

The Incidence of Aspiration Associated with the Laryngeal Mask Airway: A Meta-Analysis of Published Literature

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Study Objective: To determine the incidence of pulmonary aspiration with the laryngeal mask airway (LMA).

Design: A meta-analysis of all published literature on the LMA to September 1993. Measurements and Main Results: All 547 publications were reviewed and coded, and those observational studies in which the LMA was the main form of airway management were analyzed. Pulmonary aspiration was defined as either the presence of bilious secretions or particulate matter in the tracheobronchial tree or, if bronchoscopy was not performed, a postoperative chest radiograph with infiltrates present on preoperative chest radiograph or physical examination. In the study population, there were 3 cases of aspiration in 12,901 patients, and when combined with four independent reports excluded from the detailed analysis, this gave a final incidence of 2 in 10,000. Ten confirmed pulmonary aspiration events from published case reports showed that most cases had one or more predisposing factors. No death or permanent disability occurred.

Conclusions: The evidence to date suggests that pulmonary aspiration with the LMA is uncommon and comparable to that for outpatient anesthesia with the face mask and tracheal tube. Meticulous attention to selection of low-risk patients and appropriate operative procedures and avoidance of light anesthesia should reduce the incidence even further.

Keywords: Aspiration, pulmonary: complications; laryngeal mask airway.

Introduction

The laryngeal mask airway (LMA) was introduced into clinical practice in 1988, and it has since been used in an estimated 10 million patients in over 60 countries.¹ The majority of authoritative reviews²⁻⁵ and editorials⁶⁻⁹ consider that it has an important place in anesthetic practice, and it has been incorporated into the guidelines for management of the difficult airway.¹⁰ Its single most limiting feature remains the risk of aspiration.

When ideally positioned, the LMA tip occludes the upper esophageal sphincter, with the cuff forming a seal around the laryngeal inlet to a variable

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Reprints will not be available.

Received for publication January 28, 1994;
revised manuscript accepted for publication August 3, 1994.

ventilatory pressure of 15 to 25 cm H₂O. This does not comprise either an antireflux or an anti-aspiration mechanism, and regurgitated fluid may leak around the piriform fossae into the bowl of the LMA. Three recent small studies have raised the question of whether the presence of the LMA cuff in the pharynx actually promotes gastroesophageal reflux,¹¹⁻¹³ although these findings have been challenged.¹⁴⁻¹⁶ Pulmonary aspiration associated with the LMA has been documented in case reports¹⁷⁻²⁵ and prospective surveys.^{26,27} In most instances, however, risk factors can be identified indicating that the LMA was used inappropriately rather than there being any inherent defect of the device itself.

The true incidence of aspiration with the LMA is unknown, although a survey of cases of LMA-related aspiration admitted to Australian intensive care units (ICUs) over a 2-year period allowed an estimation of between 0.04 and 1.1 per 10,000.²⁵ Cumulative data from two of the largest prospective surveys suggest an incidence of aspiration of 2.3 per 10,000, with no subsequent pulmonary complications.^{26,27} This figure is comparable to that found for elective²⁸ and outpatient general anaesthesia²⁹ prior to the availability of the LMA. There have been no large prospective, randomized trials comparing the incidence of aspiration between the LMA, face mask, and tracheal tube, and such a trial would require a minimum of 500,000 cases. We felt that a retrospective survey of all the currently available information would provide an estimate of the incidence of aspiration-related mortality or morbidity associated with the LMA.

The aims of this analysis were twofold: (1) to analyze the data from published studies on the LMA, and so to estimate the incidence of aspiration and aspiration-associated morbidity; and (2) to examine all published case reports of aspiration to identify and evaluate common risk factors.

Materials and Methods

Studies

A literature search was conducted to obtain all publications on the LMA up to September 1993. Three medical databases (48 Hours, Medline, and Reference Manager Update) were searched for citations containing keywords, subject headings, and text entries related to the LMA. Additional references were obtained from the indices of 14 major anesthetic journals.* All publications were reviewed and coded as editorials, reviews, papers, case reports, abstracts, or letters to the editor, which were further subdivided into case reports and "mini-papers" (i.e., studies presented in letter form).

