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Comparison of cuff-pressure changes in silicone and PVC laryngeal masks during nitrous oxide anaesthesia in spontaneously breathing children

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Abstract

Background. The purpose of this study was to evaluate the cuff pressures of four different laryngeal masks in paediatric patients undergoing routine surgery and to determine whether there is a substantial increase in cuff pressure when silicone masks are used compared to PVC laryngeal mask airways.

Methods. Hundred and forty patients aged < 16 yr were randomly allocated to receive one of four extraglottic airway devices: LMA-Classic; LMA-Unique; Soft Seal; or Cobra-PLA. Intracuff pressure was monitored continuously throughout the operative intervention. The primary outcome was measurement of an increase in cuff pressure. First attempt success rate, effective airway time, anatomical position of the airway and incidence of airway morbidity data were monitored.

Results. Mean cuff pressure increased within 5 min of N_2O exposure, and was substantially higher in the silicone LMA-C, compared to the PVC-based extraglottic airway devices tested, reaching a plateau of the cuff pressure after 45 min. The overall first attempt success rate (97%) and the mean effective airway time (24 ± 9 sec) were very satisfactory and all patients underwent successful surgery. Anatomical position was adequate in most airways, although in 34% of the patients in the Cobra group herniation of either the epiglottis or arytenoids were detected. Airway morbidity due to the devices was insignificant.

Conclusions. This study demonstrated a substantial increase in cuff pressure during anaesthesia for children in whom a silicone-based LMA-C was used, whereas PVC-based extraglottic airway devices showed a much lower increase.

Key words: anaesthesia, pediatrics, airway; equipment, laryngeal masks, intracuff pressure

When Archie Brain designed the laryngeal mask airway in 1981, it was hardly possible to imagine the popularity this elegant device was going to achieve among anaesthetists and physicians involved in critical care and emergency medicine. The device forms a low-pressure airtight seal against the glottis, combining the ease of insertion and adequate airway patency. As such, the laryngeal mask has replaced the use of endotracheal intubation for a large variety of procedures in adults and children.

The use of extraglottic airway devices (EADs) in paediatric anaesthesia has become immensely popular and currently EADs are used in the vast majority of paediatric anaesthetic procedures. Paediatric sizes of EADs are scaled-down versions of adult EADs, in spite of differences in the airway anatomy of infants [1]. In contrast to adults for whom three sizes of EAD are generally available, in paediatrics the industry provides even more sizes (0.5––1–1.5–2–2.5 and 3).

Nevertheless, there is a certain number of inconsistencies in the use of paediatric EAD: 1) manufacturer's recommendations regarding (maximum) inflation volumes of the SGA cuff vary, and clinical endpoints have shown to be associated with cuff hyperinflation (cuff pressure > 60 cm H_20/5.9 kPa), both in *in vitro* and in vivo settings, and increased leakage around the EAD [2–5]; 2) measurement of intracuff pressure of the EAD is still not routine practice (70% of consultant paediatric anaesthetists from 7 countries have not been using cuff pressure monitoring on a regular basis or at all) [2]. The known risks of cuff hyperinflation are airway morbidity (sore throat, hoarseness, dysphagia, dysphonia, hypoglossal/lingual/recurrent laryngeal nerve palsies by exerting

pressure on the laryngeal and pharyngeal structures) [6], and increased leakage around the EAD (risk for inhalation of gastric contents) [5, 7].

Intracuff pressure of EAD not only may be too high at insertion of the device into the patient's mouth, but also increase during maintenance of anaesthesia, especially when N_20 is used, as demonstrated in adults [8, 9] and in an in vitro study on paediatric EADs [2]. This continuous increase in intracuff pressure can be as high as > 250% with the classic LMA [10] and results in cuff pressure > 120 cm H_20 (11.8 kPa) in all EADs tested when the maximum recommended inflation volumes are used [2].

In paediatric patients, an increase in cuff pressure might even be more detrimental than in adults, as the recommended injection volumes result in substantial rises in pharyngeal wall pressure, likely to exceed the pharyngeal mucosal capillary perfusion pressure [11, 12].

