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Comparison of the LMA-ProSeal™ and LMA-Classic™ in children

H. Shimbori[1]*, K. Ono[1], T. Miwa[1], N. Morimura[2], M. Noguchi[1] and K. Hiroki[1]

[1]Department of Anaesthesia, Kanagawa Children's Medical Centre, 2-138-4 Mutsukawa, Minami-ku, Yokohama 232-8555, Japan. [2]Trauma and Critical Care Center, Teikyo University School of Medicine, 2-11-1 Kaga, Itabashi-ku, Tokyo, 173-8606 Japan

**Corresponding author. Present address: Department of Anaesthesia, Fujisawa City Hospital, 2-6-1 Fujisawa, Fujisawa City 251-8550, Japan. E-mail: epi@yk.rim.or.jp*

Background. The LMA-ProSeal™ is a new laryngeal mask airway with a rear cuff and drainage tube that allows a higher seal pressure than the LMA-Classic™ for the same intra-cuff pressure, and it permits drainage of gastric secretions and access to the alimentary tract. The LMA-ProSeal can be used in children but it does not have a rear cuff. This study compared the LMA-ProSeal and the LMA-Classic in children for ease of insertion, airway sealing pressure and fibre-optic visualization.

Methods. Sixty ASA I–II children undergoing herniorrhaphy, orchiopexy or myringotomy were included. The patients were randomly assigned to size 2 LMA-Classic™ or size 2 LMA-ProSeal groups for airway management. We assessed success rates at first attempt of insertion, airway sealing pressure, fibre-optic position, success rates of gastric tube placement and postoperative blood staining of the device, tongue–lip–dental trauma and hoarseness.

Results. There was no statistical difference between the two groups for the success rates at first attempt of insertion, airway sealing pressure and fibre-optic position. Gastric tube insertion was successful in 90% of cases in the LMA-ProSeal group. The LMA-Classic had a higher rate of postoperative blood staining, but there was no tongue–lip–dental trauma or hoarseness in either group.

Conclusion. We conclude that ease of insertion and airway sealing pressure are similar between the LMA-ProSeal and the LMA-Classic in children.

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The LMA-ProSeal™ is a new laryngeal mask airway with a rear cuff and drainage tube that allows a higher seal pressure than the LMA-Classic™ for the same intra-cuff pressure and permits drainage of gastric secretions and access to the alimentary tract.[1] These characteristics may contribute to protection against gastro-oesophageal regurgitation and reduction in the risk of gastric insufflation. Details of the structure and an explanation of these devices is available on the manufacturer's web site (http://www.lmaco.com/html/proseal.html). Recent studies showed that the LMA-ProSeal provided effective ventilation during laparoscopic cholecystectomy without severe complications.[2 3] On the other hand, the LMA-ProSeal had a larger and more flaccid cuff compared with the LMA-Classic, and difficulty of insertion has also been pointed out.[4–6]

An LMA-ProSeal specially designed for children (size 1.5, 2, 2.5) is now available. One of its features is the lack of a rear cuff, which is different from the adult ones. We hypothesized that the absence of the rear cuff in the LMA-ProSeal for children may not produce a superior seal pressure or more difficult insertion compared with the LMA-Classic. We therefore compared the LMA-ProSeal and the LMA-Classic in children concerning ease of insertion, airway sealing pressure and fibre-optic visualization.

Methods

After approval by the institutional human studies committee and parental consent, 60 ASA physical status I–II paediatric

patients (aged 1–6 yr, weight 10–20 kg) undergoing herniorrhaphy, orchiopexy or myringotomy were included in the study. Patients with lung disease, known airway problems, upper respiratory tract symptoms or any condition that increases the risk of gastro-oesophageal regurgitation were excluded. After enrolment, the patients were randomly assigned to a size 2 LMA-Classic group or a size 2 LMA-ProSeal group for airway management using the sealed envelope method.

