J Anesth (2014) 28:662–667
DOI 10.1007/s00540-014-1811-0

ORIGINAL ARTICLE

Does cuff pressure monitoring reduce postoperative pharyngolaryngeal adverse events after LMA-ProSeal insertion? A parallel group randomised trial

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Received: 25 December 2013 / Accepted: 19 February 2014 / Published online: 19 March 2014

Abstract
Purpose The incidence of postoperative pharyngolaryngeal complications after laryngeal mask airway (LMA) insertion can be as high as 50 %. Over-inflation of the LMA cuff may be a causal factor. We conducted a single-centre parallel group randomised trial to determine whether maintaining LMA-ProSeal intra-cuff pressures below 60 cm H_2O decreases postoperative pharyngolaryngeal complications.
Methods We recruited 120 adult patients who were scheduled to undergo elective surgery under general anaesthesia. Appropriate sized LMA-ProSeal was inserted and the cuff was inflated with air (to no more than the maximum recommended volume) until there was no audible leak. Patients were randomised to either the control group ($n = 60$), where the intra-cuff pressure was noted and no further action was taken, or to the pressure-monitored group ($n = 60$), where intra-cuff pressure was maintained below 60 cm H_2O. Pharyngolaryngeal complications consisting of sore throat, dysphonia and dysphagia were assessed at 1, 2, and 24 h postoperatively. Patients, anaesthesiologists and assessors were blinded to group allocation. The primary outcome was a composite endpoint of any pharyngolaryngeal complication at any of the three time points. Secondary outcomes were the incidence of individual outcomes at each time point.
Results The incidence of pharyngolaryngeal complications at any time point was 42 % in the routine care group and 32 % in the pressure-monitored group (95 % CI for difference +28 to −7 %, $p = 0.26$). There was no difference between groups for any of the secondary outcomes.
Conclusion Our study failed to demonstrate a statistically significant reduction in postoperative pharyngolaryngeal complications by limiting intra-cuff pressures in the LMA-Proseal.

Keywords Laryngeal masks · Postoperative complications · Pharyngitis

Introduction

Laryngeal mask airways (LMAs) are widely used for airway management during anaesthesia. These devices have advantages over endotracheal intubation, such as lesser skills required for insertion and the ability to be used in difficult airway situations; however, the incidence of postoperative pharyngolaryngeal adverse effects (sore throat, dysphagia and dysphonia) after LMA use may be as high as 50 % [1–4]. One of the factors that has been postulated to cause pharyngolaryngeal side effects is inflation of the LMA cuff to a pressure of more than 60 cm of H_2O, which is the critical perfusion pressure of the pharyngeal mucosa [1]. Previous randomised studies using the LMA-classic have looked at the association between intra-cuff volumes or pressures and postoperative pharyngolaryngeal adverse events with equivocal results. In four studies, intra-cuff pressure or volume reduction decreased pharyngolaryngeal complications [1, 2, 5, 6]. However, other studies have shown no relation between the two [7, 8].

The LMA-ProSeal is structurally different from the LMA-classic in that it has an additional dorsal cuff, a larger ventral cuff and a deeper bowl [9, 10]. While these modifications offer a better pharyngeal seal, it is possible that

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they may lead to increased pressure on the pharyngeal mucosa. However, it is also postulated that the LMA-ProSeal may reduce the likelihood of throat irritation because of a softer silicone cuff [10]. Therefore, the results of previous studies with the LMA-classic may not be applicable to the LMA-ProSeal. We conducted a parallel group randomised trial to study the effects of maintaining cuff pressure below 60 cm H_2O on postoperative pharyngolaryngeal adverse effects following LMA-ProSeal insertion.