Our practice is not to rely on the inflation volume, but to inflate the cuff until a pressure of 60 cm H_20 (5.9 kPa) is obtained. In the following study, we compared the use of four EADs available in our hospital and recorded the cuff pressure in paediatric patients breathing spontaneously. The primary variable was cuff pressure values during maintenance of anaesthesia. We hypothesize that in paediatric patients cuff pressure increases when silicone masks are used and that the increase is substantially higher compared to PVC masks.

METHODS

Institutional Review Board approval and parental informed consent were obtained. The study was classified as a quality of care audit, with no change in the normal anaesthesia practice. We prospectively performed an observational study, including 140 ASA physical status I or II, consecutive, supinely anesthetised children, scheduled for elective surgery with the use of an EAD with an estimated duration of anaesthesia < 2 h. Patients aged < 16 yr were enrolled. Exclusion criteria were: age > 16 years, oral or nasal surgery, non-supine position required for surgery, necessary changes in position during procedures, preoperative sore throat or respiratory tract pathology, anticipated difficult airway, and cases considered unsuitable for the use of an EAD. The EADs were inserted for a wide range of routine general surgery.

The patients were randomly allocated according to a computer-generated sequence to receive one of the four EADs: 1) LMA-C/Classic; 2) LMA-U/Unique (both manufactured by the Laryngeal Mask Company Ltd, Seychelles); 3) Soft Seal/LM, (Portex, UK); or 4) Cobra/PLA (Engineered Medical Systems, Inc., USA). The LMA-C is made from silicone rubber and is a standard 'in clinical use', while the other three EADs are made from latex-free, medical grade polyvinyl chloride (PVC) and are single-use products.

A standard anaesthesia protocol was followed, and routine monitoring was applied. After the EAD was taken out of its sterile packet, routine pre-insertion tests of the cuff for leaks and herniation were performed immediately before use, as recommended by the manufacturers. The posterior aspect of the EAD was lubricated with a water-based lidocaine gel. Anaesthesia was in the supine position with the patient's head in the neutral position. Induction of anaesthesia involved the use of sevoflurane in oxygen via a facemask. Two anaesthesiologists, who had used each EAD at least 50 times, inserted all the devices according to the manufacturer's instructions. The manufacturer's weight-based recommendations were used for size selection (Table 1). The successful placement of an effective airway and adequate ventilation was confirmed by the presence of clinical endpoints, i.e. resistance to further downward movement,

Table 1. Sizing of EAD and maximal cuff inflation volume according to manufacturer's recommendations based on patient weight, as printed on a tube and/or package

EAD	LMA–Classic		LMA-Unique		SoftSeal*	CobraPLA	
Size	Weight (kg)	Max cuff volume (mL)	Weight (kg)	Max cuff volume (mL)	Weight (kg)	Weight (kg)	Max cuff volume (mL)
0.5	N/A	N/A	N/A	N/A	N/A	> 2.5	8
1	< 5	4	< 5	4	< 5	> 5	10
1.5	5–10	7	5–10	7	5–10	> 10	25
2	10–20	10	10–20	10	10–20	> 15	40
2.5	20–30	14	20–30	14	20–30	N/A	N/A
3	30–50	20	30–50	20	30–50	> 35	65
4	50–70	30	50–70	30	50–70	> 70	70
5	70–100	40	70–100	40	70–100	> 100	85
6	> 100	50	> 100	50	> 100	> 130	85

N/A: not available
*No indication of maximum cuff volume on EAD

observation of a slight outward movement of the device when inflating the cuff and chest wall movement with manual lung ventilation, listening the escape of any air leak by ventilating the patient against an outlet-valve pressure of 20 cm H_20 (2.0 kPa), good ability to ventilate with a sufficient seal, detection of a square-wave trace capnograph during manually-assisted ventilation and observation of reservoir bag movement on spontaneous ventilation.

