |                    |       |
| More than 1                          | 0               |                    | 0               |                    |       |
| Passive smokers                      |                 |                    |                 |                    | 0.183 |
| Yes                                  | 20              |                    | 13              |                    |       |
| No                                   | 23              |                    | 30              |                    |       |

TP: TIVA with propofol; IS: Inhalation with sevoflurane; SD: Standard deviation; ASA: American Society of Anesthesiologists; PLMA: ProSeal laryngeal mask airway.



**TABLE 2**  
Incidence of respiratory events

|   | TP group (n=43) | IS group (n=43) |          |
|---|-----------------|-----------------|----------|
| Respiratory event                           | n               | n               | <i>p</i> |
| Occurrence of any 1 event                   | 4               | 15              | 0.004    |
| Cough                                       | 1               | 4               | 0.167    |
| LMA biting                                  | 0               | 2               | 0.152    |
| Teeth clenching                             | 0               | 0               | -        |
| Oxygen desaturation (SpO <sub>2</sub> <95%) | 0               | 0               | -        |
| Breath holding                              | 1               | 5               | 0.090    |
| Laryngospasm                                | 0               | 0               | -        |
| Bronchospasm                                | 0               | 0               | -        |
| Upper airway obstruction                    | 2               | 4               | 0.397    |

TP: TIVA with propofol; IS: Inhalation with sevoflurane; LMA: Laryngeal mask airway; SpO<sub>2</sub>: Peripheral oxygen saturation.

out of 86 children were exposed to passive smoking. However, the number of children exposed to passive smoking was comparable in both groups (Table 1).

A RAE occurred in 15 patients in the IS group (34.8%) and in four patients in the TP group (9.30%;  $p=0.004$ ). In each patient only one of the adverse effects occurred (Table 2). When individual RAEs were compared, we found no difference in the occurrence of each individual event in the two groups (Table 2). Airway hyperreactivity scores were higher in the IS group compared to the TP group ( $p=0.032$ ). However, both groups had only mild hyperreactivity.

The emergence time was quicker in the IS group compared to the TP group ( $p<0.001$ ). The distribution of emergence agitation scores, the median (interquartile range) of emergence agitation scores, and the incidence of emergence delirium was higher in the IS group ( $p=0.001$ ,  $p=0.003$ , and  $p=0.0296$ , respectively). The incidence of excessive salivation was higher in the IS group compared to the TP group ( $p=0.026$ ), whereas the incidence of PONV and time taken to achieve a modified Aldrete score  $>9$  was comparable ( $p=0.314$  and  $p=0.546$ , respectively; Table 3).

Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, and SpO<sub>2</sub> were comparable in both groups at baseline and before and after PLMA removal (Table 4).

## DISCUSSION

Inhalational anesthesia with sevoflurane, intravenous anesthesia with propofol, and a combination of inhalational and intravenous anesthesia are the commonly used anesthesia regimens in pediatric patients. Both sevoflurane and propofol are effective bronchodilators. Animal studies have shown that propofol can attenuate bronchoconstriction induced by airway manipulation by inhibition of 5-HT (5-hydroxytryptamine) receptor activity on bronchial smooth muscle cells and suppression of ATP (adenosine triphosphate)-induced constriction.<sup>[17]</sup> As a result, propofol seems to have an advantage over sevoflurane in reducing laryngospasm, coughing, hypoxemia, and respiratory obstruction. Sevoflurane also protects against adverse RAEs by reducing activity of the parasympathetic nervous system and inhibiting voltage-gated calcium, potassium, and chloride ion channels in the bronchial smooth muscles.<sup>[17]</sup>

We found that the incidence of RAEs during emergence from anesthesia and PLMA removal was significantly higher in the IS group (34.8%) compared to the TP group (9.3%). Individual respiratory events encountered included breath holding in six patients (one in TP and five in the IS group), upper airway obstruction in six patients (two in TP and four in the IS group), cough in five patients (one in TP and four in the IS group) and biting on the PLMA in two patients

(both in the IS group). However, the incidence of these individual events was comparable in both groups. Excessive salivation was more common in the IS group. The airway hyperreactivity scores were mild in both groups but were higher in the IS group. While emergence was more rapid in the IS group, emergence agitation was higher. The duration of PACU stay, PONV, and hemodynamic parameters before and after PLMA removal were comparable in both groups.