Observational studies in which the LMA was the main

**Acta Anaesthesiologica Scandinavica*, *Anaesthesia*, *Anaesthesia and Intensive Care*, *Anesthesia and Analgesia*, *Anesthesiology*, *British Journal of Anaesthesia*, *Canadian Journal of Anaesthesia*, *European Journal of Anaesthesiology*, *Journal of Cardiothoracic and Vascular Anesthesia*, *Journal of Clinical Anesthesia*, *Journal of Neurosurgical Anesthesiology*, *Journal of Obstetric Anaesthesiology*, *Journal of Pediatric Anaesthesiology*, and *Regional Anesthesia*.

airway management technique were selected for final analysis. Studies were excluded if (1) the LMA was not the main form of airway management, (2) the study did not involve patients, (3) duplicate publication (As judged by similarity of content and authorship, abstract or "mini-paper" excluded), or (4) reliable translations were unobtainable. Patients in whom LMA insertion failed were included in the study population. The relevance of studies with respect to aspiration were graded as follows: 4-aspiration specifically mentioned or excluded; 3-authors stated that there were no problems or complications; and 2-no statement was made, but text suggested that aspiration would have been noted if it occurred; and 1-no mention or inference concerning aspiration.

Pulmonary aspiration was defined as either the presence of bilious secretions or particulate matter in the tracheobronchial tree or, if bronchoscopy was not performed, a postoperative chest radiograph with infiltrates present on preoperative chest radiograph or physical examination.²⁸ In addition to demographic data, the mode of ventilation was recorded either as spontaneous, intermittent positive pressure ventilation (IPPV), or mixed/unspecified (all weighted by sample size). The "study population" was defined as the total number of patients included in studies undergoing final analysis.

Case Reports

All case reports of suspected aspiration were examined (case report population). Patient details, diagnostic criteria, predisposing factors, management, and outcome were documented and analyzed where possible. Case reports were taken from all publications, including observational studies.

Data Abstraction

By September 1993, the total number of publications in which the LMA was the main focus was 532, and there were a further 15 in which the LMA was not the main topic. Included in this number were 89 papers, 71 abstracts, and 48 mini-papers; 50% of publications were letters to the editor. All publications were independently reviewed by both authors and the relevant information was downloaded first onto separate databases (Reference Manager) and then separate structured spreadsheets (Quattro Pro) for comparison and verification. Sixty-four papers,^{11,12,22,26,27,30-88} 26 abstracts,*†‡§¶#-13,16,89-106 and 11 "mini-papers"^{17,107-116} met the criteria for final analysis.

*Miyasaka K, Suzuki Y, Nakagawa S, Asahara S: The use of the laryngeal mask in pediatric anesthesia [Abstract]. *Proceedings of the 8th Asian-Australian Congress of Anaesthesiologists* 1990;1:S5-6;158.

†Ragg P, Thomas G: The laryngeal mask airway: a clinical audit [Abstract]. *Anaesth Intensive Care* 1991;19:295.

‡Versichelen L, Van Der Schueren G, Mergaert C, Rolly G: The use of the laryngeal mask airway during short lasting ENT surgery in children [Abstract]. *Bordeaux International Congress*, July 2-3, 1992.

Table 1. Analysis of Publications Included in "the Study Population"

Publication Type	Total Publications	Total Patients	SV	IPPV	Mixed/Unknown	Children
Papers	64	9,583	6,058	2,459	1,066	1,459
Abstracts	26	1,743	355	50	1,338	532
Mini-papers	11	1,575	160	0	1,415	400
Total	101	12,901	6,573	2,509	3,819	2,391

SV = spontaneous ventilation; IPPV = intermittent positive pressure ventilation.

Results

Studies

The total study population was 12,901. At least 85% of patients were ASA physical status I and II; the remainder were ASA physical status III. The mean age was 32 years (0 to 98 yrs) and approximately 20% were classified as children (under 18 yrs), with a mean age of 5 years. Spontaneous ventilation was employed in 52.6%, IPPV in 19.4%, and in 28% the ventilatory mode was either mixed or unspecified (Table 1). The male to female ratio was 49:51 and the median relevance grading was 1.9. There were no significant differences in demographic details or relevance grading between papers, abstracts, or mini-papers.

There were 3 cases of aspiration in the total study population (2.3 per 10,000). Two were from a mini-paper describing a series of 546 patients¹⁷ and the other was from a prospective survey of 1,925 patients.²⁷ There were no cases of aspiration in children. The 3 cases comprised 2 females and 1 male, aged 29 to 55 years. Two of the aspirations occurred during spontaneous ventilation and the third during IPPV. In two cases there was a predisposing factor to aspiration: (1) emergency anesthesia and (2) Trendelenburg position with intra-abdominal insufflation. In the third case, the LMA was removed when the patient developed bronchospasm during light anesthesia and was noted to regurgitate during IPPV with a facemask prior to intubation. The investigators considered that aspiration could not be attributed to the LMA. In 2 of 3 cases, pulmonary morbidity did not occur (normal postoperative chest radiograph); pulmonary outcome was not described in the third case.