Once the black line (LMA-C, LMA-U, Cobra) or blue line (Soft-Seal) was centrally positioned, the EAD pilot balloon cuff pressure was measured by using Endotest (Rush, Germany) to monitor the initial cuff pressure and adjusted to 60 cm H_20 (5.9 kPa) [13]. From this point on (time zero), EAD cuff pressures were monitored continuously until the end of the procedure using a pressure transducer S/5 AM (Datex-Ohmeda, GE Healthcare, Finland). The transducers were calibrated and zeroed to atmospheric pressure and placed on the patient's shoulder throughout the study. No further attempts were made to reduce the cuff pressure until the completion of surgery. The patient's head and neck were placed in a neutral position resting upon a closed silicone head ring to improve stabilization. The EAD was securely fixed using tape.

Two attempts were allowed before insertion was considered a failure. An insertion attempt was defined as placement of the EAD in the mouth. A failed attempt was defined as removal of EAD from the mouth. The time between picking up the EAD and obtaining an effective airway was recorded. If an effective airway could not be achieved, an alternative airway device or a different size was used, but no further data were collected.

All patients were allowed to breathe spontaneously on the EAD. Maintenance of anaesthesia was with 2–3% sevoflurane in N_2O/O_2 (F_IO_2-0.33) using a fresh gas flow of 2 L min^{-1}. Analgesia was with iv. fentanyl 3 µg kg^{-1} as required, and the wound was infiltrated with local anaesthetics by the surgeon. Patients underwent manually assisted ventilation until spontaneous ventilation resumed. At the end of surgery, the anaesthetic gas mixture was replaced by 100% O_2 to allow patient recovery; the EAD was removed (when protective reflexes returned to normal) and inspected for blood. Postoperative analgesia was standardised according the hospital's protocol for pain relief in children.

The following parameters of each patient were collected: gender, age, height, body weight, type of surgery and duration of EAD in situ. The ease of insertion was assessed by the effective airway time (the time between picking up the EAD and obtaining an effective airway), the number of EAD insertion attempts before successful placement, and the occurrence of complications (laryngospasm or SpO2 < 95%). Oropharyngeal leak pressure was determined by closing the expiratory valve of the circle system at a fixed gas flow of 2 L min^{-1} and noting the airway pressure (maximum allowed was 40 cm H_20/3.9 kPa) at which equilibrium was reached.

Anatomical position of the airway tube, as determined by passing a rigid endoscope through the airway tube to a position 1 cm proximal to the end of the tube and scoring the view, was performed immediately after fixation of EAD. The technique involves disconnecting the EAD from the anaesthesia breathing system, adopting the sniffing position to align the glottis and mouth, and advancing a 30° rigid 4 mm endoscope — Hopkins II Forward-Oblique Telescope (Karl Storz, Germany) to the distal end of the airway tube. The high-resolution images are then viewed on an external monitor. The position of EAD was assessed on the view of the glottis and graded as: 4 — complete visualization of the glottic aperture; 3 — partial visualization of the glottic aperture and the posterior epiglottis seen; 2 — partial visualization of the glottic aperture and the anterior epiglottis seen; 1 — vocal cords not visible; 0 — not possible. The further endoscopic evaluation regarded the visibility of the arytenoids and hypopharynx, the epiglottis-mask aperture bars contact, correct position of EAD and proper size choice or otherwise.

A research assistant recorded cuff pressure at 5 min intervals until the completion of surgery, (but no further action was taken). The attending anaesthesiologist was blinded to the intracuff pressure recordings during the procedure. The following complications were documented: aspiration or regurgitation, peripheral oxygen desaturation (SpO_2 < 95%), bronchospasm, airway obstruction, gastric insufflation, coughing, gagging or retching, hiccup, blood staining of the EAD, and tongue, lip, or dental trauma.

Postoperatively a research assistant, who was blinded to the patient group allocation, interviewed, where possible, the patients using a predetermined questionnaire to collect perioperative data, including predetermined definitions of pharyngolaryngeal complications for assessment. Age permitting, patients were asked about sore throat (constant pain, independent of swallowing), dysphonia (difficulty or pain on speaking), dysphagia (difficulty or pain on swallowing 2 and 24 h after surgery). Symptoms were graded as mild, moderate, or severe. The occurrence of rare complications of EAD insertion (nerve palsies) was noted.

