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Safety of removal of ProSeal laryngeal mask airway in children in the supine versus lateral position in a deep plane of anesthesia: A randomized controlled trial

Shweta Dhiman[1] | Anju R. Bhalotra[1] | Kavita R. Sharma[2]

[1]Department of Anaesthesiology and Intensive Care, Maulana Azad Medical College and Associated Hospitals, New Delhi, India
[2]Department of Anaesthesiology, Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi, India

Correspondence
Shweta Dhiman, Department of Anaesthesiology and Intensive Care, Maulana Azad Medical College and Associated Hospitals, New Delhi 110002, India.
Email: shwetadhimankapoor@gmail.com

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ABSTRACT

Importance: When a ProSeal laryngeal mask airway (PLMA) is removed with the child in a deep plane of anesthesia, the upper airway muscle tone and protective upper airway reflexes may be obtunded.

Objective: To determine whether the supine or lateral position is safer for the removal of a PLMA in deeply anesthetized children by comparing the incidence of upper airway complications.

Methods: This randomized single-blind comparative trial was conducted at a tertiary care hospital between January 2020 and September 2020. Forty children of the American Society of Anesthesiologists class I/II of ages 1–12 years age undergoing surgery under general anesthesia with PLMA used as the definitive airway device were recruited. Patients were randomly allocated to lateral group or supine group for PLMA removal in a deep plane of anesthesia in the lateral or supine position. The primary outcome was the number of patients experiencing one or more upper airway complications and the secondary outcomes were incidence of individual respiratory adverse effects and of severe airway complications.

Results: The incidence of airway complications was 30% in the supine group and 20% in the lateral group ($P = 0.6641$). Incidence of laryngospasm, immediate stridor, and excessive secretions were similar. Early stridor and oxygen desaturation were higher in the supine group ($P = 0.0374$, $P = 0.0183$ respectively).

Interpretation: The overall incidence of upper airway complications was similar with the removal of a PLMA in the supine or lateral position in deeply anesthetized children. The incidence of oxygen desaturation and stridor were higher with PLMA removal in the supine as compared to the lateral position.

KEYWORDS

Airway management, General anesthesia, Laryngeal masks, Pediatrics

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INTRODUCTION

The use of supraglottic airway devices has several advantages over endotracheal intubation and is being increasingly used in all patient populations. The use of the laryngeal mask airway (LMA) in children has been found to be very safe and efficacious in various studies.[1–4] In adult patients the ProSeal LMA (PLMA) is almost always removed once the patient is awake and protective airway reflexes have returned. However, children behave differently than adults. Children may not respond to verbal commands and it becomes difficult sometimes to ascertain whether they are fully awake or still lightly anesthetized. Also, they do not tolerate an LMA in lighter planes of anesthesia. In children, LMA removal with the patient still deeply anesthetized state may be beneficial in some conditions, such as asthma, in which case it may decrease the occurrence of airway complications such as coughing, biting, hypersalivation, and oxygen desaturation. A study by Lee et al.[5] reported that the optimal minimum alveolar concentration of sevoflurane that allows LMA removal without coughing, moving, or airway-related complications is 1.84% end-tidal sevoflurane concentration in 50% of anesthetized children and the 95% effective dose for successful removal was 2.17% (95% confidence limits, 2.02%–3.48%). However, a major concern is that the protective laryngeal reflexes remain attenuated in the deep plane of anesthesia and this may lead to upper airway obstruction,[6] and as the airway is unprotected, trickling of secretions may result in adverse airway-related events during recovery. This may be more of a problem if the child is in the supine position. In the lateral position, the effect of gravity helps to direct any secretions away from the larynx, and hence it may be safer to remove the LMA in the lateral position. A recent meta-analysis has discussed LMA removal in deep versus awake children but there is very scanty literature on the best position for LMA removal in deeply anesthetized children.[6] We thus conducted this study to assess the safety of removing a PLMA in children in the supine versus lateral position in a deep plane of anesthesia in terms of the incidence of upper airway complications after removal. We hypothesized that removing the LMA in the lateral position in deeply anesthetized children would result in a lower incidence of airway complications as compared to removal in the supine position.