The incidence of aspiration from studies where aspiration or any complication were specifically mentioned or excluded was 3:6,562 (grades 3 and 4 studies). The incidence for all grades was 3:12,901. Additional infor-

mation about aspiration came from four reports not included in the study population. In a 1991 review, Leach and Alexander³ came to the conclusion that the incidence of regurgitation was very low when patient selection was appropriate, and they reported no cases of aspiration in over 7,000 patients from Hastings Hospital, Sussex, UK. Brain^{21,117} noted 2 cases of aspiration (one confirmed by fiberoptic bronchoscopy, the other by postoperative expectoration of a bilious plug) from a personal series of over 8,500 patients. A survey of all Australian ICUs between 1990 and 1991 revealed a total of 8 cases of suspected aspiration from an estimated 34,000 to 340,000 uses.²⁵ Finally, Moylan and Luce¹¹⁸ reported the use of the LMA in 145 children undergoing radiotherapy on 2,500 occasions without incident.

Case Reports

In the case report population, there were 18 cases of suspected pulmonary aspiration documented in the literature (Table 2). Comprehensive details were lacking in many of these cases, and diagnostic criteria frequently were not given. In only 10 cases could pulmonary aspiration be confirmed according to the above diagnostic criteria. The age range was 8 to 74 years, and the male to female ratio was 6:5 and included 2 children. ASA physical status was I, II, and III. In 4 cases aspiration occurred at, or shortly after, induction, in 2 cases during the procedure, in 2 cases at the end of the procedure, and in 2 cases timing was unspecified. Most cases had one or more predisposing factors including emergency anesthesia,^{17,20} obesity,²¹ dementia,^{20,25} previous gastric surgery,^{20,25} elective upper abdominal surgery,^{18,21} Trendelenburg position with intra-abdominal insufflation,¹⁷ inadequate anesthetic depth,^{18,19,23,24} and airway difficulties.²⁷ There was no correlation with ventilatory mode. Significant pulmonary complications occurred in 3 patients who required IPPV postoperatively for between 20 and 168 hours.^{18,19,25} All patients subsequently recovered fully with no long-term disability.

Discussion

Large pre-LMA epidemiologic studies have documented low incidences of perioperative pulmonary aspiration in both adults and children.^{119,120} The overall incidence of aspiration related to general anesthesia has been variably reported as 1.4 to 6.5 per 10,000, with an associated

§Tachaires D, Andres J: Laryngeal mask and tonsillectomies [Abstract]. Bordeaux International Congress, July 2-3, 1992.

¶Dubreuil M, Cros AM, Boudey C, Esteben D, Milacic M: Is adenoidectomy in children safer with laryngeal mask than with facial mask or with endotracheal intubation? [Abstract]. Bordeaux International Congress, July 2-3, 1992.

#Toulouse C: Use of the laryngeal mask in gynecological surgery [Abstract]. VIII Congress of SARANF, Dakar, November 26-28, 1991.

Table 2. Analysis of Cases of Pulmonary Aspiration

Source	Age	Gender	ASA Physical Status	Diagnostic Criteria Met	Timing	Predisposing Conditions	Outcome
(17)*	50	F	n/a	Yes	1.5 h after induction	Multitrauma. Fasting 26 hours. Opioids	Not available
(17)*	29	F	I	Yes	Just before end of procedure		
(18)	26	F	I	Yes	After surgery during epidural insertion	Patient movement. Cholecystectomy. Cuff deflated early	ICU for 24 h. No IPPV. Good recovery
(19)	51	M	II	Yes	Immediately after insertion	Hiccough following insertion	ICU. IPPV 20 h. Good recovery
(20)	74	M	III	Yes	Following displacement of femoral head	Fractured neck of femur Dementia. PMH peptic ulcer and esophageal dilatation	ICU. IPPV for 4 days. Discharged to ward day 5
(21)	n/a	n/a	n/a	Yes	During anesthesia	n/a	No sequelae
(21)	n/a	F	n/a	Yes	At induction	Obesity. cholecystectomy	No sequelae
(23)	8	F	?II	Yes	Following transfer and positioning in lithotomy	Movement. Procedure abandoned	Full recovery
(27)*	55	M	I-II	Yes	During procedure	Bronchospasm. LMA removed. Aspiration during IPPV with FM	No sequelae
(24)	15	n/a	I-II	?	After 2 h	Inadequate anesthetic depth	ICU. No IPPV. Rapid recovery
(25)†	75	M	III	Yes	During anesthesia	Lithotomy position, dementia, hiatus hernia	IPPV for 1 week. Survived

*Included in the study population. Other cases not from observational studies.