The primary outcome measure of the study was the continuous measurement of intracuff pressure of four different EADs. We also recorded the number of insertion attempts, effective airway time, overall success rate, oropharyngeal leak pressure, endoscopic scores, position of EAD, choice of EAD and satisfaction scores as evaluated by the anaesthesiologist (1 — excellent; 2 — good; 3 — fair; 4 — poor; 5 — failure).

In order to calculate the sample size, we estimated that the final cuff-pressure difference between the silicone LMA-C and the other three EADs (PVC made) to be 33% lower in the latter. Sample size calculations were performed using H0:μ1 = μ2 (no difference between population means), two-sided hypothesis [14]. Standardised difference: 0.50 (SD) and estimated sample size — 30 patients per group. Power calculation required 120 patients to detect a 0.2 difference in the primary outcome with 95% power and 5% β error. The *U* and Kruskal-Wallis non-parametric tests were used for analysis of variables accordingly, in addition to the χ^2-test. All data are presented as a $\bar{x} \pm$ SD. Statistical significance was accepted at $p < 0.05$.

RESULTS

A total of 140 patients were studied. Five patients were excluded because cuff pressure monitoring was accidentally interrupted and another 2 because of the need for tracheal intubation due to conversion to open abdominal surgery; 133 children aged 1 to 182 months were included in this study. There were no important differences in the characteristics of patients between the four groups (Table 2).

A wide range of EAD sizes was used, i.e. sizes 1.0–5.0 for the LMA-C, LMA-U and Soft Seal group and sizes 0.5–3.0 for the Cobra group. Thirty-five children received the Cobra, 36 the Soft Seal, and two groups (31 patients each) were given either the LMA-C or the LMA-U. A successful operation and satisfactory anaesthesia were obtained in all patients and none of them experienced desaturation to $SpO_2 < 95\%$ during the surgical intervention. Laryngospasm did not occur and coughing at emergence was limited (4.8% of the patients) and of minimal consequences.

The mean effective airway time was shorter ($p < 0.05$) for LMA-C (22 ± 7 sec) and Soft Seal (23 ± 8 sec) patients than for LMA-U (26 ± 10 sec) and Cobra (27 ± 10 sec) patients (Table 3). The first attempt success rate on average reached 97%. All insertions of EAD were successful and no EAD insertions failed at the second attempt. Mean oropharyngeal seal pressure was 27.3 ± 6.1 cm H_20 (2.68 ± 0.6 kPa) and did not differ among the studied groups.

Cuff pressure increased within 5 min of N_2O exposure, and was substantially higher ($p < 0.01$) in the silicone EAD (LMA-C), compared to the PVC-based EAD (Fig. 1). Cuff pressure readings reached a plateau after 45 min, and at the end of surgery were higher ($p < 0.01$) in the LMA-C group (82.3 ± 4.7 mm Hg/11.0 ± 0.6 kPa), vs the LMA-U (52.9 ± 6.6 mm Hg/7.0 ± 0.9 kPa), Soft Seal (53.9 ± 9.1 mm Hg/7.2 ± 1.2 kPa) and Cobra (50.1 ± 5.6 mm Hg/6.7 ± 0.7 kPa) groups. The maximum values of cuff pressures at the end of the operation were observed in the LMA-C group, in which 74% of patients reached a cuff pressure > 75 mm Hg (9.9 kPa), compared to 3% in the LMA-U, 6% in Soft Seal and none in

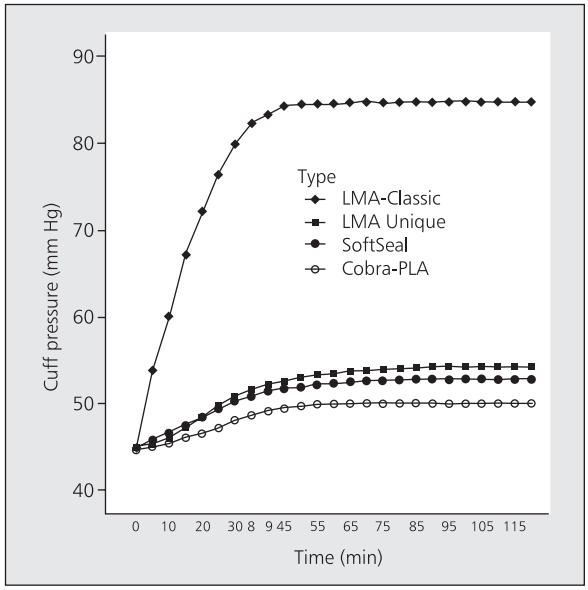

Figure 1. Cuff pressure increase during anaesthesia

Table 2. Demographic data of patients (numbers, $\bar{x} \pm$ SD, range)

