PROSEAL LARYNGEAL MASK AIRWAY IN INFANTS AND TODDLERS WITH UPPER RESPIRATORY TRACT INFECTIONS: A RANDOMIZED CONTROL TRIAL OF SPONTANEOUS VS PRESSURE CONTROL VENTILATION

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Implication statement

Laryngeal masks, especially ProSeal have made it possible to deliver pressure control ventilation with PEEP without requiring paralysis in infra umbilical surgeries, thereby obviating the need for endotracheal intubation and minimizing the associated adverse respiratory events. This randomized prospective study was conducted to assess the influence of mode of ventilation on adverse respiratory events in infants and toddlers having upper respiratory tract infection, when using ProSeal™ laryngeal mask as the airway device.

Abstract

Background: ProSeal LMA (PLMA), one of the advanced supraglottic devices has been successfully used to provide both spontaneous and controlled ventilation in children with upper respiratory tract infection (URTI). URTI does not imply restriction of disease to upper respiratory tract; it has been shown to produce pulmonary dysfunction. PEEP has been shown to improve oxygenation in such cases. This randomized prospective study was designed to compare postoperative adverse events associated with spontaneous respiration (SR) and pressure control ventilation (PCV) with PEEP in infants and toddlers with URTI when using PLMA as an airway device.

Methods: In the present study, 90 children, 6 months-2 years, scheduled for infra umbilical surgery were randomized to receive either SR or PCV with PEEP of 5cm H_2O.Patients with risk of aspiration, bronchial asthma, anticipated difficult airway, snoring, passive smoking, morbid obesity, coexisting pulmonary and cardiac disease, lower respiratory tract infection, fever>38°C and sneezing, were excluded. At emergence, airway secretions, coughing, breath holding, bronchospasm, upper airway obstruction or laryngospasm (LS) were assessed.

Results: The adverse events were significantly higher in spontaneously breathing patients. Score of adverse events was 6.33±1.6 in PCV and 7.7± 2.2 in SR group (P=0.001).The mean SpO_2 (%) in PACU was 96.5±2 in PCV and 94.4±1.37 in SR (P = 000).

Conclusion: Pressure control ventilation with PEEP using PLMA is associated with lower incidence of adverse events in comparison to spontaneous respiration in infants and toddlers with upper respiratory tract infection undergoing infra umbilical surgeries under general anesthesia.

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Introduction

Upper respiratory tract infection (URTI) is a frequently encountered clinical condition and has remained a matter of debate and concern to the pediatric anesthesiologists all over the world. The inception of laryngeal mask airway (LMA) has changed the conduct and outcome of anesthesia over last few decades particularly in patients with URTI.

Most previous studies have not been consistent with the type of airway device, age of subjects, anesthetic technique, type of surgery and mode of ventilation used in patients with URTI. Homer et al have shown that adverse events are affected by the airway device employed, that is, device used and the timing of its removal for the management of the case[1]. Some previous studies ascertain the usefulness and performance of LMA over tracheal tube (TT) and facemask (FM) and show that use of laryngeal mask airways has significantly lowered the incidence of postoperative sore throat; while others demonstrate no clinically significant difference between the devices[2-5].

PLMA has challenged the assumption that TT is the only way to provide positive pressure ventilation (PPV).Recently, use of pressure-control ventilation in nonparalysed patients has been popularized with the use of laryngeal mask airways in pediatric patients and has been shown to improve oxygenation[6]. No previous study compares the different modes of ventilation using PLMA in children with URTI.

We hypothesized that mode of ventilation has influence on postoperative adverse respiratory events in preschool children with URTI when using ProSeal LMA as airway device.

Patients and Methods

After approval of Hospital Ethics Committee and parents' written informed consent we selected 90 consecutive children, 6 months to 2 years, having acute URTI and who met the exclusion and inclusion criteria for this randomized prospective study. Each patient's parents was interviewed and patient examined in detail to determine presence of any symptoms suggestive of URTI. We used criteria defined by Tait and Knight[7] i.e. sore or scratchy throat, rhinorrhea, congestion, malaise, nonproductive, cough, fever <38˚C and laryngitis. Identification of two or more of these symptoms was declared as having URTI.All patients were scheduled to undergo infra umbilical surgery under general anesthesia (GA).

