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Flexible laryngeal mask with pharyngeal suction for nasal surgery

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ABSTRACT

Method: Peri-operative data of 71 healthy patients who underwent nasal surgery using flexible laryngeal mask attached with two pharyngeal suction catheters were retrospectively analyzed to examine the evidence of glottic contamination and to assess the relationship between postoperative sore throat and the pharyngeal suction.
Results: No patient experienced hypoxemia or laryngospasm during the surgery and emergence. Visually, examination showed no evidence of blood contamination on the laryngeal surface of the laryngeal mask. The amount of blood evacuated from the pharynx through the attached catheters correlated with the amount of estimated blood loss and the duration of surgery (rho = 0.82 and 0.51, respectively; $P < 0.001$). The incidence of postoperative sore throat (19.3%) was similar to that reported in the literature, while the duration of surgery and the amount of blood evacuated from the pharynx were not different between patients with and without sore throat ($P = 0.98$ and 0.70, respectively).
Conclusions: The flexible laryngeal mask with pharyngeal suction catheters provided safe airway management for nasal surgeries without apparent glottic contamination or other airway-related complications and was not associated with an increased risk of postoperative sore throat in this retrospective observational study. A large controlled prospective study is needed to confirm these findings.

1. Introduction

Bleeding into the pharynx during nasosinusal and other upper airway surgeries presents a persistent challenge to anaesthesiologists. While tracheal intubation is known to protect the lower airway, blood can be trapped in the subglottic area above the tracheal tube cuff [1], soiling and irritating the lower airway when the cuff is deflated at the time of extubation. Both awake and deep extubations pose the risk of airway complications in this setting [2]. In contrast, the laryngeal mask airway device protects the lower airway by isolating the glottis from the pharynx, and can be left in situ to maintain airway patency and protection until the patient is fully awake [1–6], with return of protective airway reflexes but minimal impact on haemodynamic stability [7,8].

While the laryngeal mask may cover and seal around the glottis, this end-to-end seal is “soft” in nature and can be weakened or broken by various factors, particularly during emergence or periods of inadequate depth of anaesthesia. Studies have demonstrated, through either visual inspection or bronchoscopy, variable incidences (2–19.5%) of glottic contamination with blood when laryngeal masks were used for nasosinusal surgeries [1–5]. More importantly, blood can easily descend into the lower airway once reaching the glottic area [1]. As a result, blood aspiration and laryngospasm do occur, especially if the bleeding is significant during the surgery or if the patient is not fully awake during emergence [9,10], and the consequences can be devastating. Therefore, pooling of blood and secretions above the laryngeal mask during maintenance and emergence of anaesthesia remains a concern for both novice and experienced practitioners. Throat packing has been used to absorb blood; however, its efficacy in blocking blood from entering the aerodigestive tract is questionable and may cause postoperative sore throat (POST) [11–14]. As a result, a reliable mechanism that can reduce or eliminate pharyngeal blood accumulation and clot formation may be the key to mitigating the risk of airway contamination and blood aspiration during nasosinusal and upper airway surgeries.

Previously we reported the application of a flexible laryngeal

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mask affixed with two pharyngeal suction catheters (PS-fLM) for a patient undergoing rhinoplasty-septoplasty that lasted over 5 h [15]. In this retrospective study, our primary aim is to determine the incidence of glottic contamination and airway complications associated with PS-fLM use within a cohort of patients undergoing ambulatory nasal surgery. The secondary aim is to assess the incidence of POST associated with this method.