Characteristic	Overall EAD n = 133	LMA-Classic n = 31	LMA-U n = 31	SoftSeal n = 36	CobraPLA n = 35
Sex, male: female	111:22	27:4	26:5	28:3	25:10
Age (months)	61 ± 45 (1–182)	57 ± 40 (3–169)	78 ± 53 (6–182)	56 ± 43 (8–174)	54 ± 42 (1–164)
Height (cm)	108 ± 28 (53–180)	108 ± 26 (58–152)	116 ± 31 (63–180)	105 ± 27 (72–175)	105 ± 29 (53–160)
Weight (kg)	21.6 ± 14.6 (4-82)	19.8 ± 11.2 (6–62)	27.9 ± 20.9 (7–82)	19.9 ± 12.4 (5–60)	19.3 ± 11.3 (4–52)
Maximum mouth opening (mm)	36 ± 9	35 ± 6	36 ± 9	38 ± 7	36 ± 9
Dentition: double: single: none	120:0:13	28:0:3	30:0:1	34:0:2	28:0:7

Table 3. Anaesthetic characteristics (numbers, $\bar{x} \pm SD$)

EAD	Overall n = 133	LMA-Classic n = 31	LMA-Unique n = 31	SoftSeal n = 36	CobraPLA n = 35
Duration of anaesthesia (min)	41.7 ± 16.6	40.5 ± 13.7	39.7 ± 16.2	42.2 ± 21.3	44.1 ± 14.0
Size					
0.5:1:1.5:2:2.5:3:4:5 (n)	2:5:21:53:28:18:5:1	0:2:0:13:11:5:0:0	0:0:3:12:7:4:4:1	0:0:7:12:10:6:1:0	2:3:11:16:0:3:0:0
0.5:1:1.5:2:2.5:3:4:5 (%)	1:4:16:40:21:13:4:1	0:6.5:0:42:35.5:16:0:0	0:0:10:39:22:13:13:3	0:0:19:33:28:17:3:0	6:8:31:46:0:9:0:0
(size range)	(0.5-5.0)	(1.0-3.0)	(1.5-5.0)	(1.5-4.0)	(0.5-3.0)
Effective airway time (sec)	24 ± 9	22 ± 7	26 ± 10	23 ± 8	27 ± 10
Number of insertion attempts					
1:2:3, n (%)	129:4:0 (97:3:0)	31:0:0 (100:0:0)	29:2:0 (94:6:0)	36:0:0 (100:0:0)	33:2:0 (94:6:0)
Oropharyngeal leak pressure (cm H_20)	27.3 ± 6.1	26.4 ± 7.0	28.1 ± 6.3	28.3 ± 3.7	± 7.2
Mean cuff pressure (mm Hg)					
start of operation	45 ± 0	45 ± 0	45 ± 0	45 ± 0	45 ± 0
end of operation	59.4 ± 15.9	82.3 ± 4.7[a]	52.9 ± 6.6	53.9 ± 9.1	50.1 ± 5.6
increase	14.4 ± 15.9	37.3 ± 4.7[a]	7.9 ± 6.6	8.9 ± 9.1	± 5.6
Maximum cuff pressure at end of operation, n (%)					
45 to < 75 mm Hg	107 (80%)	8 (26%)[a]	30 (97%)	34 (94%)	35 (100%)
75 to < 100 mm Hg	22 (17%)	19 (61%)[a]	1 (3%)	2 (6%)	0
100 to 125 mm Hg	4 (3%)	4 (13%)[a]	0	0	0
Anatomical position of EAD via endoscopy					
Epiglottis		22:9 (71:29)	24:7 (77:23)	33:3 (92:8)[b]	22:13 (63:37)
— seen: yes:no; n (%)	101:32 (76:24)	3:28 (10:90)	2:29 (6:94)	†	13:22 (37:63)[c]
— touching MAB: yes:no; n (%)	18:79 (19:81)	0:31 (0:100)	0:31 (0:100)	†	8:27 (23:77)[c]
— herniation thru MAB: yes:no; n (%)	8:89 (8:92)				
Glottis		28:3:0 (90:10:0)	27:4:0 (87:13:0)	33:3:0 (92:8:0)	27:7:1 (77:20:3)
— vocal cords seen: full:partial:no; n (%)	115:17:1 (86:13:1)	31:0 (100:0)	31:0 (100:0)	36:0 (100:0)	30:5 (86:4)[d]
— arytenoids seen: yes:no; n (%)	128:5 (96:4)				
— herniation arytenoids thru MAB:		0:31 (0:100)	0:31 (0:100)	0:36 (0:100)	4:31 (11:89)[d]
• yes:no; *n* (%)	4:129 (3:97)	27:4 (87:13)	29:2 (94:6)	36:0 (100:0)	28:7 (80:20)
• hypopharynx visible: yes:no; n (%)	120:13 (90:10)	28:3 (90:10)	31:0 (100:0)	36:0 (100:0)	††
Cuff position optimal; yes:no, n (%)	95:3	8:20:0:3:0	7:24:0:0:0	4:32:0:0:0	13:19:0:3:0
Endoscopic score; 4:3:2:1:0, n (%)	32:95:0:6:0	(26:65:0:9:0)	(23:77:0:0:0)	(11:89:0:0:0)	(37:54:0:9:0)
	(24:71:0:5:0)	30:1 (97:3)	31:0 (100:0)	36:0 (100:0)	34:1 (97:3)
Correct choice size EAD; yes:no, n (%)	131:2 (98:2)				
Satisfaction score, 1:2:3:4:5, n (%)	126:6:1:0:0	31:0:0:0	29:2:0:0	34:2:0:0	32:2:1:0
	(95:4.5:0.5:0:0)	(100:0:0:0)	(94:6:0:0)	(94:6:0:0)	(91:6:3:0)