Methods

This study was carried out after approval from the Institutional Review Board, and voluntary written informed consent was obtained from all participants. The trial was registered with the Clinical Trials Registry of India. (CTRI/2013/12/004234). We included adult patients (aged 18–80 years) with ASA physical status I, II and III scheduled to receive general anaesthesia with LMA-ProSeal for short duration elective procedures like orthopaedic, urologic and breast surgeries that were carried out in the supine position. Exclusion factors were any contraindication for the use of LMA (such as morbid obesity, gastro-esophageal reflux or previous upper abdominal surgery) or recent (within 7 days) history of upper respiratory tract infection. Patients were randomly allocated into pressure-monitored and control groups. Randomisation was carried out by a computer-generated table of random numbers, by a centrally located clinical research secretariat that informed the random allocation telephonically. On arrival in the operation theatre, all patients received routine monitoring consisting of pulse oximetry, non-invasive blood pressure, and electrocardiography. Induction of anaesthesia was achieved with intravenous propofol 2–3 mg/kg, fentanyl 2 mcg/kg and vecuronium 0.1 mg/kg, followed by ventilation with 100 % oxygen and isoflurane. Size 3 LMA-ProSeal was used for adults weighing <50 kg and size 4 LMA-ProSeal was used for adults more than 50 kg, as per the manufacturer's guidelines [10]. The LMA-ProSeal was lubricated dorsally with water-soluble jelly (K-Y jelly®, Johnson & Johnson Limited, India) before insertion. Once adequate relaxation was achieved, LMA-ProSeal was inserted by an anaesthesiologist with more than 3 months of experience with the device, according to the individual's preferred technique of insertion. The LMA-ProSeal was inflated with air to no more than the maximum recommended volume (20 ml for size 3 LMA-ProSeal, 30 ml for size 4 LMA-ProSeal) to just achieve a seal without audible leak during positive pressure ventilation with a tidal volume of 8 milliliters (ml) per kg and a peak inspiratory pressure below 25 cm H_2O. General anaesthesia was maintained with isoflurane in air-oxygen mixture with controlled intermittent positive pressure ventilation via a circle breathing system. The LMA-ProSeal was repositioned if ventilation was deemed inadequate. If more than three attempts were required for LMA-ProSeal insertion, further airway management was left to the discretion of the attending anaesthesiologist. Once LMA placement was satisfactory, an assistant measured the LMA-ProSeal intra-cuff pressure using a portable airway pressure manometer (Portex cuff inflator pressure gauge, Smiths Medical International Limited, UK). In the pressure-monitored group, if the intra-cuff pressure was higher than 60 cm H_2O, it was decreased to 60 cm H_2O. If there was an unacceptable leak with cuff pressures below 60 cm H_2O, a bigger size LMA-ProSeal was used. If there was still a leak, the LMA-ProSeal was removed and further airway management was decided by the attending anaesthesiologist. In the control group, the intra-cuff pressure was noted but no changes were made. Cuff pressures were re-checked every hour intra-operatively in both groups and were re-adjusted to 60 cm H_2O in the pressure-monitored group. Intra-operative analgesia was maintained with further doses of fentanyl; in addition, patients received paracetamol and/or diclofenac at the discretion of the anaesthesiologist. After completion of surgery, the anaesthesiologist removed the LMA-ProSeal when the patient was awake. Presence of blood on the LMA was noted. Oropharyngeal airways and pharyngeal suctioning were used only when indicated. Patients were observed in the Post-Anaesthesia Care Unit and were discharged to the ward when recovery was deemed adequate. Postoperative analgesia was maintained with combinations of paracetamol, diclofenac and tramadol.

We collected data regarding patient demographics, volume of air used to inflate the LMA cuff, duration of surgery, the use of oro-pharyngeal airway, the incidence of laryngospasm, the presence of blood on the LMA-ProSeal after removal, use of pharyngeal suctioning and total intra-operative and postoperative (first 24 h) analgesic requirements (opioid, paracetamol, diclofenac). Patients were questioned about symptoms of sore throat, dysphagia and dysphonia at 1, 2, and 24 h postoperatively. Sore throat was defined as "constant pain or discomfort in the throat independent of swallowing". Dysphonia was defined as "difficulty in speaking or pain on speaking". Dysphagia was defined as "difficulty or pain provoked by swallowing". These definitions were based on those in an earlier study by Seet et al. [1]. The primary outcome was the incidence of any pharyngolaryngeal complication at any time point of 1, 2, or 24 h. Secondary outcomes included the incidence of individual pharyngolaryngeal complications of sore throat, dysphonia, or dysphagia at specific time points of 1, 2, and 24 h postoperatively. Patients,

operating room anaesthesiologists and outcome assessors were blinded to group allocation.