2. Methods

The study was approved by the Yale University Institutional Review Board with a full waiver of consent. We retrospectively identified 97 patients age 16 years and older who underwent nasal surgery at the Yale-New Haven Hospital Temple Surgery Centre from March 1, 2016 to March 31, 2018. All 71 patients whose airways were managed with a PS-fLM (described below) were included for the analysis (Fig. 1). Peri-operative data from electronic medical records were collected and included patient characteristics, operative variables [duration of anaesthesia, duration of surgery, estimated blood loss (EBL) and amount of pharyngeal blood suctioned through the PS-fLM], and peri-operative adverse events (hypoxemia, laryngospasm, coughing, POST, nausea and vomiting). The incidences of airway-related complications were compared with those reported in the literature; the duration of surgery, EBL and amount of pharyngeal blood suctioned through the PS-fLM were compared between patients with and without POST, which was assessed and documented by a nurse or an anaesthesiologist in the postanaesthetic care unit (PACU) and/or during the follow-up call on postoperative day 1 or day 2. The duration of anaesthesia was defined as the time from PS-fLM placement to removal, and the duration of surgery was from injection of local anaesthetics to the completion of packing and/or casting by the surgeon. The time to laryngeal mask removal was measured from the completion of packing and/or casting to the removal of PS-fLM, with “0” minute indicating the PS-fLM was removed before completion of packing and/or casting.

The assembly, insertion and management of PS-fLMs follow the methods previously reported [15]. Briefly, two 12F Tri-Flo suction catheters (CareFusion, Yorba Linda, CA) are secured to the distal barrel of the flexible LMA™ (Teleflex Medical, Research Triangle Park, NC) at the barrel-mask junction (Fig. 2), using three pieces of Steri-Strips (3M Health Care, MN). Care is taken to ensure the distal end of the catheters positioned in the grooves on the pharyngeal surface of the LMA™. After induction, the PS-fLM is inserted without deflation, with care taken to avoid back-folding or other misplacement of the suction catheters. The position of the PS-fLM is confirmed by assessing airway compliance, minimal leak pressure, and the capnography waveform. A small amount of air is added to the cuff if the seal is inadequate; otherwise, the PS-fLM is removed and replaced with a differently sized device, or tracheal intubation is performed. During the surgery and upon the onset of active surgical bleeding, blood in the pharynx is intermittently evacuated with brief suction alternating through the catheters on the PS-fLM. The frequency of suction varies depending on the amount of surgical bleeding, with the goal of preventing blood accumulation in the pharynx while also avoiding potential injury to the mucosa. During emergence, the operating table is placed in a back-up position with the patient's head raised to facilitate drainage of post-nasal blood and to better support spontaneous respiration. Suction is frequently applied to the catheters on the PS-fLM. When the patient is able to open his/her mouth on command, the PS-fLM is removed without cuff deflation and with continuous suction applied to one of the catheters and inspected for blood soiling inside its mask (Fig. 2). The blood, surgical debris, and secretions