Patients with history of asthma, risk of aspiration, difficult airway, snoring, passive smoking, morbid obesity, coexisting pulmonary and cardiac disease, fever >38˚C and evidence of lower respiratory tract infection, were excluded from the study. No child was premedicated and baseline oxygen saturation was obtained with room air. Any child with SpO_2<95% in preoperative area was excluded from the study.

They were randomized to receive either SR or PCV. All patients in PCV group received a PEEP of 5 cm H_2O. The nurse in preoperative area allocated the patients into groups using computer generated random numbers. No muscle relaxant was used for any patient.

All cases were conducted in same period of the year for 3 consecutive years which are winter months in this country.

Anesthesia was induced using O_2 and N_2O and 8% sevoflurane using uniform flows for all patients. The anesthetic was titrated to allow spontaneous respiration for children in SR group whereas in PCV group were ventilated using pressure control ventilation and PEEP of 5 cmH_2O was applied. In the PCV group the pressure limit was set at 15 cm H_2O and the respiratory rate was adjusted to maintain the $PEtCO_2$ between 4.6 and 5.8 kPa (35–45 mmHg).Anesthesia was maintained using 1-2% sevoflurane in oxygen and nitrous oxide mixture. PLMA was inserted by anesthetist with experience of more than 500 cases of PLMA insertion. It was in accordance with manufacturer's instructions. After PLMA placement, caudal block was administered. Paracetamol suppository was inserted per-rectally in all patients. Any patient developing a rise of heart rate by more than 20% at skin incision, received fentanyl citrate 1ug/kg, and was excluded from the study. At emergence, O_2 and air mixture was used. Patients requiring more than one attempt at PLMA insertion were not included in the study. Pulse oximetry (SpO_2), electrocardiography (ECG), respiratory rate, end-tidal CO_2 ($EtCO_2$) and automated blood pressure (NIBP), were monitored for all patients.

The values were mean of readings taken every five minutes throughout the period. During emergence,

Fig. 1
Scores of various respiratory events as based on system given by Levy et al[8]

	1	2	3
Cough	None or Occasional	Frequent	Continuous
Breath holding	None or <15 seconds	15-30 seconds	>30 seconds
Laryngospasm (LS) (relieving factors)	None or Partial (reposition)	Partial (CPAP)	Complete (muscle relaxant)
Bronchospasm	None or Expiration	Inspiration and Expiration	Difficult to ventilate
Secretions	None or Minimal (no suction)	Moderate (suction once)	Copious (suction more than once)

The numbers in top row indicate the grades of the events in the left column
LS: laryngospasm, RF: relieving factor

the PLMA was removed inside the operation theatre at onset of swallowing in all patients by the anesthetist conducting the case. On removal, the device was observed for any evidence of blood.

A co-anesthesiologist who was blinded to mode of ventilation made all observations for adverse events at removal of PLMA and in the PACU. The respiratory adverse events that were evaluated were: presence of airway secretions, coughing, breath holding, bronchospasm and upper airway obstruction or laryngospasm (LS). These events were assessed and graded in accordance with details in Fig 1. All children with bronchospasm received nebulization with salbutamol in the PACU. No antiemetic was used in any patient and they were kept in the PACU till discharge readiness.

The observations were graded for their severity from 1 to 3 using the scale similar to one published by Levy et al[8]. Score 1: mild or no signs, 2: moderate and 3: severe. An experienced anesthesiologist, who was blinded to the mode of ventilation made all observations. The mean scores, which ranged from minimum of 3 to maximum of 15, were used for comparison. The mothers were contacted telephonically to find about any respiratory adverse events upto 24 hrs after discharge.

Statistics

The primary variable was the mean adverse events score. Demographic data and incidence values were compared using chi-square test. The collected data was analysed using analysis of variance i.e. ANOVA. Mann-Whitney U-test and Wilcoxan W-tests were applied for nonparametric data. P value <0.05 was considered statistically significant. From preliminary data, we calculated with alpha-set at 0.05, that 90 patients would give a statistical power of 82% to detect 20% difference in mean respiratory adverse events score between the PCV and SR groups. Secondary variables were SpO_2 in PACU and $PEtCO_2$. The data are expressed as mean ± standard deviation. Software SPSS Inc Chicago IL, USA 12.0 version, was used for the analysis.

