INTRODUCTION

Laryngeal mask airway (LMA) is widely used in the vast majority of surgical procedures due to ease of placement, improved haemodynamic stability during insertion and reduced airway morbidity.\(^1\) The cuff of classic LMA is made up of silicone-based rubber, which is highly permeable to volatile anaesthetics and nitrous oxide (N\(_2\)O).\(^2\) During maintenance of anaesthesia with N\(_2\)O and oxygen (O\(_2\)), N\(_2\)O diffuses into the air-filled cuff of LMA more rapidly than nitrogen in the air can diffuse out leading to increase in cuff volume and pressure.\(^{[3-5]}\) Increase in cuff pressure (CP) may cause displacement of LMA, which may affect the performance of LMA as a conduit for ventilation as well as increase the risk of gastric insufflation, regurgitation and aspiration of gastric contents due to change in oropharyngeal leak pressure (OLP).\(^6\) The
OLP is defined as the pressure in anaesthesia circuit at which a gas leak occurs around the supraglottic airway device. The over-inflation of cuff may also cause an increase in pressure on peri-glottic tissues leading to an increase in post-operative laryngo-pharyngeal morbidity.\cite{7,8}

A properly placed LMA forms an effective low-pressure seal with peri-glottic tissues and provides a direct fibre-optic view of the vocal cords. The displacement of LMA can lead to the suboptimal view of vocal cords, which can easily be detected by fibrescope.\cite{9} Previous studies in adult patients have shown conflicting results regarding the stability of LMA during N\textsubscript{2}O-O\textsubscript{2} anaesthesia, reporting either no change or significant change in position over a variable time period.\cite{10-11} Since the paediatric LMA is not anatomically designed and is merely a scaled-down version of adult LMA, the effects of an increase in CP may be different in children. Though the increase in CP of LMA during N\textsubscript{2}O-O\textsubscript{2} anaesthesia in paediatric patients has been reported by various studies,\cite{4-6,12} the change in position of LMA has not been studied so far. This study was conducted with the primary aim of evaluating effect of N\textsubscript{2}O-O\textsubscript{2} anaesthesia on change in fibre-optic position (FP) of LMA in children undergoing elective infra-umbilical and urological surgeries. The secondary outcomes measured were changes in CP and OLP during surgery and the incidence of post-operative laryngo-pharyngeal morbidity.

**METHODS**

This prospective, randomised, double-blind study was conducted after obtaining approval from the Institutional Ethics Committee (NK/2424/MD/11112-13) and written informed consent from parents/legal guardians. The study included 84 children of the American Society of Anesthesiologists physical status I–II of either sex, aged 2 to 8 years undergoing elective infra-umbilical surgery of more than 90 minutes duration [Figure 1, CONSORT]. Children with upper respiratory tract infection (cough, rhinorrhoea), anticipated difficult airway, increased risk of aspiration, limited head and neck movements and body mass index >30 kg/m\textsuperscript{2} were excluded.

The children were randomly allocated to one of the two groups with the help of computer-generated random numbers kept in opaque envelopes numbered sequentially and opened before induction of anaesthesia. In group 1, anaesthesia was maintained with 33% O\textsubscript{2} in the air and sevoflurane, and in group 2, anaesthesia was maintained with 33% O\textsubscript{2} in 67% N\textsubscript{2}O and sevoflurane. The children were examined on an evening before surgery for any comorbid illness, drug allergy and previous anaesthesia exposure and were kept fasting for 6 hours for solids and 2 hours for clear liquids. All the children were premedicated with syrup midazolam 0.5 mg/kg orally 20 to 30 minutes before the induction of anaesthesia.

Anaesthesia was induced with 5% to 8% sevoflurane in O\textsubscript{2}, and after securing an intravenous line, fentanyl 2 µg/kg was administered intravenously. The children were placed in lateral decubitus position, and under all aseptic precautions, caudal block was administered with 0.75 mL/kg of 0.2% ropivacaine using a 23-G needle by loss of resistance technique. The patients were then turned to supine position and an appropriately sized classic LMA was inserted via the midline approach. After insertion, the LMA cuff was inflated with air up to 60 cm of H\textsubscript{2}O CP (measured by Hi Lo hand pressure gauge, Mallinckrodt Medical, Germany) as per the recommendations of the manufacturer.\cite{5} The volume of air required to achieve cuff pressure of 60 cm of H\textsubscript{2}O was noted.

