Risk of pulmonary aspiration with laryngeal mask airway and tracheal tube: analysis on 65 712 procedures with positive pressure ventilation

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Summary

We compared the risk of pulmonary aspiration in patients whose lungs were mechanically ventilated through a laryngeal mask airway (35 630 procedures) or tracheal tube (30 082 procedures). Three cases of pulmonary aspiration occurred with the laryngeal mask airway and seven with the tracheal tube. There were no deaths related to pulmonary aspiration. The incidence and outcome of pulmonary aspiration detected in this study were similar to those previously reported. The adjusted odds ratio (OR) for pulmonary aspiration with the laryngeal mask airway was 1.06 (95% CI 0.20–5.62). Unplanned surgery (OR 30.5, 95% CI 8.6–108.9) and male sex (OR 8.6, 95% CI 1.1–68) were associated with an increased risk of aspiration and age < 14 years with a reduced risk (OR 0.21, 95% CI 0.07–0.64). There were contraindications and exclusions to the use of the laryngeal mask airway but in this selected population the use of an laryngeal mask airway was not associated with an increased risk of pulmonary aspiration compared with a tracheal tube.

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The laryngeal mask airway (LMA) has several advantages over tracheal intubation in patients undergoing general anaesthesia. Postoperative hoarseness, sore throat, impairment of swallowing, pain, nausea and vomiting, and coughing are reduced, post-anaesthesia recovery unit length of stay is shortened, and increases in intra-ocular pressure and derangements in cardiovascular and respiratory function are less likely [1–11]. Furthermore, the LMA can be useful in the management of the difficult airway when facemask ventilation is inadequate [12].

Despite its advantages, concerns exist over the safe use of the LMA and its ability to prevent pulmonary aspiration [13]. Positive pressure ventilation may be a risk factor for pulmonary aspiration with the LMA [14] secondary to gastric inflation [15–18].

Safety is an important anaesthetic issue with significant clinical and legal implications. Not surprisingly, pulmonary aspiration is a key factor when considering the role of supraglottic airway devices [19]. There is little evidence evaluating the risks of pulmonary aspiration with an LMA compared with tracheal intubation during mechanical ventilation. The aim of the present study was to test the hypothesis that using an LMA increases the risk of pulmonary aspiration compared with tracheal intubation in patients undergoing positive pressure ventilation.

Methods

The study design was a retrospective analysis of prospectively collected data. The analysis was conducted on the anaesthesia database of Poliambulanza Foundation Hospital (a university affiliated not for profit hospital). The institutional ethics committee (Comitato Etico Istituzioni Ospedaliere Cattoliche) approved the data analysis.

The database is constructed as follows: anaesthetists fill out structured file cards with data relating to their anaesthetic procedures. The departmental assistant then checks and enters file cards into the electronic anaesthesia database on a daily basis. The database records have the following fields: procedure-related information (day of surgery, surgical specialty, type of procedure, length of surgery, if surgery was elective or unplanned);

patient-related data (sex, age, weight, ASA classification); anaesthesia-related data (anaesthesia and ventilation modalities, device for airway management, name of anaesthetist); and any major complications occurring during the operating room and recovery room stay. Surgery was defined as elective if it had been planned in the 24 h before the procedure. Pulmonary aspiration was considered to have occurred if: (i) gastric contents, bilious fluid or other non-respiratory secretion was suctioned from the trachea; or (ii) dyspnoea, hypoxia, auscultatory abnormalities and/or new infiltrates on chest X-ray appeared after the appearance of gastric contents, bilious fluid or other non-respiratory secretion in any part of the LMA or in the oropharynx. Patients with pulmonary aspiration were followed up until hospital discharge.

Records were extracted from the database if they met all of the following criteria: (i) data collected from September 1st 1997 to April 30th 2008; (ii) general anaesthesia; (iii) LMA or tracheal tube as airway device; (iv) positive pressure ventilation as ventilatory modality. At Poliambulanza Foundation Hospital, both reusable and disposable LMAs are supplied by the Laryngeal Mask Company Ltd, Nicosia, Cyprus. Different kinds of LMA (classic, ProSeal, flexible or intubating) are the only supraglottic devices used in our hospital. We restricted the analysis to procedures carried out with classic LMAs because other LMAs are rarely used. We can therefore not make any comments about the impact of different LMA models on the risks of pulmonary aspiration.

Database validation was carried out to avoid both misclassification and omission of cases of pulmonary aspiration. In every case of pulmonary aspiration that was identified, the original chart was examined to confirm all details. Moreover, two departmental surveys with structured interviews were conducted during the study period in order to detect any missed cases of pulmonary aspiration. The structured interviews were administered to all anaesthetists in the department by one of the authors (GN). No further cases of pulmonary aspiration were detected.