Results

A total of 7 patients (6 of PCV group, and 1 of SR group) could not complete the study.. Of these 4 patients required a second attempt at PLMA insertion and 3 patients had inadequate analgesia.

The demographic profile, general characteristics; baseline SpO_2 and their distribution into the PCV and SR type of ventilation, are listed in Table 1.

However in the PACU, the SpO_2 (%) in the SR group (mean 94.5, range 89-96, median 94) was lower than the values than the PCV group (mean 96.5, range 90-100, median 97), achieving statistical significance.

The incidence of adverse events was significantly higher in SR (7.75±2.2) as compared to PCV (6.33±1.7) group; P = 0.001. All adverse events were significantly higher in SR group (Table 2, 3). Most adverse events in both groups were of mild degree (Table 2). The mean $PEtCO_2$ during intra operative period was 41.3±3.9 in SR and 36.6±4.4 in PCV group (P = 0.000). In contrast to 17% patients in PCV group, 41% in SR

Table 1
Demographic profile and general characteristics

	PCV	SR	Level of Significance (P)
Number	39	44	P>0.05
Age (years)	1.5±0.6	1.3±0.5	P>0.05
Weight (kg)	10.9±2	9.8±1.8	P>0.05
Gender (M/F)	33/6	40/4	P<0.05
Duration (minutes)	61.4±24	77±22	P>0.05
Baseline SpO_2%	97	96.6	P>0.05

M/F: Male/Female, PCV: Pressure Control Ventilation, SR: Spontaneous Respiration.

Table 2
Adverse respiratory events of PCV and SR groups

	BREATH HOLDING	SECRETIONS	BRONCHOSPASM	LS	COUGH
MILD (PCV/SR)	25/13	36/31	29/22	36/31	26/23
MODERATE (PCV/SR)	10/27	2/11	9/18	3/12	10/17
SEVERE (PCV/SR)	4/4	1/2	1/4	0/1	3/4
P-value	0.003	0.036	0.110	0.039	0.236

The figures in the table represent number of patients in PCV/SR group.
PCV: pressure control ventilation, SR: spontaneous respiration, P>0.05=NS: not significant;
P<0.05 = significant. LS is Laryngospasm.

Table 3
Comparison of various events between the two modes of ventilation

	PCV	95% Confidence Interval Lower/Upper	SR	P value	95% Confidence Interval Lower/Upper
COUGH	1.08±0.3 (0.04)	1.02/1.14	1.32±0.6 (0.07)	0.011	1.21/1.43
BREATH HOLDING	1.46±0.7 (0.10)	1.31/1.61	1.8±0.6 (0.09)	0.019	1.68/1.93
BRONCOSPASM	1.28±0.5 (0.08)	1.17/1.39	1.77±1.5 (0.23)	0.06	1.44/2.10
SECRETIONS	1.10±0.4 (0.06)	1.02/1.19	1.34 ±0.6 (0.08)	0.030	1.22/1.46
LARYNGOSPASM	1.4±0.6 (0.10)	1.27/1.55	1.5±0.6 (0.08)	0.40	1.39/1.65
$PEtCO_2$	36.6±4.4 (0.70)	35.67/37.56	41.3±3.9 (0.59)	0.000	40.48/42.16
PACU* SpO_2 (%)	96.5±2 (0.33)	96.09/96.99	94.4±1.37 (0.20)	0.000	94.11/94.70
NEBULIZATION	7/39 (17%)	9.6/25.3	18/44 (41%)	0.013	32/54
ADVERSE EVENTS SCORE (mean)	6.33±1.6 (0.25)	5.99/6.68	7.75±2.2 (0.32)	0.001	7.28/8.22

PCV: Pressure Control Ventilation, SR: Spontaneous Respiration. Nebulizations is with salbutamol. Values in parenthesis are Standard error mean. P<0.05 = significant

group required nebulisation in the PACU (P = 0.013) (Table3).

A total of 16 patients required assisted ventilation after removal of PLMA of which 13 were in SR group. The minimum SpO_2 experienced during study was 89% (SR group, immediately after removal of PLM). There was no evidence of device malposition, dislodgement or air leak in any patient; however blood was seen on device of 4 patients, 3 of which belonged to PCV group.

