Use of the ProSeal™ laryngeal mask airway for pressure-controlled ventilation with and without positive end-expiratory pressure in paediatric patients: a randomized, controlled study

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Background. Tracheal intubation and positive end-expiratory pressure (PEEP) are frequently used in children to avoid airway closure and atelectasis during general anaesthesia. Also, the laryngeal mask airway (LMA) is frequently used. However, one of the limitations with its use in children is that its low-pressure seal is often inadequate for positive pressure ventilation with PEEP. The ProSeal™ LMA (PLMA) has been shown to form a more effective seal than the Classic™ LMA. The ability to apply PEEP with the PLMA might improve gas exchange during positive pressure ventilation in children when the LMA is used.

Methods. Twenty anaesthetized, non-paralysed children aged 55 (range 27–89) months, weighing 18 (SD 3) kg, were randomly allocated into two groups. Anaesthesia management and positive pressure ventilation were standardized. Size 2 and 2½ PLMA were used. Artificial ventilation in Group I was with pressure controlled ventilation (PCV) and PEEP = 5 cm H₂O, in Group II with PCV without PEEP. A FIO₂ = 1.0 was used for 20 min during induction of anaesthesia. Sixty minutes after induction of anaesthesia an arterial blood gas sample was taken under a FIO₂ = 0.3.

Results. Groups were comparable with respect to demographic data. Pao₂ in Group I [22.1 (1.6) kPa] was significantly (P=0.001) higher than in Group II [19.2 (1.7) kPa].

Conclusions. The PLMA can be used for PCV with PEEP in paediatric patients. Application of PEEP improves gas exchange.

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The safety and efficacy of the laryngeal mask airway (LMA) for airway management in paediatric patients has been shown in several studies. However, there are well known limitations of the Classic™ LMA (CLMA) in paediatric patients. One of the main concerns is that its supraglottic low-pressure seal might be inadequate for positive pressure ventilation.

In the very young patient, closing volume tends to increase and functional residual capacity to decrease during general anaesthesia, resulting in atelectasis and subsequent decreased arterial oxygenation. Application of adequate tidal volumes and positive end-expiratory pressure (PEEP) play an important role in counteracting airway closure and atelectasis in adult and paediatric patients under general anaesthesia when the tracheal tube is used.

Because of its low-airway leak pressure (P_leak), application of large tidal volumes or PEEP may be impossible or result in gastric insufflation when the CLMA is used for positive pressure ventilation. As a consequence, the CLMA is usually used without PEEP and it has been recommended to limit tidal volumes to 6–8 ml kg⁻¹ using low inspiratory flow rates. The size 2 and 2½ ProSeal™ LMA (PLMA) (LMA North America, Inc., San Diego, CA) has been shown to form a more effective seal and to allow for a greater tidal volume than the CLMA in paediatric patients. This randomized study was designed to test the hypothesis that in anaesthetized paediatric patients the PLMA can be used effectively to apply PEEP during...
pressure-controlled ventilation (PCV) and that this leads to an improved arterial oxygenation.

Methods
After obtaining approval from the local ethics committee and written parental consent, 20 ASA I patients, undergoing elective genitourinary, orthopaedic, or trauma surgery were studied. Patients were excluded if they were ASA physical status greater than I, were at risk of aspiration, had a potential difficult airway or pulmonary disease. The inability to place the PLMA with two attempts and the inability to take an arterial blood gas sample with a single puncture were also considered as exclusion criteria.