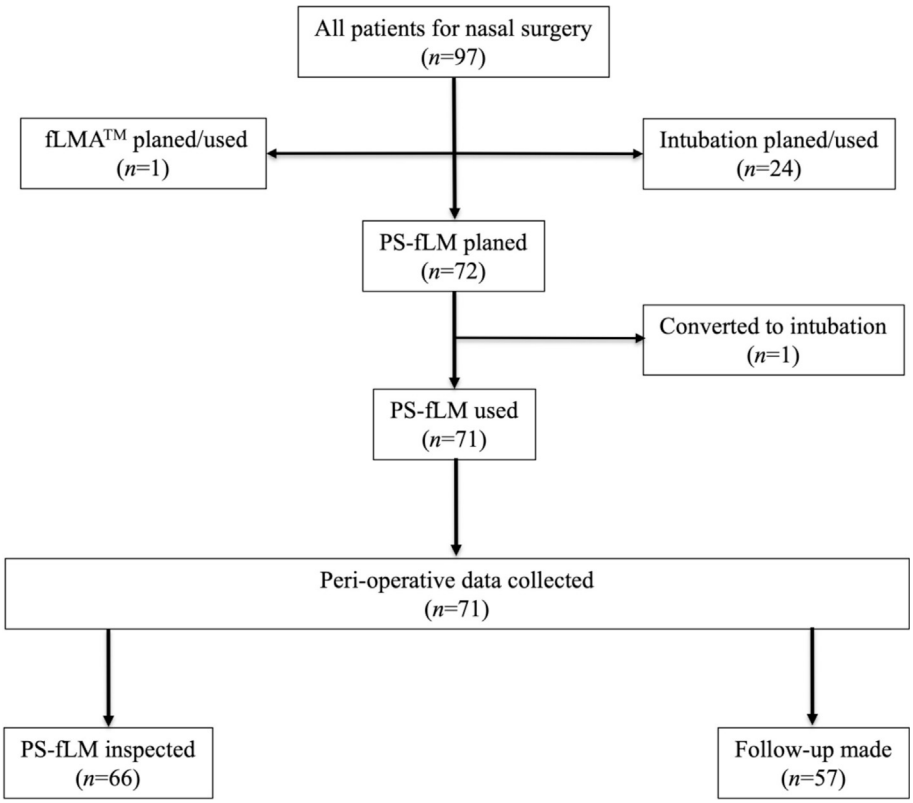

Fig. 1. Study flow diagram.
fLMA™: flexible LMA™; PS-fLM: flexible LMA™ with two pharyngeal suction catheters.

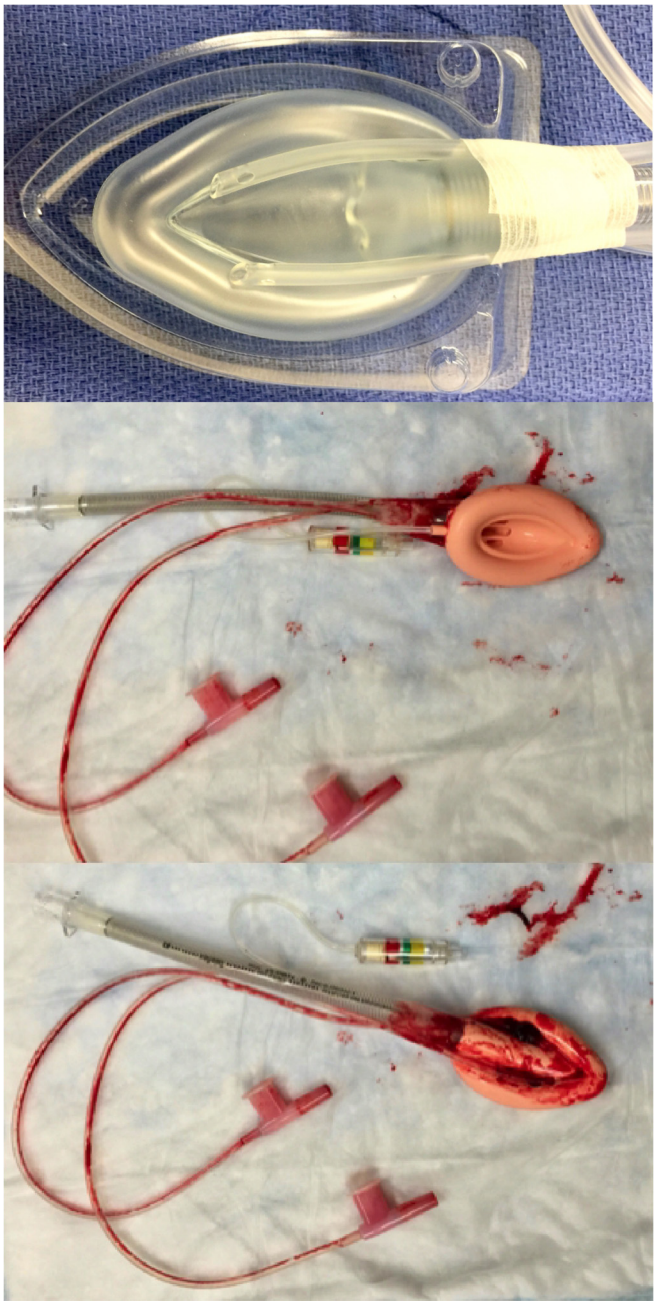

Fig. 2. PS-fLM before and after use.
Two 12F Tri-Flo catheters secured to a flexible™ LMA® using Steri-Strips (Top, PVC mask); Laryngeal (Middle) and pharyngeal (Bottom) surfaces of PS-fLM after use (Silicone mask).

removed from the pharynx through the catheters on the PS-fLM are collected in a canister and measured with a syringe after the surgery. The EBL is calculated according to routine and includes the blood evacuated from the pharynx through the PS-fLM catheters and the surgical field and absorbed in the surgical sponges.