†Survey of Australian Intensive Care Units. A total of 8 alleged cases. Lack of detail in 7 cases.

IPPV = intermittent positive pressure ventilation; LMA = laryngeal mask airway; FM = face mask.

mortality of approximately 5%.^{29,120-123} A recent large prospective trial of 215,488 non-LMA general anesthetics, in which rigid criteria were used to define aspiration, estimated that aspiration occurred in 11 of 10,000 patients undergoing emergency surgery and 2.6 per 10,000 undergoing elective surgery.²⁸ The overall mortality, which was confined to ASA physical status III, IV, and V patients, was 0.14 per 10,000. A large survey of 529,150 outpatient anesthetics showed an aspiration rate of 1.7 per 10,000, with no significant difference between the face mask and tracheal tube.²⁹

The results of this current study and other series suggest that the overall incidence of pulmonary aspiration with the LMA is likely to be in the region of 2 per 10,000 (5:24,562). This comprises 3:6,562 from grade 3*†‡^{30,34,36,40,46,72,91,104} and grade

4^{11,16,17,26,27,32,42,70,80,88} of the study population, 2:8,500 from Brain's personal series,^{21,117} 0:7,000 from Leach and Alexander,³ and 0:2,500 from Moylan and Luce.¹¹⁸ There have been no published reports of long-term morbidity or mortality associated with the LMA either secondary to aspiration or any other cause.

The case reports of aspiration must represent the tip of the iceberg. If the LMA has been used 10 million times and the incidence of aspiration is 2 per 10,000, there should have been at least 2,000 cases of pulmonary aspiration associated with its use worldwide. Less than 1% of this hypothetical subgroup of patients have been documented in the LMA literature. Detailed reports from all of this hypothetical group could provide invaluable information for evaluating risk factors and determining the benefits of therapeutic regimens. There are, however, some important lessons to be learned from the case reports available. Exclusion criteria for LMA anesthesia should include patients with recent multitrauma

*Ragg P, Thomas G: The laryngeal mask airway: a clinical audit [Abstract]. *Anaesth Intensive Care* 1991;19:295.

†Versichelen L, Van Der Schueren G, Mergaert C, Rolly G: The use of the laryngeal mask airway during short lasting ENT surgery in children [Abstract]. Bordeaux International Congress, July 2-3, 1992.

‡Tachoures D, Andres J: Laryngeal mask and tonsillectomies [Abstract]. Bordeaux International Congress, July 2-3, 1992.

and heavy opioid administration, those unable to give an adequate history, and those scheduled for upper abdominal surgery. Inadequate anesthetic depth should be avoided.

The incidence of regurgitation of small amounts of gastric contents is estimated at between 4% and 26% in general anesthesia¹²⁴⁻¹²⁷ and subsequent aspiration into the tracheobronchial tree ranges from 10% to 20%.^{124-126,128} This fact is of uncertain significance, although it has been suggested as one of the causes of postoperative pulmonary complications.¹²⁹ Blitt *et al.*¹²⁸ demonstrated that regurgitation occurs in 4.5% of patients undergoing general anesthesia with a face mask and 12.5% with a tracheal tube, and of these, 17% and 7%, respectively, go on to aspirate.

The incidence of regurgitation with the LMA was not specifically examined in this study population, because such events were considered more unlikely to be incidentally reported than aspiration events. The presence of regurgitated fluid may be difficult to differentiate from oral secretions or bronchial material. Figures derived from publications where the incidence of regurgitation was specifically addressed varied between 6 and 150 per 10,000 patients, with an average of 16 per 10,000 (18:11,405). This data was derived from the following publications: 5:8,500,^{21,117} 8:546,¹⁷ and 5:2,359.²⁶ Regurgitation has been noted on two occasions in non-fasted patients,^{22,130} as well as in a patient with a small hiatus hernia,¹³¹ and in a 45-year old man undergoing routine myringoplasty with no predisposing condition.¹³²

Physiologically, vomiting differs from simple regurgitation, because the glottis is closed and aspiration is less likely. In studies where vomiting was specifically mentioned, the incidence varied between 15 and 500 per 10,000, with an average of 39 per 10,000 (11:2,846). These data were derived from the following studies: 4:1,925,²⁷ 1:671,⁴⁹ 4:200,³⁶ and 2:50,⁴⁵ and occurred either at induction or, more commonly, during the recovery phase following LMA removal. Koehli¹⁹ has suggested that the LMA preferentially directs vomit into the trachea. Brain, however, believes that since the LMA obliterates the pharyngeal reservoir there is less fluid available to be aspirated at any one moment, and that regurgitated fluid will follow the low pressure pathway up the LMA tube on expiration.²¹ Eldor¹³³ has suggested the use of a paratracheal audible respiratory monitor to facilitate the early detection of regurgitation.