All patients were premedicated with oral diazepam 0.5 mg kg^{-1} or midazolam 0.3 mg kg^{-1}, 1 h before induction of anaesthesia. After standard monitoring devices had been applied, anaesthesia was induced by inhalation of nitrous oxide (N_2O), oxygen and sevoflurane. Once an adequate depth of anaesthesia had been achieved, each device was inserted by experienced anaesthesiologists who had used the LMA-Classic more than 100 times and the LMA-ProSeal more than 20 times, with the index finger insertion technique as per manufacturer's instructions. Both devices were fixed by taping the tube over the chin and the cuff was inflated with air to 60 cm H_2O using an ergonomic pressure gauge (Hi-Lo Hand Pressure Gauge; Mallinckrodt Medical, Germany). An effective airway was judged by a square-wave capnograph trace, normal thoraco-abdominal movement and inaudibility of stridor. If an effective airway could not be achieved, the device was removed and three attempts were permitted before failure of insertion was recorded. If the three attempts were unsuccessful, either an alternative device was inserted or the trachea was intubated. The number of insertion attempts were recorded. Five minutes after establishment of a patent airway with the LMAs, intracuff pressure was set at exactly 60 cm H_2O using the pressure gauge again. The airway sealing pressure was determined, as described previously, by closing the expiratory valve of the circle system at a fixed gas flow of 3 litre min^{-1}, noting the airway pressure (maximum allowed was 40 cm H_2O) at which equilibrium was reached.[7] At this time, gas leakage was determined at the mouth (audible), the stomach (epigastric auscultation) or the drainage tube (bubbling of lubricant placed on the proximal end of the drainage tube). The fibre-optic position of the airway tube was determined by passing a fibre-optic scope through the airway tube to a position 1 cm proximal to the end of the tube. The airway view was scored using an established scoring system[8] (1=vocal cords not seen; 2=vocal cords and anterior epiglottis visible; 3=vocal cords and posterior epiglottis visible; 4=only vocal cords visible). In the LMA-ProSeal group only, a lubricated 10-French gastric tube was inserted through the drainage tube. Successful placement (aspiration of gastric contents or detection of injected air by epigastric auscultation) or failure (failure to advance the gastric tube within two attempts) was recorded. At the end of the surgical procedure, anaesthesia was discontinued and the device was removed. Postoperative blood staining of the LMA, tongue–lip–dental trauma and hoarseness were recorded after removal of the device.

Table 1 Patient characteristics. Data are mean (range) for age or mean (SD)

	LMA-Classic (*n*=30)	LMA-ProSeal (*n*=30)
Gender (male/female)	23/7	19/11
Age (months)	43 (16–72)	39 (12–72)
Weight (kg)	14.5 (3.1)	14.2 (3.7)
Height (cm)	95.9 (11.3)	94.2 (12.3)
Type of surgery		
Herniorrhaphy	22	21
Orchiopexy	5	3
Myringotomy	3	6

Table 2 Comparison between the LMA-ProSeal and the LMA-Classic

	LMA-Classic (*n*=30)	LMA-ProSeal (*n*=30)	*P*-value
Attempts at insertion (*n*)			0.47
1	24	27	
2 or 3	6	3	
Seal pressure (cm H_2O)	18 (6)	19 (7)	0.56
Fibre-optic grade (*n*)			0.77
1	8	6	
2	7	10	
3	4	5	
4	11	9	
Complications (*n*)			
Blood staining	4	2	0.67
Tongue–lip–dental trauma	0	0	
Hoarseness	0	0	

Sample size was based on a crossover pilot study of 10 patients and was selected to detect a projected difference of 30% between the groups for airway sealing pressure for a type 1 error of 0.05 and a power of 0.8. Parametric data were analysed with the unpaired *t*-test and non-parametric data were analysed with the χ^2-test. Unless otherwise stated, data are presented as mean (SD). Significance was taken as $P<0.05$.