2.1. Statistical analysis

Data are presented as frequency (%) for categorical variables and mean ± SD or median (IQR 25th –75th percentile) for continuous variables. Nonparametric correlations between operative variables were assessed using Spearman rank correlation coefficients (rho). Comparisons of these variables between patients with and without POST were conducted using the Wilcoxon rank sum test. All statistical analyses were performed using the statistical software SAS v9.4 (Cary, NC). A two-sided *P*-value of less than 0.05 was considered to be statistically significant.

3. Results

A total of 97 patients who underwent nasal surgery were identified during the study period. As shown in Fig. 1, 24 patients were managed with tracheal intubation and one with an unmodified flexible LMA™. The PS-fLM was chosen for 72 patients, of which one patient was excluded because the PS-fLM was changed to tracheal intubation after an adequate seal could not be achieved and an alternative size PS-fLM was not available. Therefore, 71 patients were included for data collection and analysis. Table 1 summarises their characteristics and procedures. Most patients had more than one procedure with some including additional non-nasal cosmetic procedures.

Table 2 shows that the duration of surgery and EBL varied widely among patients. Spearman analysis (Table 3) indicates the EBL correlated with the duration of the surgery (rho = 0.53, $P < 0.001$), and the amount of pharyngeal blood evacuated through the attached catheters correlated with the EBL as well as the duration of surgery (rho = 0.82 and 0.51, respectively; $P < 0.001$). Specifically, among patients with surgery duration ≥120 min, six (20%) had more than 100 ml of EBL and 13 (41%) had more than 30 ml of blood evacuated from the pharynx (Table 4).

The PS-fLM was successfully placed with a first-pass insertion rate of 93% (Table 4). In five cases, a second attempt was required, usually for a PS-fLM size change. The functional status of the pharyngeal suction catheters was documented or verified in all but three cases. In nearly 90% of cases, both suction catheters functioned properly; in the remaining seven cases, only one catheter worked.

Table 1
Patient characteristics.

Age (years), mean ± SD	29.4 ± 11.9
Body Mass Index (kg/m^2), mean ± SD	22.9 ± 3.3
Female, *n* (%)	48 (67.6)
ASA-PS I or II, *n* (%)	71 (100)
Procedure, *n*	
Septoplasty	51
Rhinoplasty	38
Reconstruction	14
Nasal fracture	9
Additional[a]	6

ASA-PS: American Society of Anesthesiologists Physical Status.
[a] Additional procedures included chin implant (4), breast implants (1), blepharoplasty (1).

Table 2
Operative Data (*n* = 71 except where indicated).

	Median (IQR)	Range
Duration of Anaesthesia (min)	86.0 (68.0–196.0)	32–347
Duration of Surgery (min)	70.0 (55.0–184.0)	23–337
Time to LM Removal[a] (min)	7.0 (3.0–10.0)	0–19[a]
EBL (*n* = 68)[b] (ml)	30.5 (16.5–60.0)	7–297
Pharyngeal Blood (*n* = 68)[b] (ml)	10.5 (6.0–26.0)	0–71
First Modified Aldrete Score	9.8 ± 0.5[c]	8–10

[a] LM = laryngeal mask; "0" indicating the PS-fLM was removed before completion of packing and/or casting.
[b] . *n* = 68 because three patients had no documentation of EBL or pharyngeal blood, i.e. blood evacuated from the pharynx via the attached suction catheters.
[c] Mean ± SD.

Table 3
Spearman Correlation Coefficient rho (*P*-value) between Operative Variables.