MAB = mask aperture bars; EAD = extraglottic airway device; N/A: not applicable

† No assessment made as Soft Seal has no mask aperture bars; †† observation not possible as the position of the cuff is too high to evaluate

Compared to the other EADs: [a]the cuff pressure with LMA-C increased substantially ($p < 0.01$); [b]the epiglottis was seen more frequently ($p < 0.05$) with SoftSeal; [c]the epiglottis was touching and herniating through the grille of Cobra-PLA more frequently ($p < 0.01$); [d]the arytenoids were touching and herniating through the grille of Cobra-PLA more frequently ($p < 0.05$)

Cobra group. Cuff pressures were not higher in smaller sizes than in larger sizes.

The epiglottis was more frequently ($p < 0.05$) visible with Soft Seal (92%) than LMA-U (77%), LMA-C (71%) and Cobra (63%). The epiglottis was in contact with mask aperture bars in 10% of LMA-C, 6% of LMA-U and 37% of Cobra patients. Herniation of the epiglottis (23%) and arytenoids (11%) did occur only in the Cobra group. In general, with the Soft Seal EAD no herniation of the epiglottis or arytenoids occurs, as these EADs have no mask aperture bars.

The position of the cuff was optimal for the LMA-U and Soft Seal groups, and no rotation was detected. The cuff position was optimal in all but 3 patients of the LMA-C group, showing some distortion of the cuff. The position of the Cobra cuff was too high to be determined. Blood was not detected during endoscopy.

The correct choice of the EAD determined via endoscopy was obtained in 97% of patients in the LMA-C and Cobra groups and 100% of patients in the LMA-U and Soft Seal groups. The overall satisfaction score revealed by the anaesthesiologist was excellent to good in all cases, except for one patient in the Cobra group who seemed to be inflicted with a cold. Blood staining on the EAD, mouth, lip or tongue injury at the time of removal, and airway morbidity were found incidentally, but did not differ among the groups (Table 4). In 40 patients, no information could be obtained about airway morbidity, due to the patients` age.