Successful LMA insertion was judged clinically by adequate bag movement, square wave capnography, normal thoraco-abdominal movement and absence of audible leak or stridor with the peak airway pressure <20 cm of H\textsubscript{2}O. In the event of partial or complete airway obstruction, audible leak or stridor, the LMA was removed and reinsertion was attempted. The number of attempts required for the successful insertion of LMA and the time taken for placement (from picking up LMA till the appearance of the capnographic trace) was recorded.

Anaesthesia was maintained with 33% O\textsubscript{2} in the air and sevoflurane till the first set of readings of CP, OLP and FP was noted (time 0). After that, the patients received either 33% O\textsubscript{2} in the air or 33% O\textsubscript{2} in 67% N\textsubscript{2}O according to the group allocation. Sevoflurane was administered to maintain end-tidal minimum alveolar concentration (MAC) 1.0–1.2. Neuromuscular blocking agents were not used. Pressure-controlled ventilation (PCV) was used to maintain end-tidal carbon dioxide between 35 and 40 mmHg. Maximum airway pressure was set not to exceed 25 cm of H\textsubscript{2}O. Furthermore, CP, OLP and FP were recorded at 30, 60 and 90 minutes after insertion of LMA and then at the end of surgery. The subjects, parents, surgeons...
and the investigator recording intraoperative and post-operative data were blinded to group allocation. The readings for fibre-optic view of LMA position, CP and OLP at the specific time points were taken by the anaesthesiologist not involved in the patients’ anaesthetic management, and the monitor was covered during the recording of these parameters. OLP was measured by closing the adjustable pressure limiting valve at 40 cm of H₂O to avoid barotrauma and keeping a fixed flow rate of 3 L/minute. The airway pressure at which gas could be heard leaking around LMA by auscultation of neck, lateral to thyroid cartilage, was noted. Simultaneously, air entering the stomach was detected by auscultation of the epigastrium.

The position of LMA was evaluated by flexible fibre-optic bronchoscope (VBM India, size 3.5 mm OD, Pentax, Tokyo, Japan) introduced through the self-sealing connector to the airway tube of LMA. The tip of the bronchoscope was kept 1 cm above the grill of LMA and fibre-optic view was graded as Grade 4 being only cord visible, Grade 3 as cords plus posterior epiglottis visible, Grade 2 as cords plus anterior epiglottis visible and grade 1 being cords not visible.[13] Grades 3 and 4 were considered as optimal LMA positions, whereas grades 1 and 2 were taken as displacement of LMA.

Heart rate, blood pressure and oxygen saturation (SpO₂) were recorded at 5-minute intervals till the end of surgery. Any adverse intraoperative events such as complete or partial airway obstruction, desaturation (SpO₂ < 95%) and gastric distention were recorded. At the end of the procedure, the children were allowed to breathe 100% O₂ and the LMA was removed after regaining adequate spontaneous respiration and consciousness. The children were shifted to post-anaesthesia care unit and assessed for sore throat, hoarseness of voice and dysphagia for 24 hours after surgery.

The sample size was estimated based on the previous study by Ghai et al.[14] in which incidence of fibre-optic grades 4 and 3 after LMA insertion was found to be 60%. Assuming a 30% incidence of change in the fibre-optic grade 4/3 to 2/1 after N₂O–O₂ anaesthesia with power analysis with alpha 0.05 and beta 0.90, 38 patients were required to be recruited in each group. Allowing for possible dropouts, a total of 84 children were enrolled. The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) Version 17.0 for Windows. The normality of data was checked by measures of skewness and Kolmogorov–Smirnov tests of normality. Normally distributed variables were compared using paired t-test, whereas Mann–Whitney U test was used for skewed data. Wilcoxon signed-rank test was applied for fibre-optic grading. Qualitative or categorical variables were described as frequencies and proportions and compared using
McNemar’s test or Fisher’s exact test, whichever was applicable. For comparison of time-related variables, repeated-measures analysis of variance was applied followed by Student’s t-test and Bonferroni analysis. All statistical tests were two-sided and were performed at a significance level of $\alpha = 0.05$.

