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Intracuff Pressures Do Not Predict Laryngopharyngeal Discomfort after Use of the Laryngeal Mask Airway

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***Background*: The laryngeal mask airway (LMA) is a large foreign body that exerts pressure on the pharyngeal mucosa, which may lead to throat discomfort. To determine whether intracuff pressures are associated with such discomfort, a randomized, double-blind study was performed to determine the effect of high *versus* low intracuff pressures.**

***Methods*: Seventy healthy women were randomly allocated to two groups with different LMA intracuff pressures: 30 mmHg (low pressure) or 180 mmHg (high pressure). Pressures were controlled with a microprocessor-controlled monitor. Insertion of the LMA was performed by one investigator and facilitated with propofol and verified fiberoptically. Anesthesia was maintained with enflurane and nitrous oxide. The LMAs were removed while the patients were still asleep. Patients assessed their laryngopharyngeal complaints (sore throat, dysphagia, hoarseness) at 8, 24, and 48 h after operation on a 101-point numerical rating scale.**

***Results*: No significant difference was found in the overall incidence of complaints between both groups (low pressure: 50%; high pressure: 42%). On the day of surgery, dysphagia (38%) was more frequent than sore throat (16%) or hoarseness (6%) ($P < 0.05$) within the high-pressure group. In the low-pressure group, the incidence of these complaints was not significantly different (33%, 20%, and 23%, respectively). On the following day, dysphagia was still present in 20% of the women in both groups, and other symptoms comprised 10% or less of the reported complaints.**

***Conclusions*: Differences in LMA intracuff pressures did not influence either the incidence or severity of laryngopharyngeal complaints. (Key words: Airway: management. Complications: dysphagia, hoarseness, sore throat. Laryngeal mask airway: cuff pressure.)**

THE laryngeal mask airway (LMA) has become an increasingly accepted alternative to endotracheal intubation and mask ventilation during elective surgery.[1] The air-inflated cuff of the laryngeal mask covers the laryngeal inlet and fills the hypo- and part of the mesopharyngeal space.[2] Thus, it is not surprising that patients sometimes report a sore throat. The incidence of postoperative throat complaints is reported to be between 0 and 50% of cases.[3-8] Research in children has shown no difference in the incidence of sore throat after LMA and endotracheal intubation; in a recent study comparing LMA and endotracheal intubation in adults, a similar incidence of minor laryngopharyngeal complications was found.[9,10] Apart from rare injuries that are caused during insertion, the pressure of the cuff of the LMA on the pharyngeal mucosa may be responsible for the discomfort. Evidence is lacking that the levels of intracuff pressures of the LMA play an important role for the development of laryngopharyngeal discomfort. Nevertheless, some authors recommend the measurement and control of intracuff pressures, although others disagree.[3,11-15]

In the present study, we examined the effect of carefully controlled intracuff pressures on postoperative complaints.

Materials and Methods

After we received approval from the local ethics committee and written informed consent, 70 nonsmoking women, classified as American Society of Anesthesiologists (ASA) physical status 1 or 2 and Mallampati classification 1 or 2, were enrolled in a prospective, randomized, and double-blinded study. Women with a body mass index more than 30 kg/m^2, with any symptoms

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of upper respiratory tract infection, or long-term use of analgesic medication were excluded. All patients were scheduled for breast surgery with an expected duration of approximately 90 min. Before induction of anesthesia, the patients were randomly allocated, by opening a sealed envelope, to two groups in which the intracuff pressure was maintained at different levels: high pressure (intracuff pressure, 180 mmHg; n = 35) and low pressure (intracuff pressure, 30 mmHg; n = 35).