Table 4. Trauma and airway morbidity data

	All EAD n = 133	LMA-Classic n = 31	LMA-Unique n = 31	SoftSeal n = 36	CobraPLA n = 35
Blood staining at time of removal no:stain:yes	126:5:2	30:0:1	30:1:0	35:1:0	30:3:2
Mouth, lip or tongue injury	4	0	1	1	2
Airway morbidity, grade 0:1:2:?					
— sore throat	87:5:1:40	14:1:0:16	25:1:1:4	28:1:0:7	20:2:0:13
— dysphonia	91:1:1:40	15:0:0:16	26:1:0:4	29:0:0:7	21:0:1:13
— dysphagia	92:1:0:40	15:0:0:16	26:1:0:4	29:0:0:7	23:0:0:13

? — no assessment possible

DISCUSSION

This is the first prospective observational quality of care study providing evidence that a standard insertion technique, comparing four different brands of EADs, results in satisfactory airway management during anaesthesia in children. The ease of insertion was excellent with a high first-attempt success rate, a short effective airway time, adequate oropharyngeal leak pressures and anatomical positions of EADs and a low incidence of postoperative airway morbidity.

However, our study registered a substantial increase in cuff pressures during anaesthesia in the silicone-based LMA-C group, as compared to much lower increases noted in the PVC-based EAD group. Our study revealed that cuff pressures of EAD could markedly increase during anaesthesia with the use of N_20 in children, confirming the findings of others [2, 3, 12, 14, 15]. It was demonstrated that in children cuff inflation with a mixture of $N_20/0_2$ prevented N_20 diffusion into the cuff, hence cuff overinflation, whereas cuff inflation with air, prior to administration of N_20 anaesthesia, resulted in additional diffusion of N_20 into the cuff [16]. Some authors found that the use of clinical endpoints alone was associated with significant hyperinflation of cuffs in almost all EADs studied, with an exacerbation when N_2O was used [15]. During anaesthesia, the increase in intra-cuff pressure when filled with air results from diffusion of O_2 and inhalation anaesthetics into the cuff, warming of gases inside the cuff, and mainly, diffusion of N_2O into the cuff. Various other factors affect the rate of diffusion of N_20 inside and outside the cuff, such as the area available for diffusion, the cuff material, the number of EAD uses, or duration and depth of anaesthesia. Moreover, the insertion technique itself, the size of the EAD used, as well as position and manipulation of the head during the intervention, influence the level of cuff pressure. On the other hand, intermittent use of manometry, by disconnecting each time the manometer from the pilot balloon, results in partial deflation of the cuff.

Head and neck movements can more easily distort the oropharyngeal space and affect the anatomical position and function of EAD in children than in adults [17]. Changes of the head and neck position (neutral, maximal flexion/extension, rotation to the left/right) result in substantial differences in effective airway time [18], oropharyngeal leak pressures and fibreoptic images [17]. The use of flexible EAD may lead to additional pressure exerted by the EAD onto the mucosa because of the flexion forces with the EAD tubing following taping [19]. In our study, we carefully avoided any movement of the head and neck once cuff pressure measurements were started. Since cuff pressure monitoring is not routinely used by many anaesthetists, the latter may be unaware of the correct volume of air required to insufflate the cuff (clinical endpoints should not be used as a sole guide for determining cuff inflation in EAD). N_2O may rapidly diffuse into the air-filled EAD cuff causing a rise in cuff pressure and volume. Some findings proved that cuff pressure increased > 250% within 5 min in an in vitro experiment [20]. Extreme values of cuff pressures, exceeding 250 mm Hg (33.3 kPa) in adults were reported, when silicone cuff EADs were used, combined with the use of N_20 during maintenance of anaesthesia [21].