**RESULTS**

The groups were comparable for demographic data and the type of surgery [Table 1]. The size of LMA, time for placement of LMA, number of attempts and the duration of anaesthesia were also comparable between the two groups [Table 1]. No patient was excluded as there were no difficulties in insertion and ventilation through LMA. Only mild (grade 1) change in LMA position in six out of 42 patients in group 2 was detected that was not statistically significant [Table 2]. The mean cuff pressures at 30, 60 and 90 minutes and at the end of surgery were significantly higher in group 2 as compared to group 1 ($P < 0.05$). The cuff pressure increased from $80.12 \pm 12.12$ cm H$_2$O to $93.23 \pm 14.86$ cm H$_2$O at 90 minutes in group 2, whereas there was no significant increase in cuff pressure from baseline in group 1 [Table 3]. OLP was comparable between the two groups till 60 minutes after the placement of LMA and then slightly increased in group 2 [Table 3].

The children were haemodynamically stable during perioperative period in both the groups. None of the patients required manipulation or change in airway device. No other complications such as loss of capnographic trace, desaturation ($<95\%$) and audible leak were recorded in any patient. However, the incidence of post-operative sore throat was significantly higher in group 2 (16 children, 38%) as compared with group 1 (six children, 14%; $P = 0.014$). A greater number of children in group 2 (eight children, 19%) had dysphagia than in group 1 (three children, 7%). Three patients in group 2 also reported hoarseness of voice at 2 hours post-operatively.

**DISCUSSION**

In the present study, although there was no significant change in the FP of LMA in both groups, LMA cuff pressures were significantly higher at all time intervals in the patients maintained with N$_2$O-O$_2$ anaesthesia. The incidence of post-operative sore throat and dysphagia was also high in children receiving N$_2$O. LMA has various advantages over tracheal intubation and can be used safely with spontaneous as well as controlled ventilation. Mahdavi et al.$^{[15]}$ reported low peak inspiratory pressure and high dynamic compliance during mechanical ventilation with LMA as compared with endotracheal tube in children. In a meta-analysis of 19 studies, the incidence of desaturation, laryngospasm, cough and breath-holding was significantly lower with the use of LMA.$^{[16]}$ For appropriate ventilation through LMA, a good oropharyngeal seal, determined by OLP measurements is required, which can be achieved only with proper placement of LMA over the laryngeal inlet.$^{[17]}$ However, the diffusion of anaesthetic gases into cuff may lead to increase in CP and displacement of LMA, and it may not be advantageous to use LMA for prolonged surgical procedures. Though previous studies conducted to evaluate the change in LMA position during inhalational anaesthesia using fibre-optic laryngoscope in adults have shown conflicting results, Brimacombe and Berry$^{[10]}$ could not find any change in fibre-optic view of larynx. Coorey et al.$^{[18]}$ reported significant change in the position of LMA having air-filled cuff in four out of 10 patients receiving N$_2$O-O$_2$ anaesthesia as compared with none with saline-filled cuffed LMA. Ghai et al.$^{[14]}$ assessed FP of LMA in children just after insertion by using different techniques, but no study has been conducted to evaluate the change in FP of LMA in paediatric patients so far. In the present study, the incidence of grades 3 and 4 fibre-optic view of LMA position just after insertion was about 71%, which is almost similar to that reported by Ghai et al.$^{[14]}$ (61.5%) after using the standard technique. In another study, Thakur and Malde$^{[19]}$ reported significant displacement of LMA with a decrease in oropharyngeal seal and an increase in fractional volume loss when children were positioned from supine to lateral for caudal anaesthesia. The authors, however, did not visualise the fibre-optic view of the laryngeal inlet. We did not encounter this problem as we inserted LMA once the children were made supine after the caudal block.

In previous studies, Epstein et al.$^{[12]}$ and Algren et al.$^{[4]}$ have shown a 25% to 50% increase in CP, 30 minutes after the placement of classic LMA during N$_2$O-O$_2$ anaesthesia in paediatric patients. Chen et al.$^{[20]}$ observed a nearly 200% increase in CP in children receiving N$_2$O even with the use of ProSeal LMA. However, Brimacombe and Berry$^{[10]}$
reported a self-limiting increase in CP, and Ouelette\cite{9} reported a gradual increase in CP over 3 hours in adult patients receiving N₂O–O₃ anaesthesia. We also found a gradual increase in CP up to 90 minutes in patients maintained with N₂O–O₃ mixture with a percentage increase of 55.3\% from baseline (group 1 mean CP 39.78 ± 7.75 cm H₂O; group 2 mean CP 93.23 ± 14.86 cm H₂O at 90 minutes). Also, in post hoc power analysis, the sample size of our study was found to be adequately powered to detect the mean difference in CP in both groups at 90 minutes.