About 1 h before induction, all patients were premedicated with 7.5 mg midazolam given orally. Standard monitors were applied. Anesthesia was induced with alfentanil given intravenously (10 μg/kg body weight) and propofol (2 mg/kg body weight), both given intravenously. After loss of the eyelash reflex, patients were manually ventilated *via* a face mask without the use of an oral airway. Approximately 2 min later, a LMA was inserted according to the technique described by Brain,[16] with the cuff completely deflated and pressed against the hard and soft palate by the anesthesiologist's index finger during insertion. In all patients, the LMA was inserted by the same anesthesiologist (A.R.). A size #3 LMA was chosen for patients weighing as much as 65 kg, and in patients weighing more than 65 kg, a #4 LMA was used. The laryngeal masks were prepared with a nonanalgesic lubricant applied in a thin layer on the dorsal part of the cuff (Endosgel; Farco Pharma, Cologne, Germany). Patients in whom the LMA could not be advanced to its final position on the first attempt were excluded from the final analysis.

After placement of the LMA, a microprocessor-controlled intracuff pressure monitor (CDR 2000; ESW-Exte! Systems Wedel, Wedel, Germany) was connected to the pilot line of the cuff of the LMA. The CDR 2000 was developed to control high-volume low-pressure endotracheal tube cuffs. The internal algorithm of the device was changed by the manufacturer for this study to allow regulation of high intracuff pressures. It measures and regulates the intracuff pressure to maintain preset levels with a tolerance of ± 3 mmHg. The device was calibrated against a mercury column.

Five minutes after insertion of the LMA and 10 min after incision, the LMA was checked for air-tight connection with the laryngeal inlet by applying a positive airway pressure of 20 cm H_2O. Fifteen minutes after induction, the position of the LMA was verified by fiberoptic endoscopy through the tube of the LMA. Care was taken not to move the LMA during and after fiberoptic endoscopy.

Anesthesia was maintained with enflurane and 66% nitrous oxide in oxygen at a fresh gas flow of 3 l/min. Heat and moisture exchangers were not used within the anesthetic circuit. Alfentanil (30 μg/kg body weight) was given intravenously before incision to all patients. Ventilation was manually assisted when end-tidal carbon dioxide partial pressure exceeded 45 mmHg.

At the end of the surgery, the LMA was disconnected from the CDR 2000, the cuff deflated, and the LMA removed while the patients were still unresponsive to pharyngeal stimulation. Pharyngeal suction was not performed. Ventilation was assisted *via* a face mask without an oral airway during emergence.

Piritramid was used for postoperative analgesia in the recovery room (6-mg intravenous initial dose, with 1.5-mg increments as needed). Eight, 24, and 48 h after the end of anesthesia, the patients were asked about laryngopharyngeal discomfort by an independent observer using a standardized questionnaire. The observer and the patients were blinded to the level of intracuff pressure. Three types of complaints were distinguished: sore throat (constant pain, independent of swallowing), dysphagia (discomfort with swallowing provoked by drinking), and hoarseness. Patients assessed the severity of their complaints on a 101-point numerical rating scale (0 = no pain at all, 100 = worst pain possible).[10,17] The use of the rating scale and the differentiation between sore throat and dysphagia had been explained to the patients on the day before surgery.

Statistical Analysis

Continuous data were compared using Mann-Whitney U and the Wilcoxon Rank Sum W tests for independent samples. Nominal data were compared using the Mantel-Haenszel or Fisher's exact test for small samples. Demographic data are reported as means ± SD, and pain ratings are presented as median (min-max). Probability levels less than 0.05 were considered significant.

Results

We found no demographic difference between the two groups (table 1). Seventy patients were initially enrolled in the study, but nine were excluded from the final analysis because more than one attempt to insert the laryngeal mask was needed, although difficulties with LMA insertion could not be predicted in these patients (normal anatomy, weight, and height). The advancement of the LMA was smooth, and fiberoptic en-

Table 1. Biometric Data, Choice of Laryngeal Mask Airway, Duration of Anesthesia, and MAC-hours

	Low Pressure Group (n = 30)	High Pressure Group (n = 31)
Age (yr)	51 ± 16	53 ± 15
Height (cm)	167 ± 5	165 ± 5
Weight (kg)	66 ± 7	68 ± 9
Body mass index (kg/m^2)	25 ± 3	25 ± 3
LMA 3/LMA 4	16/14	16/15
Duration of anesthesia (min)	99 ± 32	102 ± 48
MAC-hours	1.6 ± 0.3	1.6 ± 0.4