A standard anaesthesia protocol was followed. All patients were premedicated orally with midazolam 0.4–0.5 mg kg\(^{-1}\) and EMLA\textsuperscript{TM} cream (Astra-Zeneca, Wilmington, DE) was applied to the back of both hands 30 min before induction of anaesthesia. Standard monitoring consisted of a precordial stethoscope, a rectal temperature probe, an automated arterial pressure monitor, ECG, pulse oximetry, and capnography. In all patients general anaesthesia was induced intravenously with alfentanil 0.02 mg kg\(^{-1}\) followed by propofol 3–5 mg kg\(^{-1}\). Anaesthesia maintenance was with propofol 0.1–0.15 mg kg\(^{-1}\) min\(^{-1}\) and remifentanil 0.2–0.3 \mu g kg\(^{-1}\) min\(^{-1}\). After cessation of spontaneous ventilation the lungs of the patients were ventilated manually via a facemask until a sufficient depth of anaesthesia was reached. The PLMA (a size 2 for children <20 kg, a size 2½ for children >20 kg body weight) was then placed using the standard technique recommended by Brain.\textsuperscript{13} Manual ventilation was commenced after the breathing tube had been connected to the anaesthesia machine (Primus\textsuperscript{®}, Draeger, Luebeck, Germany). Auscultation of the epigastrium and larynx took place before the device was taped.\textsuperscript{13} Thereafter a drain tube (DT) test (DT-test), as described in the PLMA instruction manual, was conducted in order to confirm correct position of the distal end of the DT at the proximal end of the oesophagus.\textsuperscript{14} The head of the child was then placed in a neutral position on a soft 3-cm high head-ring and the \(\text{P}_{\text{PEEP}}\) in the neutral head position was determined at an intra-cuff pressure (\(\text{P}_{\text{intracuff}}\)=60 cm H\(_2\)O (VBM Cuff Pressure Gauge, VBM Medizintechnik, Sulz a.N., Germany), as described previously.\textsuperscript{15} During \(\text{P}_{\text{PEEP}}\) measurement, auscultation of the epigastrium was performed again to detect any air entry into the stomach. Fibre-optic examination of the position of the LMA was performed thereafter (2.8 mm flexible endoscope, Karl Storz, Tuttingen, Germany). The position of the LMA was graded in accordance with the fibre-optic scoring system described previously.\textsuperscript{16} Thereafter, a 12 French gauge gastric tube was placed through the DT. Gastric fluid was aspirated using a syringe and the amount of fluid noted. Once the \(\text{P}_{\text{PEEP}}\) measurement and the fibre-optic examination had been completed PCV was used to ventilate the lungs throughout the procedure. PEEP was set either to 0 or 5 cm H\(_2\)O according to the group the patient had been randomized to. Randomization to two groups of equal size (n=10) had happened before commencement of the trial using the StatView (SAS Institute, Cary, NC, USA) computer program: Group I was PCV with PEEP=5 cm H\(_2\)O and Group II PCV without PEEP. The information of the allocated group was contained in sealed envelopes—numbered from 1 to 20—that were opened before induction of anaesthesia by a study nurse not participating in the investigation.

PCV was commenced in the anaesthesia induction room immediately after fibre-optic inspection of the PLMA. Apart from the PEEP level, all other respirator settings were identical for both groups. Peak inspiratory airway pressure (PIP) was set to deliver a tidal volume of 8–10 ml kg\(^{-1}\) and kept unchanged throughout the entire anaesthetic. The ventilatory frequency was adjusted to achieve an end-tidal carbon dioxide (\(\text{CO}_2\)) of 5.1 (0.3) kPa. Peak inspiratory flow rate was set to 50 litre min\(^{-1}\), fresh gas flow was set to 2 litre min\(^{-1}\), and inspiratory:expiratory (I:E) ratio was set to 1:1. The fraction of inspired oxygen (\(\text{F}_{\text{IO}_2}\)) was kept for a duration of 20 min at \(\text{F}_{\text{IO}_2}=1.0\). The child was then transferred into the operation room and the \(\text{F}_{\text{IO}_2}\) reduced to 0.3. After 60 min total anaesthesia time an arterial blood gas sample was obtained from the radial artery by a single sterile puncture and an arterial blood gas (ABG) measurement took place immediately (Radiometer ABL-System 625, Radiometer, Copenhagen, Denmark). The actual respiratory settings at the point of time of blood gas measurement were recorded. At the end of surgery anaesthesia was discontinued and the PLMA removed once the child was fully awake. Any adverse event, apparent oropharyngeal injury or problem with the devices was documented. A postoperative visit took place 6–8 h later.