Some studies have suggested that the LMA puts the patient at greater risk of aspiration than the face mask alone.^{11,12} Barker *et al.*¹¹ demonstrated swallowed dye regurgitating into the LMA in 7 of 28 patients with the LMA compared with 0 of 28 patients for the face mask and Guedel airway. Rabey *et al.*,¹² in a study of 40 patients, showed that there was a significant decrease in lower esophageal sphincter pressure with the LMA compared with the face mask. They postulated that the LMA caused reflex relaxation of the lower esophageal sphincter by distention of the pharyngeal muscles, similar to the effect of a food bolus. Both of these studies in-

involved small groups of patients and have been criticized on methodologic grounds.^{14,15} Two recent abstracts have provided further conflicting data. El Mikatti *et al.*¹⁶ repeated the dye study in 60 patients and found no incidence of regurgitation in either group. Owens *et al.*,¹³ in a study of 55 patients using esophageal electrodes, showed a higher incidence of lower esophageal regurgitation with the LMA than the face mask (57% versus 22%). In a further small study, Vanner *et al.*⁸³ showed that the upper esophageal sphincter remained competent during LMA and face mask anesthesia, but became incompetent with a tracheal tube where muscle relaxants were used. In summary, studies to date that have examined the risk of regurgitation with the LMA are inconclusive and need to be repeated using more rigorous methodology and greater patient numbers.

It is interesting to note that inability to successfully manage difficult airways is responsible for 30% of deaths totally attributable to anesthesia,¹³⁴ whereas aspiration pneumonitis per se is an infrequent cause of anesthesia related mortality. Eight-five percent of all respiratory-related closed malpractice claims involve a brain-damaged or dead patient. Inadequate ventilation (33%), esophageal intubation (18%), and difficult tracheal intubation (17%) account for 68% of these claims. The incidence of failed tracheal intubation is between 5 and 35 per 10,000 patients.¹³⁵ Aspiration represents only 5% of respiratory claims against the anesthesiologist, and it is a common adverse outcome of failed or difficult intubation. In this context it is interesting to point out that the LMA can provide a clear airway within 20 seconds in up to 98% of patients,¹¹⁶ and ease of insertion is not generally compromised in patients with anticipated intubation difficulty.^{94,116} The risk of esophageal intubation is avoided and the LMA has been lifesaving on occasion in the management of difficult tracheal intubation.^{8,10,135} Whether anesthesia-related morbidity following critical incidents may be similarly reduced through the immediate availability of the LMA is yet to be established. Interestingly, Haden *et al.*¹³⁶ collected data from over 9,600 patients and found a significantly lower incidence of difficult placement and laryngospasm with the LMA than the tracheal tube (0.9% versus 3.4%) (grade 3 letter to the editor). There is evidence that, compared with the tracheal tube, the LMA has minimal effect on the cardiovascular system^{38,55} and intraocular pressure^{31,54} on insertion, it allows more normal respiratory physiology to be maintained,¹³⁷ and it has a low incidence of pharyngeal morbidity.^{60,138}

A large, randomized, prospective trial comparing the incidences of regurgitation and aspiration between the LMA, the face mask and oral airway, and the tracheal tube in "low-risk" patients would be valuable. Because aspiration is a rare event, however, it will be difficult to study the impact of any management regimen on outcome. In the majority of published reports on aspiration the LMA was removed, and the patient was paralyzed and intubated followed by fiberoptic inspection and/or suction of the tracheobronchial tree. Brain²¹ recom-

mends a different approach based on the philosophy that while regurgitation or aspiration has occurred, the LMA continues to function as an airway, and that hypoxia is likely to precipitate further reflux. At the first sign of regurgitation or aspiration, the LMA is left in situ and the patient placed in a Trendelenburg position while informing the surgeon; FiO₂ is increased to 100% and anesthesia is deepened while controlling ventilation with gentle manual bag-squeezing. As soon as oxygenation is satisfactory, tracheal suction is performed through the tube of the LMA. Brain²¹ claims success with this approach in 4 patients, and it may be the optimum first line approach while preparing for intubation and fiberoptic bronchoscopy.

In summary, the evidence to date suggests that pulmonary aspiration associated with the LMA is rare and has an incidence comparable to that of outpatient anesthesia with the face mask and tracheal tube. Meticulous patient selection and adherence to the guidelines for its use should reduce the incidence of aspiration even further. We would suggest that a system of formal reporting of all general anesthesia related aspirations and analysis of accumulated data could be a valuable and educational development.

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