Data are mean ± SD where indicated. MAC-hours were obtained by multiplying the quotient of mean end-tidal enflurane concentration by MAC with the time of application. There were no significant differences between both groups.

doscopic examination showed the correct position of the LMA in all remaining patients. The epiglottis was visible inside the lumen of the LMA in 53% (low-pressure group) and 45% (high-pressure group) of patient, respectively (difference not significant). We detected no blood on the surface of the LMA after removal.

The quality of the airway was satisfactory in all cases. There was no difference in the incidence of audible air leaks when positive airway pressure was applied for 5 min (33% *vs.* 43%; difference not significant) or for 10 min after incision (16.1% *vs.* 16.6%). Ventilation and oxygenation were not compromised in either group. The intraoperative course and emergence from anesthesia was uncomplicated in all patients.

On the day of surgery, 50% of patients in the low-pressure group and 42% of patients in the high-pressure group had symptoms of laryngopharyngeal discomfort (difference not significant). The rate of complaints decreased to 23% in the low-pressure group and to 32% in the high-pressure group on the following day, and to 7% (low-pressure group) and 10% (high-pressure group) on the second postoperative day, with no significant differences between the groups.

We found no difference in the overall incidence of sore throat, hoarseness, and discomfort with swallowing between the groups on the day of surgery and on the following 2 days (fig. 1). The severity of complaints was rated 5 to 50 on the 101-point numerical rating scale, with no significant difference between symptoms and between groups (table 2). Patient satisfaction with the procedure of anesthesia was 86% and 84% in the low-pressure and high-pressure groups, respectively.

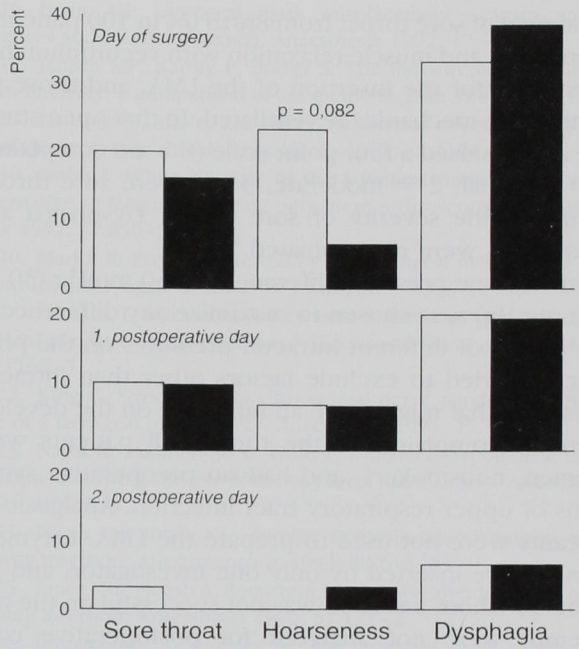

Fig. 1. Incidence of sore throat, hoarseness, and dysphagia after use of the laryngeal mask airway. Open square = 30-mmHg intracuff pressure; n = 30. Filled square = 180-mmHg intracuff pressure; n = 31.

Discussion

Our results suggest that laryngopharyngeal discomfort after LMA use cannot be attributed solely to high intracuff pressures. These findings are in contrast to a recently published study in which the reduction of intracuff pressures to a "just sealing" pressure decreased the

Table 2. Postoperative Analgesia and Patient Assessment of Complaints on a 101-Point Numerical Rating Scale*

	Low Pressure Group	High Pressure Group
Mean dosage of piritramid IV (mg)	8.3 ± 2.6	8.0 ± 2.4
Sore throat (points)	19 (5–45) (n = 6)	20 (5–50) (n = 5)
Hoarseness (points)	18 (5–50) (n = 7)	20 (20) (n = 2)
Dysphagia (points)	19 (5–50) (n = 10)	16 (5–30) (n = 12)

Data are mean ± SD for analgesic requirement and median (minimum – maximum) for rating the severity of complaints (n is number of patients with complaints).