Data was entered into statistical software SPSS 19.0 (SPSS for Windows, USA). Categorical data was expressed as percentages and was compared using the Chi square test or Fisher's exact test. 'p' values <0.05 were considered significant for all comparisons. No adjustment was made for multiple comparisons. Analysis was by intention-to-treat.

Sample size calculation: The incidence of postoperative pharyngolaryngeal complications after LMA insertion has been reported to be as high as 50 %. We hypothesised that the use of cuff pressure monitoring would decrease this incidence to 25 %. To detect this difference with 80 % power at 5 % significance level, 58 patients would be needed in each arm. We planned to recruit 60 patients in each group to adjust for missing data.

Results

Between February and August 2012, 120 patients were included in the study, of which 60 each were randomised to the control and pressure-monitored groups, respectively. One patient in the control group had failure of LMA-ProSeal insertion (unsuccessful after three attempts) and needed alternate airway management. Outcome data was missing for this patient. 119 patients (59 in control group and 60 in pressure-monitored group) were included in the final analysis. The demographic characteristics, airway management and analgesic requirements of the two groups were similar (Tables 1, 2, 3). No change in intra-cuff pressure was noted after 1 h in either group. No patient needed a change in LMA size. Five patients (three in the control group and two in the pressure-monitored group) had blood on the LMA during removal, suggesting traumatic insertion. Table 4 lists the incidence of the primary and secondary outcomes in the two groups. No differences were noted at any time-point for any of the outcomes.

Table 1 Demographic characteristics of patients

Parameter	Control group ($n = 60$)	Pressure-monitored group ($n = 60$)
Age (in years)	49.7 (±14.3)	48.5 (±11.7)
Sex (M/F)	10/50 (16.7/83.3 %)	5/55 (8.3/91.7 %)
Weight (in kg)	58.0 (±9.9)	60.8 (±10.4)
ASA status I/II/III	36/22/2 (60/36.7/3.3 %)	38/21/1 (63.3/35/1.7 %)
Breast surgery	51 (42.5 %)	49 (40.8)
Urological procedures	4 (3.3 %)	7 (5.8 %)
Orthopaedic surgery	5 (4.1 %)	4 (3.3 %)
Duration of surgery (in min)	108.5 (±38.2)	111.7 (±56.1)

Data is expressed as mean (±standard deviation) for continuous data and actual numbers (percentages in parentheses) for categorical data

Table 2 Details of airway management

Parameter	Control group ($n = 60$)	Pressure-monitored group ($n = 60$)
LMA size		
3	27 (45.7 %)	22 (36.7 %)
4	32 (54.2 %)	38 (63.4 %)
Amount of air inflated (in ml)[a]		
LMA size		
3	11.8 (±3.1)	12.7 (±3.7)
4	16.5 (±5.8)	16.4 (±6.2)
Cuff pressure (in cm H_2O)[a]	68.3 (±26.8)	71.9 (±28.7)
Pharyngeal suctioning	0	0
Use of Guedel airway	0	0
Laryngospasm	1 (1.8 %)	0

Data is expressed as mean (±standard deviation) for continuous data and actual numbers (percentages in parentheses) for categorical data

[a] Values for pressure-monitored group are prior to deflation

Table 3 Peri-operative analgesic requirements

	Control group ($n = 59$)	Pressure-monitored group ($n = 60$)
Intra-operative fentanyl requirement (in micrograms)	130 (±39)	133 (±31)
Number of patients who received Diclofenac	48 (86.0 %)	47 (81.0 %)
Number of patients who received Paracetamol	28 (50.0 %)	25 (43.0 %)
Number of patients who received Tramadol	1 (1.8 %)	1 (1.7 %)

Data is expressed as mean (±standard deviation) for continuous data and actual numbers (percentages in parentheses) for categorical data

Discussion

Pharyngolaryngeal complaints after anaesthesia, even if mild and short-lasting, can cause significant distress to patients and interfere with the overall anaesthesia experience. Our study shows that the use of manometry to limit cuff pressures during LMA-ProSeal insertion decreases pharyngolaryngeal complications by 10 %; however, this difference was not statistically significant. We also found that inflation of the LMA-ProSeal cuff to "just" achieve a pharyngeal seal required only around half of the maximum recommended inflation volume and resulted in intra-cuff