Statistics
The primary variable tested was \(\text{P}_{\text{AO}_2}\), \(\text{P}_{\text{ACO}_2}\) values for healthy anaesthetized paediatric patients under PCV and a \(\text{F}_{\text{IO}_2}=0.3\) using the LMA have not been reported previously. Normal \(\text{P}_{\text{AO}_2}\) values for healthy adolescents breathing room air are reported to be 12.7 (0.7) kPa.\textsuperscript{17,18} Based on the findings of Serafini and colleagues\textsuperscript{7} and pulmonary CT-scans of former paediatric patients of ours showing that atelectasis was present in most of the dependent lung regions shortly after induction of anaesthesia when a tracheal tube and no PEEP was used we hypothesized that atelectasis could possibly account for up to 15% of the lung tissue. We speculated that, as a consequence, there should be a difference in the \(\text{P}_{\text{AO}_2}\) of a similar magnitude with and without PEEP. A 10% higher \(\text{P}_{\text{AO}_2}\) for PCV with PEEP=5 cm H\(_2\)O was considered to be clinically relevant, therefore a sample size of 12 patients was calculated to detect a projected difference of 10% between the groups with respect to \(\text{P}_{\text{AO}_2}\) for a type I error of 0.025 (one-tailed testing) and a power of 0.9. Allowing for possible dropouts due to the inability to place the PLMA within
two attempts or the inability to collect an arterial blood gas sample with a single puncture we chose to examine 20 patients. Results were analysed using the SPSS (SPSS Inc., Chicago, IL, USA) computer program. Unless otherwise stated data are expressed as mean values (SD) (95% CI) or mean values (range). The distribution of data was determined using Kolmogorov–Smirnov analysis. Statistical analysis was performed using t-test (one-tailed). Results were considered statistically significant for a P-value <0.025.

Results

Sixteen male and four female patients were included in the study. One patient in Group II had to be excluded from the study. One patient in Group II had to be excluded from the final ABG analysis since inadvertently a PEEP=5 cm H2O had been applied after induction of anaesthesia. Data were normally distributed. The mean age, height and weight of the patients were 55 (27–89) months, 110 (11) cm, and 18 (3) kg, respectively. There were no demographic differences between groups (Table 1).

The patients were anæsthetized for 105 (37) (87–122) min. The PLMA was placed in all patients at the first attempt. Air entry into the stomach was not detected by auscultation in any patient. The mean P_leak was 23 (5) (21–26) cm H2O. Fibre-optic examination indicated correct position of the PLMA in all patients. A gastric tube was placed without any difficulties in all patients. Gastric fluid was aspirated in 12 patients, the volume ranging from 3–24 ml. Both groups were comparable with respect to the ventilation parameters. Ventilation to normal Paco2 values was possible in all patients. Oxygenation was supranormal in both groups; however, there was a significant difference (P=0.001) between the groups (Table 2). No adverse events were recorded in any of the patients.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patient characteristics and anaesthesia data. Data are mean (range) or mean (SD). Differences between Groups I and II, for all parameters P&gt;0.05</th>
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<tbody>
<tr>
<td>Group I (PEEP) n=10</td>
<td>Group II (ZEEP) n=9</td>
</tr>
<tr>
<td>Age (month)</td>
<td>60 (29–89)</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>115 (10)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>19 (3)</td>
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<tr>
<td>Male:female (n)</td>
<td>9:1</td>
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<tr>
<td>PLMA size 2:2½ (n)</td>
<td>6:4</td>
</tr>
<tr>
<td>Airway leak pressure (cm H2O)</td>
<td>24 (5) (20–27)</td>
</tr>
<tr>
<td>Duration of anaesthesia (min)</td>
<td>102 (45) (68–137)</td>
</tr>
</tbody>
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<tr>
<th>Table 2</th>
<th>Blood gas parameters. *Group I vs Group II: P=0.001</th>
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<tbody>
<tr>
<td>Group I (PEEP) n=10</td>
<td>Group II (ZEEP) n=9</td>
</tr>
<tr>
<td>Paco2 (kPa)</td>
<td>22.1 (1.6) (21.1–23.2)*</td>
</tr>
<tr>
<td>Paco2 (kPa)</td>
<td>5.0 (0.4) (4.7–5.2)</td>
</tr>
<tr>
<td>Arterial pH</td>
<td>7.37 (0.03) (7.36–7.39)</td>
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Discussion