METHODS

Ethical approval

Ethical approval for this study was provided by the Institutional Ethics Committee, Maulana Azad Medical College and Associated Hospitals, New Delhi, India (Chairperson Dr. M.K. Daga) on October 25, 2019 (approval number; ECR/329/inst/DL/2013/RR-2019). The trial was prospectively registered under the Clinical Trials Registry of India (CTRI/2019/12/022241) on December 3, 2019. The trial adheres to the principles of the Declaration of Helsinki. Written and informed consent was obtained from the parents/legal guardians of all patients participating in the trial. Children older than 7 years provided additional verbal assent. This manuscript adheres to the Consolidated Standards of Reporting Trials (CONSORT) guidelines for randomized controlled trials.

Trial design and participants

This was a randomized parallel-group single-blind comparative trial. Children of ages 1–12 years of American Society of Anesthesiologists (ASA) physical status grade I/II undergoing elective lower abdominal or lower limb surgery of anticipated duration of 30–120 min requiring general anesthesia with the use of a PLMA as the definitive airway device were included in this study. The study was conducted in the Department of Anaesthesiology and Intensive Care at Maulana Azad Medical College and Associated Hospitals, New Delhi, India between January 2020 and September 2020. Children with an anticipated difficult airway, developmental delay, gastroesophageal reflux, obesity, respiratory diseases, or those undergoing procedures requiring endotracheal intubation, or scheduled to undergo airway or dental surgery were excluded from the study.

Intervention

Patients were randomly allocated in 1:1 to the two study groups: the lateral group in whom the PLMA was removed in the lateral position and the supine group in whom the PLMA was removed in the supine position.

Primary and secondary outcomes

The primary outcome measure was the number of patients experiencing one or more upper airway complications and the secondary outcomes were the incidence of individual respiratory adverse effects and severe airway complications.

Sample size

In a previous study by Thomas-Kattappurathu et al.,[7] airway-related complications were seen in 15.4% of children placed in the lateral position for LMA removal and in 50% of the children placed supine for LMA removal. Assuming these as reference values and taking the incidence of at least one airway-related complication as the primary variable, a sample size of at least 16 patients in each group was required with a power of 0.8 and type one error of 0.05. To account for any attrition, we included 20 patients in each group.

Randomization

Sequence generation was done by a computer-generated random number table. Allocation into groups was done by opening a sealed opaque envelope immediately before surgery. Patients were asked to pick up an envelope on the day of the surgery by the investigator.

Blinding

The patients and parents or guardians were blinded to the group allocation.

Anesthesia technique

A standard anesthesia technique was used for all patients. Patients were kept fasting as per ASA guidelines. All patients received premedication with oral midazolam 0.5 mg/kg 30 min prior to anesthesia. After shifting to the operating room, standard ASA monitoring was instituted consisting of electrocardiography, noninvasive blood pressure, and peripheral oxygen saturation (SpO_2). General anesthesia was induced with inhalation of sevoflurane. An appropriate size PLMA (Intravent Orthofix, Maidenhead UK) was chosen as per the manufacturer's recommendations and inserted using an introducer. The cuff of the PLMA was inflated to an intra-cuff pressure of less than 60 cm of H_2O and adequate to ensure an adequate seal pressure and thereafter the cuff pressure was maintained with the help of a constant pressure cuff controller (VBM cuff controller; VBM Medizintechnik). All patients received oxygen in nitrous oxide and sevoflurane for maintenance of anesthesia. Pressure controlled ventilation was adjusted to maintain normoxia and normocarbia. Multimodal analgesia was provided consisting of caudal analgesia, intravenous fentanyl 2 μg/kg, paracetamol and intravenous dexamethasone in all children.

At the end of the surgery, gentle oropharyngeal suction was done and nitrous oxide was discontinued. The inhaled sevoflurane concentration was adjusted to 1 minimum alveolar concentration (MAC; age-adjusted according to the Draeger Atalan Anesthesia Workstation) and we waited until the value of end-tidal sevoflurane was achieved. The child was then allowed to remain in the supine position or placed in the lateral position as per group allocation and was allowed to breathe this sevoflurane concentration for 5 min more to allow for equilibration between brain and alveolar concentrations after which the PLMA was removed. After this, a facemask was routinely applied with 100% oxygen for at least 5 min for each child.