Cuff pressures can be significantly higher in paediatrics, especially when smaller sizes are used. In a large study, cuff pressures ≥ 60 cm H_20 (5.9 kPa) were recorded in 20.5% of children, and in two thirds of patients with a size 1 laryngeal mask [4]. Depending on the initial cuff volume, size and compliance of the EAD used, only a very little fraction of air of a maximum recommended cuff filling volume is required to achieve a cuff pressure of 60 cm H_20 (5.9 kPa) [22]. The use of manometry for EADs reduces postoperative pharyngolaryngeal adverse effects by 70% [23].

The optimal intracuff pressure in EADs has not yet been determined in clinical studies. Is the maximum recommended inflation pressure the same across all EAD sizes for both adults and children? The inflation pressure of 60 cm H_20 (5.9 kPa), as recommended in adults, is higher than the mean arterial blood pressure in children and infants and may therefore be inappropriate in paediatrics. All manufacturers supply recommendations about the safe maximum filling

volumes, although the value of maximum cuff inflation volumes (room air) has seldom been challenged in clinical studies in children. Manufacturing sizing recommendations are inadequate according the new American Society for Testing and Materials (ASTM) standards adopted by the Supralaryngeal Airway Task Group, which stressed the need for expert clinical judgment in selecting the size of a supralaryngeal airway (Paul Dryden - member of Supralaryngeal Airway Task Group, 24]. Clinicians need more evidence of criteria for the choice of EAD size (based on age, gender, weight), determination of the optimal inflated cuff (initial inflation volume of the cuff; adequate oropharyngeal seal with minimal leakage around the cuff; avoiding hyperinflation), maximum cuff inflation volume, maximum cuff pressure, and ideal anatomic position of EAD (fibreoptic anatomy criteria) for both adults and children, as the parameters listed may be different.

In this study, the mean effective airway time, mean first--attempt success rate, and mean oropharyngeal leak pressure were similar to the findings of other studies in children.

During endoscopic evaluation of the EAD anatomic position, the vocal cords, arytenoids and epiglottis were more frequently visible with the LMA-C, LMA-U, and Soft Seal than with the Cobra. The overall anatomic position of EAD in children was better than in adults [25, 26], which might be explained by a more cephalad position of the larynx in children. The epiglottis was in contact with the mask aperture bars in 19% of the total patient group, and in 37% of Cobra patients. The epiglottis and arytenoids herniated through the mask aperture only in the Cobra group. Interestingly, this does not always predict worse clinical conditions.

Limitations of our study include: 1) the observational character of the study; 2) impossible blinding, although anaesthetic characteristics were recorded by an observer; 3) unreliability of airway morbidity evaluation in small children; 4) all patients breathing spontaneously; consequently our results may not be applicable to patients ventilated mechanically; 5) lack of data on the optimal cuff pressure in paediatric patients. Extrapolation of our findings to the emergency airway management context with a different spectrum of practitioners in a more hostile environment outside the operating room, awaits further evidence.

CONCLUSIONS

1. Excessive values of cuff pressure are recorded in silicone EADs when N_20 is used during maintenance of anaesthesia in children, providing further evidence for omitting the overall use of N_20 and for changing silicone to PVC EADs. Cuff pressure readings with manometry should be routinely performed throughout the use of an EAD, not only to avoid unnecessary hyper- or hypoinflation (requiring adjustment by deflating or inflating the cuff to obtain an intracuff pressure of 60 cm H_20/5.9 kPa) but also to improve cuff sealing ((as leakage may occur around the cuff)) and should be recommended as the best anaesthetic practice to obtain a good seal and to reduce pharyngolaryngeal complications.
2. Information about maximum recommended cuff--filling volumes in SGA children, as specified by the manufacturers and printed on the devices, is misleading and should be removed. We plead for recommending applying the instructions included in the clinical guidelines about the use of a minimal inflation volume of the cuff until an effective airway seal is obtained, and maximum cuff pressures at insertion and maintenance of anaesthesia, combined with the continuous use of a cuff pressure manometer, adjusting any excessive or inadequate intracuff pressure by deflating or inflating the cuff, throughout the operation. Manometers should be readily available at any anaesthesia workstation to allow routine cuff pressure measurements in both endotracheal and EAD cuffs, thus to improve safety during anaesthesia. This practice is even more important in a paediatric population.

CONFLICT OF INTEREST

No conflict of interests declared by authors.

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