Table 4 Postoperative pharyngolaryngeal complications

	Control group ($n = 59$)	Pressure-monitored group ($n = 60$)	p value	95 % CI for difference
Any pharyngolaryngeal complication	25 (42.3 %)	19 (31.6 %)	0.26	+28.0 to −7.0 %
Sore throat at 1 h	5 (8.5 %)	3 (5.0 %)	0.49	+12.0 to −6.0 %
Sore throat at 2 h	22 (37.3 %)	13 (21.7 %)	0.07	+32.0 to −1.0 %
Sore throat at 24 h	24 (40.7 %)	15 (25.0 %)	0.08	+32.0 to −1.0 %
Dysphonia at 1 h	0	0	–	–
Dysphonia at 2 h	0	1 (1.6 %)	1.0	+2.0 to −5.0 %
Dysphonia at 24 h	0	1 (1.6 %)	1.0	+2.0 to −5.0 %
Dysphagia at 1 h	5 (8.4 %)	2 (3.3 %)	0.27	+14.0 to −3.0 %
Dysphagia at 2 h	12 (20.3 %)	7 (11.7 %)	0.22	+22.0 to −4.0 %
Dysphagia at 24 h	13 (22.0 %)	10 (16.7 %)	0.43	+20.0 to −9.0 %

Data is expressed as actual numbers (percentages in parentheses)

pressures that were only slightly higher than the acceptable limit of 60 cm H_2O.

LMAs, despite their numerous advantages, have been associated with a high incidence of postoperative sore throat, dysphagia and dysphonia. Researchers have attempted to identify various factors that could influence the occurrence of this complication such as technique of insertion, LMA size, varying intra-cuff pressures (low versus high), choice of gas used to inflate the cuff (nitrous oxide versus air), mode of ventilation (spontaneous versus controlled) and the use of pharmacological agents (lubricants, steroids, local anaesthetics) [1, 2, 4–8]. Since the patho-physiology of postoperative sore throat involves trauma to the pharyngeal mucosa, it is logical that factors that minimise this damage would have the highest impact on postoperative pharyngolaryngeal morbidity. The superior pharyngeal seal of the LMA-ProSeal over the LMA-classic is due to its modified structure with an additional dorsal cuff, larger ventral cuff and deeper bowl [9, 10]. However, this improvement may be at the cost of increased cuff pressures. Elevated LMA intra-cuff pressure may reduce pharyngeal mucosal perfusion and lead to mucosal ischemia and postoperative pharyngeal discomfort. Since this is an easily modifiable factor, it has been the subject of several studies. However, there is inconclusive evidence on the role of high intra-cuff pressures in the development of pharyngolaryngeal complications. The findings of our study are in keeping with trials by Seet and Burgaard [1, 5], who found that the use of manometry to maintain cuff pressures below 60 cm H_2O reduced the incidence of postoperative pharyngolaryngeal complications. Brimacombe et al. [2] did not study cuff pressures, but found that low cuff inflation volumes were associated with decreased postoperative side-effects. In contrast, in studies by Rieger and Figueredo [7, 8], there was no association between LMA cuff pressures and incidence of postoperative pharyngeal adverse events.

These varying findings may be explained by several methodological differences between the studies. First, our study looked at the LMA-ProSeal, whereas all previous studies have been carried out using the LMA-classic. Due to differences in structure and technique of insertion between LMA-ProSeal and LMA-classic, the results of previous studies may not be applicable to ours. In the studies by Brimacombe, Burgard and Rieger [2, 5, 7], nitrous oxide was used as part of general anaesthesia. It has been shown that nitrous oxide can diffuse into the LMA cuff over time and lead to a gradual increase in intra-cuff pressure [8, 11]. However, in our study, we used an air-oxygen mixture and found no change in intra-cuff pressures in either group even 1 h after insertion. Brimacombe et al. [2] used fixed volumes of air to inflate the LMA cuff and did not measure cuff pressures. The relationship between volume and pressure is not constant and depends on compliance. This could produce variable intra-cuff pressure levels in different individuals. Burgard and colleagues [5] also used fixed inflation volumes; in their study, cuff pressures in the control group remained around 200 cm H_2O during surgery, which was much higher than manufacturer's recommendations and was significantly higher than cuff pressures in the intervention group (around 60 cm H_2O). Similarly, in trials by Seet and Rieger, there were huge differences between cuff pressures in the two study arms (30 vs. 180 and 40 vs. 114 mmHg, respectively) [1, 7]. In our study, in both the intervention and the control groups, LMA cuffs were inflated only until there was no audible leak, and were inflated to no more than the maximum recommended volumes. The cuff pressures in both groups immediately after inflation (pre-deflation) were comparable and were not much higher than the recommended limit of 60 cm H_2O. After pressures in the intervention group were decreased to 60 cm H_2O, the difference between the two groups was much less than in the earlier studies, and was probably not high enough to have a significant impact on the incidence of complications. Keller