* Eight hours following anesthesia.

incidence of sore throat from 8% to 0% in 100 patients.[3] Thiopental and muscle relaxation with vecuronium had been used for the insertion of the LMA, and those patients were mechanically ventilated. In that open study, the authors used a four-point scale (0 = no complaints, 1 = minimal, 2 = moderate, 3 = severe sore throat) to define the severity of sore throat. Dysphagia and hoarseness were not evaluated.[3]

An extreme pressure difference of 150 mmHg (30 *vs.* 180 mmHg) was chosen to maximize any difference of the effects of different intracuff pressures on the pharynx. We tried to exclude factors other than intracuff pressures that might have an influence on the development of complaints of the throat. All patients were women, nonsmokers, and had no preoperative symptoms of upper respiratory tract infection. Analgesic lubricants were not used to prepare the LMA. Laryngeal masks were inserted by only one investigator, and patients in whom insertion was not successful on the first attempt were not analyzed for postoperative complaints. Anesthetic depth during insertion was adequate in all patients to provide a smooth advancement of the LMA without coughing, gagging, or biting. Burgard *et al.*[3] removed the LMA with the patients awake, as it is recommended by the inventor and is common clinical practice. To evaluate the effect of intraoperative cuff pressures on laryngopharyngeal complications, the LMA was removed before emergence. Thus the effect of swallowing and retching with the LMA *in situ* was excluded. The duration and depth of anesthesia and the postoperative analgesic requirements were similar in both groups. No blood was detected on the surface of the LMA after removal, indicating that there was no major trauma to the pharyngeal wall. The incidence of laryngopharyngeal complaints in the present study was higher than described by other authors.[3-7] This almost certainly stems from our use of direct questioning.[18]

Hoarseness was present in only 6% of patients in the high-pressure and in 23% in the low-pressure group. This difference was not significant but needs further investigation. As fiberoptic controls revealed correct positioning of the LMA, direct trauma to the vocal cords seems to be unlikely. The incidence of hoarseness is consistent with previous findings in a different study population.[10] A lower rate of dysphonia is observed after face mask anesthesia.[19] In contrast to the face mask, the gas flow through a LMA is directly targeted on the laryngeal inlet. The beneficial effects of heat and moisture exchangers in reducing throat complaints after LMA use have not been proved.[8]

Dysphagia was the prominent symptom in both groups. In the high-pressure group, dysphagia was found significantly more often than hoarseness or sore throat, whereas in the low-pressure group there was no significant difference in the incidence of the three symptoms. However, there was no difference between both groups in the incidence of dysphagia on the day of anesthesia and on the next day. Because dysphagia was still present in 20% of the patients in each group on the day after anesthesia, this symptom seems to be the major laryngopharyngeal problem after using the LMA.

Theoretically, the calculated pressure exerted by the cuff of the LMA on the pharyngeal wall may exceed the perfusion pressure of the mucosa.[20] It remains questionable if these calculated figures, obtained by subtraction of *in vitro* (outside the patient) from *in situ* pressures, actually represent the pressure on each part of the pharynx. Direct measurement on the middle part of the outside of the LMA provided evidence that extra cuff pressure, which is exerted on the pharyngeal wall, is approximately 25 mmHg and does not correlate with intracuff pressure.[21] However, the distribution of pressures on all parts of the pharynx attached to the LMA is still unknown. Hypoglossal and recurrent laryngeal nerve palsy and bilateral compression of the lingual artery have been described after LMA use, and the potential role of high intracuff pressures has been discussed in these cases.[22-25] However, no information about intracuff pressures is available in these case reports. On the other hand, high intracuff pressures have been used even in prolonged anesthesia without harmful sequelae.[13,26]

In conclusion, subjective laryngopharyngeal complaints after the use of a LMA were not significantly different in two groups of patients with high or low intracuff pressures.

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