The occurrence of any airway complications occurring after PLMA removal was noted.

Airway complications were defined as oxygen desaturation, that is, $SpO_2 < 90\%$, stridor or noisy breathing, complete laryngospasm with paradoxical respiratory movements, retching or vomiting, excessive secretions requiring suction or biting on the stem of the LMA. All these complications were noted as immediate at 1 min, as early between 1 and 5 min, and as delayed between 5 and 15 min after PLMA removal and were managed by the attending anesthesiologist as clinically indicated, that is, by 100% oxygen and airway manipulation, insertion of an oropharyngeal airway, change of position, gentle suctioning, etc. Out of all these complications, a fall in $SpO_2 < 90\%$ and complete laryngospasm with paradoxical respiratory movements were considered severe complications.

Statistical analysis

Data was collected and analyzed using SPSS version 25.0 software. The normality of the distribution of data was assessed by using the Kolmogorov-Simirnov test. Quantitative data was expressed as mean ± standard deviation and was compared between the two groups using the student *t*-test. Qualitative data was expressed as frequencies and was compared between two groups using the Chi-square test or Fisher's exact test as appropriate. Continuous variables with non-normal distribution were compared using the Mann-Whitney *U* test. A *P*-value < 0.05 was considered statistically significant.

RESULTS

From January 2020 to September 2020, 52 patients were assessed for eligibility in this study. Nine patients refused to participate and 3 did not meet the inclusion criteria. Forty patients were enrolled for the trial and were randomly divided between the supine group and lateral group, each having 20 patients. No patient was lost to follow-up. The two groups were comparable with respect to demographic parameters (Table 1).

Primary outcome

Airway-related complications were seen in six out of 20 patients (30%) in the supine group and four out of 20 (20%) patients in the lateral group ($P = 0.6641$).

Secondary outcomes

All airway-related complications were seen within the first 5 min of PLMA removal in both groups. In the supine group, twelve airway-related complications were seen in six patients. One child developed stridor immediately upon PLMA removal and went on to develop complete laryngospasm with oxygen desaturation. Another child had immediate stridor with oxygen desaturation. Four other children developed upper airway obstruction with noisy

TABLE 1 Demographic data of patients

Parameter	Supine group ($n = 20$)	Lateral group ($n = 20$)	*P*-value
Age (year)	6.5 ± 2.91	5.05 ± 3.23	0.1441
1–6	13	8	0.2053
>6–12	7	12	
Males/Females	17/3	13/7	0.1492
ASA grade I/II	20/0	20/0	-
Duration of surgery (min)	52.75 ± 19.49	60.25 ± 32.66	0.3382
Type of surgery			1.0000
Lower abdominal	17	18	
Lower limb	3	2	

Data are expressed as mean ± standard deviation or number (*n*).
ASA, American Society of Anesthesiologists; -, not applicable.

breathing between 1 and 5 min of PLMA removal and three of these children also had oxygen desaturation to $SpO_2 < 90\%$.

In the lateral group, five airway-related complications were seen in four patients. Three children developed stridor immediately on PLMA removal. In one of these children, excessive secretions were noted. In another child, excessive secretions were seen after a minute of PLMA removal but this child did not develop any stridor or oxygen desaturation (Table 2).

On comparing the airway complications in the two groups, we found that the incidence of complete laryngospasm, immediate stridor, and excessive secretions immediately and after 5 min was similar in the two groups ($P > 0.05$). Retching vomiting and biting on the stem of the LMA were not seen in any patient in either group. However, the incidence of stridor and oxygen desaturation between 1 and 5 min were significantly higher in the supine group ($P = 0.0374$ and $P = 0.0183$ respectively) (Table 2).