It has been found that risk factors for perioperative RAEs in children include age and lung disease of prematurity, inflammatory airway conditions, atopic disease, passive smoking, disordered sleep breathing, and obesity; surgery related risks such as the approach, duration, and location of surgery and anesthesia related factors such as provider experience, anxiolytic premedication, and use of bronchodilators.<sup>[18]</sup> In our study, 33 out of 86 children had exposure to passive smoking. However, the number of children exposed to passive smoking were comparable in both groups.

With the introduction of agents such as propofol, short-acting opioids, midazolam, and dexmedetomidine, the overwhelming advantages of TIVA are emerging, and it is likely that the use of TIVA will supersede the use of inhalational anesthesia. If the incidence of respiratory complications at emergence is also reduced, this will be an additional advantage. Thus, we compared two groups of healthy children undergoing elective lower abdominal, lower limb, or genitourinary surgery under GA with TIVA with propofol (the TP group) or inhalation anesthesia with sevoflurane (the IS group). We administered caudal analgesia to all children to ensure that they emerged pain-free from anesthesia to negate any contribution of pain to the characteristics of emergence from anesthesia in terms of respiratory complications, hemodynamic responses, and emergence agitation. As per institutional protocol, all children received premedication with oral midazolam. The effect of midazolam premedication on the incidence of RAEs in high-risk children remains uncertain. As our study was conducted on healthy children with only one risk factor (passive smoking) in some of them, midazolam premedication was not considered

TABLE 3

## Other secondary outcomes

|   | TP group (n=43) |      |            |        |     | IS group (n=43) |       |            |        |     | p      |
|---|-----------------|------|------------|--------|-----|-----------------|-------|------------|--------|-----|--------|
|   | n               | %    | Mean±SD    | Median | IQR | n               | %     | Mean±SD    | Median | IQR |        |
| Airway hyperreactivity score                            |                 |      |            |        | 0-0 |                 |       |            | 0      | 1-0 | 0.032  |
| Emergence time (min)                                    |                 |      | 14.46±3.48 |        |     |                 |       | 10.90±1.84 |        |     | 0.000  |
| Emergence agitation scores                              |                 |      |            |        |     |                 |       |            |        |     | 0.001  |
| Calm  | 36              |      |            | 22     |     |                 |       |            |        |     |        |
| Not calm but easily consolable                          | 6               |      |            | 13     |     |                 |       |            |        |     |        |
| Not easily calmed restless or moderately agitated       | 1               |      |            | 8      |     |                 |       |            |        |     |        |
| Combative, disoriented, or excited                      | 0               |      |            | 0      |     |                 |       |            |        |     |        |
| Emergence agitation scores                              |                 |      |            | 1      | 1-1 |                 |       |            | 1      | 2-1 | 0.003  |
| Incidence of emergence delirium                         | 1               | 2.32 |            |        |     | 8               | 18.60 |            |        |     | 0.0296 |
| Salivation  | 1               |      |            |        |     | 7               |       |            |        |     | 0.026  |
| Vomiting  | 0               |      |            |        |     | 0               |       |            |        |     | -      |
| Time taken to achieve a Modified Aldrete score >9 (min) |                 |      | 13.41±3.52 |        |     |                 |       | 12.93±3.92 |        |     | 0.546  |

SD: Standard deviation; IQR: Interquartile range.