	Duration of Surgery	Time to LM Removal	EBL	Pharyngeal Blood	First Modified Aldrete Score
Duration of Anaesthesia	0.99 (<0.001)	−0.13 (0.28)	0.54 (<0.001)	0.50 (<0.001)	−0.22 (0.07)
Duration of Surgery		−0.22 (0.06)	0.53 (<0.001)	0.51 (<0.001)	−0.24 (0.046)
Time to LM Removal			−0.09 (0.46)	−0.18 (0.14)	0.14 (0.26)
EBL ($n = 68$)				0.82 (<0.001)	−0.14 (0.26)
Pharyngeal Blood ($n = 68$)					−0.18 (0.13)

$n = 71$ except where indicated.
LM = laryngeal mask.

Table 4
Perioperative incidents.[a]

	Duration of Surgery		Total $n = 71$
	<120 min ($n = 39$)	≥120 min ($n = 32$)	
PS-fLM Insertion First Pass	36 (92.3)	30 (93.8)	66 (93.0)
Both Suction Catheters Working ($n = 68$)	33 (91.7)	28 (87.5)	61 (89.7)
Intraoperative Events[b]	0	0	0
EBL ≥100 ml (n = 68)[c]	0	6 (20.0)	6 (8.5)
Pharyngeal blood ≥30 ml (n = 68)[c]	1 (2.8)	13 (40.6)	14 (19.7)
Emergence			
Coughing or Straining	1 (2.6)	0	1 (1.4)
Laryngospasm	0	0	0
Hypoxemia (O_2 Sat ≤93%)	0	0	0
Blood on PS-fLM laryngeal side ($n = 66$)	0	0	0
Other Incidents[d]	0	1 (3.0)	1 (1.4)
Recovery			
First Modified Aldrete Score ≥9	38 (97.4)	31 (96.9))	69 (97.2)
Sore Throat in PACU ($n = 68$)	0	1 (3.1)	1 (1.5)
Sore Throat at Home ($n = 57$)[e]	6 (20.0)	5 (18.5)	11 (19.3)
PONV in PACU ($n = 68$)			
Nausea	1 (2.8)	0	1 (1.5)
Vomiting	0	0	0
PDNV ($n = 57$)[e]			
Nausea	0	4 (14.8)	4 (7.0)
Vomiting	1 (3.3)	0	1 (1.8)

[a] Data reported as *n* (%). Denominators are not the same due to incompleteness of data recording, $n = 71$ except where indicated (in 3 cases, no record of catheter functional status, and also in 3 cases no record of sore throat or PONV in PACU). PONV: postoperative nausea/vomiting; PDNV: post-discharge nausea/vomiting.
[b] Intraoperative events include obstruction, hypoxemia, significant air leak.
[c] Three cases had no record of EBL (one in Duration of Surgery <120 min group, two in ≥120 min group) or pharyngeal blood (three in Duration <120 min group).
[d] One patient woke up confused and bit on her lower lip before removal of PS-fLM.
[e] 57 patients (30 in <120 min group, 27 in ≥120 min group) were reached by follow-up calls.

Table 5
Comparison of operative data between patients with and without POST.

	Total ($n = 57$)	POST ($n = 11$)	No POST ($n = 46$)	*P*
Duration of Anaesthesia (min)	97.0 (71.0–196.0)	84.0 (60.0–241.0)	102.0 (71.0–196.0)	0.86
Duration of Surgery (min)	79.0 (60.0–184.0)	66.0 (51.0–222.0)	87.0 (60.0–180.0)	0.98
Time to LM Removal (min)	6.0 (4.0–10.0)	6.0 (3.0–7.0)	7.0 (4.0–10.0)	0.39
First Modified Aldrete Score	10.0 (10.0–10.0)	10.0 (10.0–10.0)	10.0 (9.0–10.0)	0.56
Estimated Blood Loss (ml)	33.5 (17.0–71.0)	33.0 (17.0–67.0)	34.0 (17.0–75.0)	0.86
Pharyngeal Blood Suctioned (ml)	13.0 (7.5–27.5)	13.0 (8.0–43.0)	13.0 (7.0–26.0)	0.70

Data reported as median (IQR). *P*-values were calculated using Wilcoxon test.
POST=Postoperative sore throat.
LM = laryngeal mask.