On assessing the incidence of severe airway complications, one patient in the supine group and no patient in the lateral group had laryngospasm ($P = 0.3173$) and five patients in the supine group versus no patient in the lateral group had a fall in $SpO_2 < 90\%$ ($P = 0.0183$). Thus, severe complications were more common in the supine group. Of the six children who developed severe complications four were below 6 years, one was 6 years and one was 10 years of age.

DISCUSSION

This study was designed to assess the safer patient position, supine or lateral, for PLMA removal in deeply anesthetized children with regard to the incidence of airway-related complications after removal of the PLMA. The overall incidence of airway-related complications was similar with

TABLE 2 Airway-related complications after ProSeal laryngeal mask airway removal

Complication	Supine group ($n = 20$)	Lateral group ($n = 20$)	*P*-value
Complete laryngospasm			
Immediate (within 1 min)	0	0	-
Early (within 1–5 min)	1	0	0.3173
Delayed (within 5–15 min)	0	0	-
Stridor or upper airway obstruction			
Immediate (within 1 min)	2	3	0.6369
Early (within 1–5 min)	4	0	0.0374
Delayed (within 5–15 min)	0	0	-
Oxygen desaturation to $SpO_2 < 90\%$			
Immediate (within 1 min)	0	0	-
Early (within 1–5 min)	5	0	0.0183
Delayed (within 5–15 min)	0	0	-
Excessive secretions			
Immediate (within 1 min)	0	1	0.3173
Early (within 1–5 min)	0	1	0.3173
Delayed (within 5–15 min)	0	0	-
Retching/vomiting			
Immediate (within 1 min)	0	0	-
Early (within 1–5 min)	0	0	-
Delayed (within 5–15 min)	0	0	-
Biting stem of laryngeal mask airway			
Immediate (within 1 min)	0	0	-
Early (within 1–5 min)	0	0	-
Delayed (within 5–15 min)	0	0	-

Data are expressed as numbers.
SpO_2, peripheral oxygen saturation; -, not applicable.

PLMA removal in the supine or the lateral position in deeply anesthetized children and was seen in six of 20 patients (30%) in the supine group and four of 20 (20%) patients in the lateral group. Incidences of laryngospasm, immediate stridor, and excessive secretions were similar in the two groups. Retching, vomiting, and biting on the PLMA stem were not seen at all. Early stridor and oxygen desaturation were significantly higher in the supine group.

We excluded infants and children with an anticipated difficult airway, with respiratory disease or gastroesophageal reflux, or those requiring endotracheal intubation. Infants under 1 year of age are more difficult to position laterally and have been shown to have a higher rate of airway complications with the use of LMA.[8] Following dental and upper airway surgery, airway-related complications are likely to be higher due to blood trickling into the pharynx so we also excluded these children.

The depth of anesthesia at which deep removal should be attempted has also been described differently in various studies. Ramgolam et al.[9] considered end-tidal sevoflurane >1 MAC to be "deep". In the study by Tait et al.,[10] patients were considered asleep–deep if they were breathing 100% oxygen and 1.5–2 MAC of volatile anesthetic, had a regular respiratory pattern, and were nonresponsive to stimulation such as suctioning. Lee et al.[5] found that in anesthetized children of ages 7 months–10 years, LMA removal in 50% and 95% of patients can be safely done at 1.84% and 2.17% end-tidal concentration of sevoflurane suggesting that if children require removal of an LMA during anesthesia, safe LMA removal may be possible at approximately 0.87 MAC, which is around 2.2% of sevoflurane. However, Pappas et al.[11] suggested that the depth of anesthesia during LMA removal does not seem to affect the incidence or severity of airway hyperreactivity when sevoflurane is used for maintenance of anesthesia, unlike the case when isoflurane anesthesia is used. In our study, the depth of anesthesia at which the patient was positioned for LMA removal was at an end-tidal sevoflurane concentration of age-adjusted 1 MAC. This depth has been found to be appropriate for airway manipulation in previous studies.[5]