The OLP is a marker of the efficacy and safety of LMA\cite{8-10}. Although Epstein et al.\cite{12} reported an increase in OLP after N₂O–O₃ anaesthesia in paediatric patients, Algren et al.\cite{20} could not find any change in OLP in children receiving N₂O. Previous studies in adults also reported no significant increase in OLP after N₂O–O₃ anaesthesia.\cite{8, 10-11} In our study, the OLP was well maintained in both groups.

In the present study, although the CP decreased over time in group 1 and increased in group 2, there was no change in ventilatory parameters during PCV. Perhaps the change in pharyngeal muscle tone compensates for the increase or decrease in cuff volume and pressure. These findings are similar to the observations of Algren et al.\cite{20} Also, we did not encounter complications such as desaturation, audible leak or the need for manipulating LMA in intraoperative period.

Hyperinflated cuff causes pressure on the pharyngeal mucosa which may compromise mucosal perfusion resulting in ischaemia and pharyngo-laryngeal morbidity.\cite{6} We found a higher incidence of sore throat, dysphagia and hoarseness of voice in first 24 hours post-operatively in children receiving N₂O. Chen et al.\cite{20} also reported a higher incidence of post-operative laryngo-tracheal morbidity in patients maintained

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**Table 1: Demographic parameters and LMA placement**

| Variables                     | Group 1 (n=42) | Group 2 (n=42) | P  |
|-------------------------------|---------------|---------------|----|
| Age (years)                   | 5.10±1.81     | 5.19±2.19     |    |
| Weight (kg)                   | 16.30±4.29    | 17.21±5.00    |    |
| Gender (M:F), n               | 42:0          | 41:1          |    |
| ASA Grade I: II, n            | 41:1          | 42:0          |    |
| Duration of Anaesthesia (minutes) | 95.71±17.72   | 94.29±16.17   | 0.70 |

**Table 2: Fibre-optic position of LMA**

| Time               | Group 1 (n=42) | Group 2 (n=42) | P  |
|--------------------|---------------|---------------|----|
| Baseline (Grade 4/3/2/1) | 13 (31\%)     | 18 (42.9\%)  |    |
| 30 min             | 13 (31\%)     | 18 (42.9\%)  |    |
| 60 min             | 13 (31\%)     | 18 (42.9\%)  |    |
| 90 min             | 13 (31\%)     | 18 (42.9\%)  |    |
| End of surgery     | 13 (31\%)     | 18 (42.9\%)  |    |

**Table 3: Oropharyngeal leak pressure and change in LMA cuff pressure (cm H₂O)**

| Time               | Group 1 (n=42) | Group 2 (n=42) | P  |
|--------------------|---------------|---------------|----|
| Baseline           | 22.62±2.399   | 21.38±3.793   | 0.077 |
| 30 min             | 21.62±2.378   | 22.55±4.250   | 0.220 |
| 60 min             | 21.19±2.707   | 22.88±4.198   | 0.081 |
| 90 min             | 20.40±2.673   | 23.58±4.288   | 0.041 |
| End of surgery     | 20.71±2.479   | 23.50±4.718   | 0.042 |

Values are expressed as mean±standard deviation or number of patients (percentage). LMA: Laryngeal mask airway, n: number, M: Male, F: Female, B/L: Bilateral, ASA: American Society of Anesthesiologists

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Bharti, et al.: Nitrous oxide anaesthesia and laryngeal mask airway
on N₂O–O₂ mixture. Li et al. recommended the application of effective cuff inflating volume just adequate for satisfactory sealing, to reduce the incidence of post-operative pharyngeal complications.

One of the limitations of our study is that we did not analyse the gas composition of LMA cuff after deflation due to non-availability of equipment, which could have provided correlation between changes in CP and the composition of anaesthetic gases. Under-reporting of pharyngo-laryngeal complications by children is unavoidable as they cannot express the cause of discomfort. We recommend regular monitoring of CP and OLP throughout the surgery and maintaining minimal recommended CP just enough to avoid any leak.

CONCLUSION

In conclusion, the diffusion of anaesthetic gases during N₂O–O₂ anaesthesia does not change FP of LMA significantly in children. However, an increase in intra-cuff pressure may lead to a higher incidence of post-operative pharyngo-pharyngeal complications.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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