Intra-operative airway-related events, defined as hypoxemia, airway obstruction, laryngospasm or air leak causing loss of adequate tidal volume, were not observed in any patient (Table 4). There were no occurrences of laryngospasm or oxyhaemoglobin desaturation during the emergence. Inspection of the PS-fLM upon removal was documented in 66 patients and demonstrated no blood soiling on the laryngeal (inner) surface of the mask, neither on the rim of the cuff nor inside the mask bowl. In one patient who experienced coughing and nose bleeding without hypoxemia upon awakening, the laryngeal surface of the PS-fLM was soiled with thick respiratory secretions but not blood.

All patients were alert and oriented upon or shortly after arriving in the PACU, as demonstrated by a modified-Aldrete score ≥9 in 97% of patients during the initial assessment (Table 4). While only one patient complained of mild sore throat in the PACU, the incidence of POST was recorded in nearly 20% after discharge on the following day (Table 4). Most patients reported this as mild or not bothersome, with the exception of two patients who reported significant sore throat (with pain on swallowing) after undergoing nearly 6 h of surgery including rhinoplasty, septoplasty, chin implant and breast augmentation. However, there was no difference in the duration of surgery or anaesthesia, or in EBL and

pharyngeal blood evacuated between patients with and without POST (Table 5).

4. Discussion

The laryngeal mask is recognized as a suitable alternative airway management technique for nasosinusal and upper airway surgeries [16–20]; however, concerns over blood pooling in the pharynx above the mask have hindered its universal acceptance. Prior studies have found that bleeding during nasosinusal surgeries varies significantly, despite the application of vasoconstrictive agents or controlled hypotension techniques [2,21]. This may also be true for other upper airway surgeries. Because the seal of the glottis by the laryngeal mask is not perfect nor guaranteed, and bleeding or blood accumulation is difficult to predict, a reasonable approach to reinforce isolation of the glottis is to promptly evacuate blood from and prevent blood accumulation in the pharynx.

Surgical bleeding in our patients varied widely with the surgeon and procedure, as patients who underwent over 2 h of septoplasty and rhinoplasty had significantly more blood loss. Additionally, our study demonstrates that the amount of blood evacuated from the pharynx correlates to the duration of surgery and the EBL. The latter result suggests that the pharyngeal suction catheters of the PS-fLM functioned as intended. The significance of the timely evacuation of blood from the pharynx can be two-fold: it minimises the impact of blood leakage when the seal of the glottis by the laryngeal mask is incomplete, and it minimises or prevents clot formation. Notably, of the 66 PS-fLMs that were inspected upon removal, none showed blood spillage into the laryngeal (inner) surface of the mask, even in cases with significant intra-operative bleeding (six patients with EBL more than 100 ml) or large amount of blood in the pharynx (13 patients with more than 30 ml). This is in contrast to the findings in previous studies in which blood leakage and glottic or lower airway contamination of blood was reported in 2%–20% of patients with laryngeal masks during nasal surgery [1–5]. Similarly, blood leakage has previously been observed in patients with laryngeal masks during adenotonsillectomy [6]. Clearly, clinically significant aspiration of blood during nasosinusal and other upper airway surgeries under laryngeal mask depends on the presence and degree of leaking, as well as the amount of bleeding and the rate of blood accumulation. This likely explains the rare incidence of blood aspiration despite the imperfect seal, with a leaking rate of up to nearly 20% since routine nasosinusal surgeries generally have short duration with minimal EBL. However, blood aspiration does occur and is likely underreported as well. The impact of pharyngeal suction on the incidence of blood aspiration warrants a large controlled study, as our results indicate the likelihood of a lower incidence of glottic contamination with the PS-fLM.