Although there are several studies comparing the removal of an LMA in deeply anesthetized and awake children there are very limited studies that suggest a best position for removal.[6–9] In a previous study, Thomas-Kattappurahu et al.[7] found an overall higher airway-related complication rate of 50% in deep removal of LMA in the supine position as compared to 15.4% in the lateral position. Hence almost half of all the patients had some airway-related complication requiring the use of head tilt, chin lift, jaw thrust, or an airway adjunct like an oropharyngeal airway in order to manage upper airway obstruction while supine compared with a much lower proportion when lateral. It is not uncommon for an anesthesiologist to turn the patient into the lateral position during recovery when faced with relatively minor airway-related complications like coughing, excessive secretions, and mild stridor. In the study by Thomas et al.[7] on the best position for PLMA removal, seven children from the supine group were turned into the lateral position for airway management during recovery, but no patients were turned from the lateral to the supine position. However formal studies on the effect of positioning are lacking in the literature. In several previous studies, as a part of the study protocol, children were placed in the lateral position before LMA removal or immediately after.[11–15]

Arai et al.[16] in their study observed lower stridor scores in the lateral position indicating an increased efficiency of common airway maneuvers in relieving airway obstruction in children with adenotonsillar hypertrophy and suggested that the lateral position may enlarge both retropalatal and retroglossal airways, thereby improving stridor scores. Using magnetic resonance image analysis of the upper airway, Litman et al.[17] demonstrated that the upper airway enlarges significantly when a sedated, spontaneously breathing child is placed in the lateral position. In the supine position, the region of most narrowing within the upper airway lies at the level of the epiglottis. The base of the tongue seemed to be in direct contact with the anterior surface of the epiglottis displacing the epiglottis posteriorly with resultant narrowing of the airway in this region. Lateral positioning decreased this area of narrowing. Although the exact cause of this phenomenon could not be determined, there may be various factors that influence airway size, such as gravity and changes in tissue and airway compliance at any level of the upper airway that occur with the change in position.[17] Another advantage of lateral positioning is that any secretions tend to accumulate in the lower cheek rather than stimulating the supraglottic structures and leading to laryngospasm.

In our study, three children developed stridor in the lateral position within the first minute which was probably due to reduced muscle tone and was easily relieved by a gentle chin lift. In the supine position, two children developed stridor within a minute and another four developed a few minutes later. Their airway obstruction was not easily relieved by chin lift and required the use of more stimulating airway maneuvers like jaw thrust, despite which five of them had oxygen desaturation with $SpO_2 < 90\%$.

Because we recorded all immediate, early, and delayed adverse respiratory events after PLMA removal, the incidence of adverse events appears high. However, it should be noted that despite this fact, their overall severities were low and they were all easily managed. As the clinical implications of a fall in $SpO_2 < 90\%$ and complete laryngospasm with paradoxical respiratory movements are more worrisome, we considered these to be severe complications. We found that the incidence of oxygen desaturation was significantly higher in the supine group.

The technique of LMA removal therefore needs to be individualized depending on the likelihood of airway complications in that particular patient. Deep LMA removal may be considered in those children in whom any coughing and airway stimulation are particularly undesirable as in children after ophthalmic or neurosurgery or airway-related surgery and in children with an upper respiratory tract infection. While many anesthesiologists tend to turn the child on the side before or after LMA removal in the deep plane of anesthesia, there is a paucity of studies comparing the supine and lateral positions for LMA removal. Our results indicate that a fall in oxygen saturation < 90% was significantly more in the supine group and removing the PLMA in the lateral position in the deeply anesthetized child may be the safer option.

Our results should be interpreted within the constraints of several potential limitations. Children with pre-existing respiratory conditions like upper respiratory tract infection, running nose, or snoring were not included and these are the children most prone to develop airway-related complications as are infants who were also excluded. Although patients scheduled to undergo airway or dental surgery were excluded from the study, patients undergoing different types of surgical procedures may also have acted as a confounding factor. The sample size may have been insufficient to detect differences in the secondary outcomes of our study. Also, as the investigators had to make observations of the respiratory events we could not plan this as a double-blind study. Furthermore, we could not apply any of the previously used airway hyperreactivity scores as we took data at three time points.

In conclusion, if there are reasons to remove the PLMA while the patient is deeply anesthetized, the attending anesthesiologist might find it safer to do so in the lateral position to prevent severe complications like oxygen desaturation.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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