**TABLE 4**  
Hemodynamic parameters during emergence from anesthesia

|   | TP group (n=43) | IS group (n=43) |          |
|---|-----------------|-----------------|----------|
| Variables   | Mean±SD         | Mean±SD         | <i>p</i> |
| Baseline values   |                 |                 |          |
| Heart rate (bpm)  | 97.23±13.86     | 100.67±13.33    | 0.244    |
| SBP (mmHg)  | 101.65±12.67    | 102.16±11.20    | 0.843    |
| DBP (mmHg)  | 60.53±13.46     | 61.27±11.30     | 0.782    |
| MAP (mmHg)  | 71.79±9.7       | 73.79±13.11     | 0.425    |
| SpO <sub>2</sub>  | 99.93±0.25      | 99.90±0.294     | 0.697    |
| Pre PLMA removal  |                 |                 |          |
| Heart rate (bpm)  | 89.16±13.26     | 90.16±9.76      | 0.692    |
| SBP (mmHg)  | 101.65±11.33    | 101.20±10.82    | 0.854    |
| DBP (mmHg)  | 60.25±14.16     | 61.44±10.98     | 0.665    |
| MAP (mmHg)  | 61.44±10.98     | 73.79±12.53     | 0.102    |
| SpO <sub>2</sub>  | 100±0.00        | 100±0.00        | -        |
| Post PLMA removal   |                 |                 |          |
| Heart rate (bpm)  | 100.14±14.57    | 103.83±11.58    | 0.196    |
| SBP (mmHg)  | 108.95±10.67    | 112.20±9.21     | 0.134    |
| DBP (mmHg)  | 65.62±15.20     | 67.02±10.44     | 0.621    |
| MAP (mmHg)  | 74.69±11.14     | 77.76±14.15     | 0.267    |
| SpO <sub>2</sub>  | 99.88±0.39      | 99.88±0.39      | 1.00     |
| TP: TIVA with propofol; IS: Inhalation with sevoflurane; SD: Standard deviation; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; MAP: Mean arterial pressure; SpO <sub>2</sub> : Peripheral oxygen saturation. |                 |                 |          |

a confounding factor, as it was administered to children in both groups.

Previous studies have reported an incidence of pediatric RAEs of 18% to about 35%.<sup>[2,6,8,19]</sup> Ramgolan et al.<sup>[7]</sup> compared respiratory complications after induction in 300 children of ages eight months to eight years with at least two risk factors for developing perioperative RAEs who received inhalational or intravenous anesthesia. They reported a significantly higher incidence of perioperative RAEs in children receiving induction with sevoflurane compared to propofol (43% and 26%, respectively). However, they did not study events at emergence. Our findings were consistent with the results of a study by Karam et al.<sup>[13]</sup> in 136 children of ages six months to seven years undergoing minor surgeries of less than 2 h duration with the airway secured with an LMA. The incidence of perioperative RAEs in their study was higher in the sevoflurane group

(36%) compared to the propofol group (10.8%). We encountered a respiratory event in 15 (35%) children in the IS group and in four (9.3%) children in the TP group. The RAEs encountered in our study were breath holding, upper airway obstruction, cough, and LMA biting. No patient in either group had bronchospasm, laryngospasm, or oxygen desaturation. Although the overall incidence of respiratory events was higher in the IS group, the incidence of individual respiratory events was similar in both groups. In every child, only a single respiratory event occurred, which was managed promptly and did not deteriorate into further events. In our study, sevoflurane and propofol were discontinued well in time, and the PLMA was removed only after achieving predefined criteria for awake extubation. Upper airway obstruction was the most common RAE, which was managed easily by chin lift and jaw thrust. Breath holding was also observed but did not lead to oxygen desaturation



in any child. Cough was observed in five children, but this was probably because LMA removal was done only once the child was fully awake. In this situation, perhaps cough should be considered an adverse effect only when it is prolonged, when it impairs respiratory functionality, or when it disturbs the patient's comfort. A short but effective cough can help expel respiratory secretions and may indicate an appropriate level of respiratory recovery. Additionally, LMA biting/teeth clenching is not unexpected if the anesthesiologist waits to remove the LMA only once the child is fully awake.