The overall incidence of laryngospasm with laryngeal mask use is reportedly as low as 1.7%, compared to 7.5% with tracheal intubation [22]; however, data on the incidence of laryngospasm with laryngeal mask in nasosinusal surgeries are limited [17]. In a few small studies that examined the occurrence of laryngospasm and hypoxemia at emergence from anaesthesia, no laryngospasm was observed [2,3], although hypoxemia was noted in some patients after removal of laryngeal mask [3]. The incidence of laryngospasm during other upper airway surgeries such as adenotosillectomy using laryngeal mask is also debatable, with most studies suggesting no statistical difference when compared with endotracheal tube [6,17,23]. Using the PS-fLM in our study, none of the 71 patients experienced either laryngospasm or hypoxemia, and the incidence of coughing at emergence was also low (1.4%) when compared with values (8.3% and 8.6%) previously reported in the aforementioned studies [2,3]. The ability of the incorporated catheters to instantly evacuate residual blood immediately before as well as during the removal of the PS-fLM may have contributed to this low incidence of coughing during emergence, while its impact on laryngospasm is to be determined.

One hypothetical concern about the intermittent pharyngeal suction over the entire course of surgery is injury to the upper airway or increased risk of POST. Our data, however, shows that the incidence of POST (19.3%) in this study is comparable to or lower than the incidences (17%–35%) reported in the literature [22,24–26]. Additionally, the occurrence of POST was not related to the duration of surgery or the amount of pharyngeal blood suctioned through PS-fLM ($P = 0.98$ and 0.70, respectively). Moreover, reports of POST occurred almost exclusively after patients were discharged home rather than in the PACU regardless the duration of surgery. This latter finding is intriguing as it is consistent with the report by Seet et al. [27], and may point the causation away from acute traumatic injury. We speculate that the suction catheters communicated with each other, despite the small gap between their distal orifices, since fluid movement was frequently observed in one catheter when suction was applied to the other. In addition, air can enter along the top of the mask through the oral pharynx. These mechanisms create an open system for the pharyngeal suction and minimise the impact of negative pressure to the pharyngeal mucosa. The pharyngeal suction catheters also eliminate the need for throat packing, which offers limited efficacy in blocking the blood from entering the aerodigestive track and may even cause POST [11–13].

In approximately 10% of cases, only one catheter was functional. We believe the location of orifices is important for the efficacy of the suction catheters. The Tri-Flo catheter has only two side pores next to the distal opening. If the orifices are positioned too closely to the tip of the mask, they may be concealed in the upper oesophagus and become ineffective. Bending of the catheter tip may also occur. A manufactured laryngeal mask with embedded or integrated suction catheters is desirable in future studies.

Due to the nature of a single-centre retrospective cohort study, the generalizability of these findings is limited. Our study also lacks a formal control arm, as during the study period, all but one nasal surgery at our surgicenter were performed with either tracheal intubation or PS-fLM. As a result, our analysis of the incidence of airway complications necessitated a comparison with values reported by other studies. Additionally, anaesthesia for nasal surgeries using the PS-fLM was conducted largely by one anaesthesiologist and a few experienced nurse anaesthetists under supervision; thus, data on the widespread use of the PS-fLM amongst different anaesthesia providers are not available, and both consistency and bias in data recordings may exist. Finally, we caution everyone to use every measure to minimise gastric insufflation with the current type (i.e. first-generation) of flexible laryngeal masks, particularly if the surgery is prolonged.

In conclusion, laryngeal mask with pharyngeal suction capability provided safe airway management for nasal surgeries without apparent glottic contamination or other significant airway-related complications and was not associated with an increased risk of postoperative sore throat in this retrospective observational study. A large controlled prospective study using a manufactured device is needed to confirm if the added pharyngeal suction capability reduces the incidence of laryngospasm and/or risk of lower airway contamination during nasal and other upper airway surgeries, particularly if the surgery is prolonged or the surgical bleeding is significant.

Assistance with the study

None.

Conflicts of interest

Dr. P. Heerdt has received consulting fees from Cheetah Medical, Imperativ, LLC, Caretaker Medical, and Recro Pharma in the past 3 years. He is co-founder of RVMetrics, LLC.

All other authors declared no conflict of interests.

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