In previous studies it was shown that the size 2 and 2½ PLMA forms a more effective seal, indicated by a higher P_leak, than the same sizes CLMA in paediatric patients. The P_leak found in this study was similar to that reported in those studies. The ability, in this investigation, to apply PEEP=5 cm H2O to any patient randomized to the PEEP group proves that the higher P_leak of the PLMA enables anaesthetists to use a mode of ventilation that has not been reported with its use in paediatric patients, yet. With the CLMA, positive pressure ventilation in paediatric patients can be difficult or even impossible when the required PIP is higher than the P_leak obtained with the CLMA in that patient. Strategies to overcome this limitation of the CLMA are application of a low tidal volume of 6–8 ml kg–1, I:E ratio of 1:1, low inspiratory flow rates and avoidance of PEEP. Application of an adequate tidal volume (larger than 6–8 ml kg–1) or PEEP has been suggested to counteract lung collapse due to atelectasia and airway closure in adult and paediatric patients when the tracheal tube is used. So far, studies showing the effect of PEEP on gas exchange have not been carried out using the LMA. Therefore, the first objective of our study was to find out whether the ability to apply PEEP using the PLMA could improve gas exchange, indicated by a higher Paco2. Our results demonstrate that application of PEEP=5 cm H2O under general anaesthesia improves gas exchange when the PLMA is used for PCV. This was evidenced by a significantly higher mean Paco2 (P=0.001). A limitation of our study is that unlike Serafini and colleagues7 we did not obtain radiological confirmation; however, we consider it likely that the improved gas exchange under PCV and PEEP=5 cm H2O is associated with the recruitment of collapsed lung tissue.

As the Paco2 under Fio2=0.3 was supranormal in both groups some clinicians would not consider the increased Paco2 in the PEEP group to be clinically relevant in healthy children. However, the technique of combining the PLMA with PCV and PEEP to improve gas exchange might be beneficial in children with lung disease; furthermore, as use of the PLMA is less likely to provide inadequate seal pressures this reduces the likelihood that it might need to be exchanged for a tracheal tube in children in whom positive pressure ventilation with PEEP is required to improve oxygenation. Therefore, the PLMA may be a better choice than the CLMA in paediatric patients with low lung compliance or a high airway resistance requiring high PIP, for instance, patients with bronchopulmonary dysplasia or reactive airway disease. It has been shown that supraglottic airway devices can be less irritating to the upper and lower airway than the tracheal tube so that particularly these patients can benefit from avoidance of tracheal intubation.
hypercarbia. In the most recent study von Goedecke and colleagues were able to show that pressure support ventilation improved gas exchange compared with continuous positive airway pressure ventilation using the PLMA, but hypercarbia was present in both groups indicated by raised \( E_{\text{CO}_2} \) values of 6.1 (0.8) kPa and 6.9 (0.9) mmHg, respectively. In our study normal ventilation was possible in all children. In patients at risk, use of the PLMA with PCV should permit ventilation to a normal \( P_a_{\text{CO}_2} \). Application of PEEP could be used to potentially improve oxygenation in these patients, too.

Our results are in contrast to a study in adult patients suggesting that the use of a supraglottic airway device might not induce the same pulmonary responses, such as reflex bronchoconstriction, that can worsen gas exchange when the tracheal tube is used. We found that without use of a counter measure like application of PEEP arterial oxygenation was reduced. This suggests that in paediatric patients either similar pulmonary responses as with the use of the tracheal tube are activated or physiologic airway closure leads to an impairment of gas exchange during use of a supraglottic airway device and a controlled mode of ventilation without PEEP. This demonstrates, as for other areas of paediatric research, that the results of studies on the use of supraglottic airway devices in adults cannot automatically be translated into a paediatric population.

In conclusion, we found that PCV without PEEP leads to a decreased oxygenation compared with PCV with PEEP when a supraglottic airway device is used in paediatric patients. The PLMA can be used to apply PEEP=5 cm \( H_2O \) during PCV and thereby improve gas exchange in healthy paediatric patients. Further studies are required to assess the value of our findings in paediatric patients with pulmonary disease.

Acknowledgements

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