An earlier study on children under seven years of age with URTI undergoing emergency surgery under TIVA (with propofol) or sevoflurane anesthesia found significant differences between the groups during LMA removal in terms of oxygen desaturation, cyanosis, laryngospasm, and bronchospasm and after LMA removal in terms of stridor, cyanosis, use of accessory respiratory muscles, persistent cough, and breath holding, with all respiratory events being more common in the sevoflurane group.<sup>[20]</sup> In another study, maintenance with sevoflurane was not associated with an increased incidence of perioperative bronchospasm compared to propofol (2% *vs.* 1%) but there was a higher incidence of laryngospasm (4% *vs.* 2%).<sup>[6]</sup> On comparing TIVA with propofol plus remifentanyl and sevoflurane anesthesia in children of ages 1 to 3 years undergoing fiberoptic bronchoscopy, less coughing was observed in the TIVA group during emergence (24% *vs.* 92%).<sup>[21]</sup> Comparing propofol and sevoflurane anesthesia for children undergoing cleft palate repair, a significant decrease in the number of patients developing postoperative laryngeal spasm was found in the propofol group.<sup>[12]</sup> As already discussed, in a study similar to our study, Karam et al.<sup>[13]</sup> observed that children receiving TIVA with propofol had lower incidences of cough, laryngospasm, oxygen desaturation, and excessive salivation compared to the sevoflurane group. The results of our study support the findings of these previous studies and suggest that the use of propofol for maintenance of anesthesia appears to impart some protection for development of respiratory complications at emergence.

Although the hyperreactivity scores were significantly lower in the propofol group, we

observed only mild airway hyperreactivity scores across both the groups, with no patient exhibiting moderate or severe airway hyperreactivity scores. Karam et al.<sup>[13]</sup> also reported lower airway hyperreactivity scores in the propofol group compared to the sevoflurane group; however, they encountered some cases of moderate to severe hyperreactivity. This difference may be due to our more stringent criteria for LMA removal.

We found that emergence times were longer in the TP group. Similar findings have been reported earlier.<sup>[12,22,23]</sup> Emergence agitation was higher in the IS group, and this is also supported by several previous studies.<sup>[12,13,22-25]</sup> Duration of PACU stay, as assessed by time to achieve modified Aldrete score of 9 or more, was found to be similar in both the groups, and this too is in line with several earlier studies.<sup>[11,13,22,25]</sup> Similar to other investigations there was no significant difference in blood pressure and SpO<sub>2</sub> in both groups during emergence and LMA removal.<sup>[13,22]</sup>

Our study shows that use of TIVA with propofol reduced the incidence of adverse respiratory effects during emergence and PLMA removal in healthy children undergoing elective infraumbilical procedures under GA with caudal analgesia. Further studies are needed in children undergoing other types of surgical procedures with use of an LMA.

This study had some limitations. Although blinding was secured by an independent observing anesthesiologist for the collection of our primary outcome, investigator bias cannot be ruled out for secondary outcomes. The sample size may not have been adequate to assess the significance of the secondary outcomes. Only children undergoing infraumbilical surgeries were evaluated in the study. Midazolam was administered to all children and might have modified the results, as midazolam might alter respiratory reflex responses to an unknown extent. However, premedication with midazolam in children was the institutional protocol. We adjusted propofol and sevoflurane at doses to achieve a BIS value rather than comparing fixed dosing regimens commonly used in clinical practice.

In conclusion, the overall incidence of RAEs, airway hyperreactivity scores, emergence agitation, and excessive salivation during emergence from anesthesia and PLMA removal

were significantly lower in the TP group. The RAEs encountered in this study were upper airway obstruction, breath-holding, cough, and LMA biting, and there was no difference in the incidence of these individual respiratory events in both groups. Postoperative nausea and vomiting, time taken to achieve a modified Aldrete score >9, and hemodynamic parameters during emergence were also similar in both the groups. Only emergence times were longer in the TP group. Our results indicate that propofol is protective against respiratory complications during emergence from anesthesia and PLMA removal in healthy children undergoing elective lower limb, lower abdominal, or genitourinary surgery under GA with caudal analgesia.

**Data Sharing Statement:** The data that support the findings of this study are available from the corresponding author upon reasonable request.

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