Results

There was no difference between the two groups with respect to demographic and surgical details (Table 1). In all patients, an LMA was inserted within three attempts. The success rates at first attempt of insertion were 24/30 (80%) for the LMA-Classic and 27/30 (90%) for the LMA-ProSeal (NS). Airway sealing pressure was similar for the two devices (Table 2). Gas leakage at airway sealing pressure occurred only from the mouth, and gas leakage from the other locations was not detected in all cases. There was no difference in the fibre-optic score (Table 2). With the LMA-ProSeal, gastric tube placement was successful in 27 cases (90%). The LMA-Classic had a higher rate of postoperative blood staining, but there was no significant difference (4/30 *vs* 2/30; $P=0.67$). Tongue–lip–dental trauma and hoarseness were not detected in either group.

Discussion

The most important findings in our study were that ease of insertion and airway sealing pressure were similar between

the LMA-ProSeal and the LMA-Classic in children. These findings contrast with those described in adults. We tested only one size, No. 2, because there was only one size of the LMA-ProSeal available for children at the time of this study.

Several reports suggest that insertion of the LMA-Classic is easier and quicker than that of the LMA-ProSeal in adults. Brimacombe and colleagues presumed that the difficulties were caused by the larger cuff impeding digital intra-oral positioning and propulsion into the pharynx, the lack of a backplate making the cuff more likely to fold over at the back of the mouth, and the need for more precise tip positioning to prevent air leaks up the drainage tube.[4 6] In our study, there was no difference in ease of insertion. Several factors may have contributed to these findings. The main factor is probably the lack of a rear cuff. In practice, when we deflate the cuff of the LMA-ProSeal completely, a fold occurs and this fold may prevent smooth insertion of the device. The size 2 LMA-ProSeal does not have a rear cuff; therefore no fold occurs. Another factor may be due to the airway tube and the drainage tube linings being side by side. This prevents rotation of the airway tube during insertion, especially in the narrow oral space in children, impeding digital positioning.

On the other hand, we must also consider the possibility that our lower success rates at the first insertion attempt for the LMA-Classic contribute no difference between the two devices in ease of insertion. Previous studies have reported success rates of LMA insertion in children of 67–99%,[9–13] which are comparable with our result of 75%. The difference in the rates may result from the different definitions of successful insertion and insertion technique.

Although it has been reported that the LMA-ProSeal provides a better airway seal than the LMA-Classic in adults, there was no difference between the two devices in our study. Several reports suggest that the better sealing pressure in the LMA-ProSeal is mainly due to the back cuff.[4–6] The lack of a back cuff in size 2 LMA-ProSeal means that it could not form a better seal than the LMA-Classic. In 1999, Lopez-Gil and colleagues studied a prototype of the LMA-ProSeal for children, which had a rear cuff.[14] They stated that sealing pressure was over 40 cm H_2O in all cases. This confirms the importance of a rear cuff in airway seal pressure.

In our study, the sealing pressure was measured by closing the expiratory valve of the circle system at a fixed fresh gas flow of 3 litre min^{-1} until airway pressure reached a steady value. Lopez-Gil and colleagues compared four kinds of measurements of the airway sealing pressure,[15] which involved detection of an audible noise by listening over the mouth, detection of exhaled carbon dioxide by placing a gas sampling line for the capnograph inside the mouth, detection of a steady value airway pressure while occluding the expiratory valve of the circle system, and detection of an audible noise using a stethoscope placed just lateral to the thyroid cartilage. They concluded that all four tests were excellent.

Gastric tube insertion was successful in most cases, which is similar to the situation in adults. Whether routine gastric tube placement is needed may be controversial, but it is useful when gastric insufflation occurs after face mask ventilation.

In our study, the fibre-optically determined anatomical positions of the two devices did not differ. Brimacombe and Keller reported that fibre-optically determined anatomical position was better with the LMA-Classic, and they considered that this may be related to the larger cuff catching the epiglottis during insertion with the LMA-ProSeal.[4] Given that the pharynx structures in adults and children vary, it is not surprising that LMA positions in our study differ from those in adult studies. This fibre-optic scoring system, originally designed for adults, may also be a factor.

A limitation of our study is that the data were collected by an unblinded observer.

We conclude that there is no difference between the LMA-Classic and the LMA-ProSeal concerning ease of insertion and seal pressure in children.

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