et al. [12] found that LMAs may function better at submaximal inflation volumes, and higher cuff volumes may only increase complications without actually improving sealing pressures. They concluded that the preferred inflation volume for a size 4 LMA-classic was between 15 and 20 ml. In keeping with this, in our study, the mean inflation volume for the size 4 LMA-ProSeal was 16 ml.

Various pre- and intra-operative factors can affect the incidence of postoperative pharyngeal complications. Seet et al. [1] demonstrated that experience of anaesthesiologist, ease of LMA insertion, use of oro-pharyngeal airway, pharyngeal suctioning and traumatic insertion do not affect postoperative pharyngolaryngeal adverse events. However, to reduce bias in our study, we attempted to control for these factors. We excluded patients with confounding factors like pre-existing sore throat, and surgical interventions on the head and neck. It has been established that it takes 20–30 insertions to achieve competence with the LMA-ProSeal [3]. We therefore ensured that all LMAs were performed by anaesthesiologists with more than 3 months experience, during which period they would have attained the necessary skills. Previous studies on LMA-ProSeal have restricted the number of attempts at LMA insertion to three, before considering it as a failed insertion [9, 13, 14]. We also followed this strategy. We collected data on traumatic insertion, use of oro-pharyngeal airways and pharyngeal suctioning, and found that they were equal in the two arms. Randomisation ensured that factors such as gender, duration of surgery and LMA size were similar between the two groups in our study. The use of analgesics in the peri-operative period could affect perception of sore throat, dysphagia or dysphonia. In this study, the analgesics used were tramadol, paracetamol and diclofenac, all of which have a duration of action of around 6 h. However, our study groups were comparable in terms of amount of analgesics used, and therefore it is unlikely that this factor would have influenced the study results. Finally, patients, OT anaesthesiologists and outcome assessors were blinded to study arm assignment to eliminate evaluation bias.

Our study had some limitations. Several methods are available for insertion of ProSeal LMA (introducer, bougie-guided, digital). We did not standardise the technique of insertion but left it to the discretion of the attending anaesthesiologist. We assumed that randomisation and blinding would prevent any bias arising due to this. Also, studies have shown that there is no significant difference in success rate or complications between these techniques [3, 14]. We did not classify pharyngolaryngeal complications on the basis of severity, as has been done in some other studies [6]. This was done to maintain objectiveness of outcome assessment. We did not specifically look for nerve injuries (recurrent laryngeal nerve, hypoglossal nerve and lingual nerve) after LMA insertion; however, the incidence of this complication is very low and no patient in our study reported long-term pharyngolaryngeal sequelae. All the patients in our study received intermittent positive pressure ventilation. It has been suggested that the use of intermittent positive pressure ventilation (IPPV) may be responsible for postoperative pharyngolaryngeal adverse effects and not the cuff pressure [8]. Therefore, the contribution of IPPV to postoperative pharyngolaryngeal adverse effects cannot be ruled out, because we did not compare with spontaneous ventilation. Lastly, the sample size for our study was based on an anticipated incidence of pharyngolaryngeal complications of 50 % in the control group and 25 % in the intervention group. We found the actual incidence of complications to be 42 % in the control group versus 32 % in the intervention group with an overall incidence rate of 37 %. It is possible that our study was inadequately powered to detect this difference, which, though not statistically significant, has considerable clinical implications.

Conclusion

Our study on using manometry to limit intracuff pressures below 60 cm H_2O after insertion of the LMA-ProSeal showed a 10 % decrease in postoperative pharyngolaryngeal complications. However, this difference was not statistically significant.

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