There was no difference in the two groups at discharge readiness.

Discussion

URTI does not imply restriction of disease to upper respiratory tract; it has been shown to produce pulmonary dysfunction as well changes in oxygen saturation[9,10]. PEEP has been shown to improve oxygenation in such cases. Our results show that the overall incidence of adverse events is significantly higher in children having acute respiratory tract infection undergoing surgery under spontaneous respiration when using PLMA as airway device.

Schreiner et al in a case-control study showed that younger age group is an independent risk factor for adverse events particularly laryngospasm, however no clear age cut-off was defined. No particular anesthetic technique or airway devices were used in any of the previous studies. Different anesthetic agents including thiopentone, propofol, halothane and sevoflurane have been described in the previous studies. Most previous studies have lacked uniformity with respect to type of surgery and few of these studies included patients undergoing surgery on airway, which could be an independent factor predisposing to adverse respiratory events[11]. However all our patients underwent infra-umbilical surgery and no airway manipulation other than insertion of airway device was required.

Cohen et al in their longitudinal study showed there is 2-7 times increased chances of respiratory complications in patients with acute URTI undergoing surgery[12] and that the respiratory events increased by 11 times due to instrumentation of trachea.

PLMA, one of the advanced supraglottic devices has been successfully used to provide both spontaneous and controlled ventilation in children. Its use has been shown to lower incidence of coughing, sore throat, improved oxygen saturation and reduced anesthetic requirements for airway tolerance[13].

Tait et al[5], compared incidence of perioperative respiratory complications associated with TT and LMA. All their patients had acute but uncomplicated URTI and were allowed only spontaneous respiration and the agent used in all their cases was halothane. In our study however, sevoflurane was used for all patients there was no tracheal instrumentation.

Our results showed that individual events, namely secretions, breath holding, bronchospasm and coughing all of which could be precursor to laryngospasm, were seen more often in spontaneously breathing children and that PCV was associated with lower incidence of adverse respiratory events.

Goldman and Roettger demonstrated that application of PEEP of 5 cm H_2O with PCV under GA improves gas exchange when the PLMA is used, as evidenced by a significantly higher mean PaO_2[6]. This could explain the higher SpO_2 seen in patients on PCV in our study.

Several studies have shown increased incidence of arterial desaturation in children suffering from acute URTI which responds rapidly to oxygen supplementation and also that this desaturation is more rapid following apnea[9-11,14,15]. In our study, we observed that the incidence of desaturation was higher for spontaneously breathing children in comparison with patients on PCV. All patients responded to oxygen supplementation in post anesthesia care unit (PACU).

In a study on lambs suffering from parainfluenza virus infection, Dueck et al found that the peak airway pressure (PAP) does not significantly change after infection but there is development of shunt at a higher FRC after infection. However, its influence on outcome of anesthesia as well as surgery remains uncertain. URTI has been shown to produce fall in FRC, development of shunt at higher FRC and many more changes in lung volumes and diffusion capacity[16-24].

Conventionally, tracheal tubes have been used to provide positive pressure ventilation but the introduction of PLMA has challenged this assumption. Supra glottic devices in form of laryngeal masks,

particularly PLMA has made it possible to deliver PCV with PEEP without having to paralyze the patient, more so in infraumbilical surgeries, thereby obviating need for endotracheal intubation and minimizing adverse respiratory events in children particularly when URTI is present. There is a case report of laryngeal edema associated with use of PLMA, in an adult having suspicion of URTI[25]. If general anesthesia is required despite URTI, the evidence is that the use of LMA significantly reduces the risk compared to intubation[4]. The role of PLMA in children with symptoms suggestive of URTI, so far has remained unclear. Nevertheless it offers distinct advantages of permitting effective ventilation without air-leak and gastric distension, and providing ability to apply PEEP.

Although coexistence of URTI was seen to be associated with high incidence of adverse events, most of these were mild and no serious or life threatening complication was encountered in any of our patients. We conclude that Pressure control ventilation with PEEP using PLMA was accompanied with lower incidence of adverse events and this may be preferred mode of ventilation in infants and toddlers with upper respiratory tract infection undergoing infraumbilical surgery under general anesthesia.

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