At the Poliambulanza Foundation Hospital, the LMA is contraindicated in non-fasted patients (< 6 h from eating or < 2 h from drinking clear fluid), intestinal obstruction, pregnancy, unplanned surgery with a pre-operative fasting period < 12 h, airway surgery and the prone position. In these conditions the LMA is a second choice to be considered after a failed tracheal intubation. Mechanical ventilation was delivered using an ADU/AS3 integrated system (Datex-Engstrom Division, Instrumentarium Corp., Helsinki, Finland). The default ventilator setting was volume controlled ventilation with a tidal volume of 8–10 ml.kg^{-1} actual body weight with a respiratory rate based on the end-expiratory CO_2

(P_ECO_2) or P_aCO_2 if available). Major abdominal surgery included small bowel, colonic, abdominal vascular, upper abdominal (i.e. oesophagectomy without thoracotomy, gastric resection, laparoscopic cholecystectomy, hepatic and biliary surgery, pancreatic resection, splenectomy), urological (i.e. nephrectomy, cystectomy, prostatectomy), gynaecological and retroperitoneal surgery. Laparoscopic surgery included cholecystectomy, adrenalectomy, colonic resection, gastroplasty, oophorectomy and hysterectomy.

Missing data ranged between 0% and 2.1% for all but one variable (length of procedure; 40.7% missing) and these were treated with random multiple imputation. Cohort characteristics were compared using chi-squared test, t-test or Wilcoxon test as appropriate. The association between pulmonary aspiration and airway device (LMA compared with tracheal tube) was evaluated by the odds ratio (OR) and its 95% CI. To adjust for baseline differences between groups, we used a propensity score. The propensity score is useful in observational studies in which baseline characteristics differ between groups and the number of events is relatively small [20]. To generate a propensity score, a logistic regression model is first created in which the characteristics of patients are independent variables and the exposure group is the dependent variable. The propensity score is then calculated for each patient by applying the patient's values to the logistic model. Propensity scores range from 0 to 1 and reflect each patient's conditional probability of receiving the treatment rather than the control. Therefore, propensity score was added as covariate in a multivariate logistic regression model and adjusted OR was calculated [21].

In order to identify variables associated with pulmonary aspiration we performed univariate analysis and variables with p value lower than 0.1 were included as covariates in multiple logistic regression to estimate adjusted OR with their 95% CI. All p values lower than 0.05 were considered significant. Statistical analyses were performed using R statistical software, version 2.6.1, with the package *epicalc* (R Foundation for Statistical Computing, Vienna, Austria, http://www.R-project.org).

Results

During the study period 1 000 209 anaesthetic procedures were recorded in the database. An LMA was used in 38 200 of them (38%). We extracted 65 712 procedures involving general anaesthesia and positive pressure ventilation delivered via an LMA or tracheal tube. Cohort characteristics are shown in Table 1.

Tracheal intubation was chosen for 98.3% of the surgical procedures with contraindications to the LMA

(nose and throat surgery, thoracic and lumbar spinal surgery, caesarean delivery and surgery for intestinal obstruction). Ten cases of pulmonary aspiration were recorded in the database. Four occurred during elective surgery (two with the LMA) and six during unplanned surgery (one with the LMA). The incidence, outcome and details of the cases of pulmonary aspiration are shown in Table 2. Six patients were admitted to the intensive care unit (ICU) after pulmonary aspiration, five of whom underwent emergency surgery. One of these patients had undergone elective surgery with an LMA and a further patient had undergone emergency surgery with a tracheal tube. Both patients were discharged from ICU within 1 day and made full recoveries. In the other cases the ICU admission was prompted by the patient's status and not by the aspiration. Univariate analysis showed that LMA use had an OR of 0.36 (95% CI 0.09–1.4; $p = 0.141$) for pulmonary aspiration compared with the tracheal tube, whereas the adjusted OR was 1.06 (95% CI 0.20–5.62; $p = 0.945$). Variables associated with pulmonary aspiration during general anaesthesia with positive pressure ventilation are shown in Table 3.

Discussion

The aim of the present study was to test the hypothesis that managing the airway with an LMA increases the risk of pulmonary aspiration compared with tracheal intubation in patients undergoing positive pressure ventilation. Our data showed that the use of the LMA did not increase the risk of incurring signs or symptoms of pulmonary aspiration compared with a tracheal tube in our study population. In particular, the risk of pulmonary complications (hypoxia, new radiograph findings or auscultatory findings) and ICU admission did not differ between patients with an LMA or tracheal tube. The main factor associated with pulmonary aspiration was emergency surgery. Furthermore, pulmonary aspiration did not

Table 2 Incidence of pulmonary aspiration and outcome, and characteristics of patients and procedures, following positive pressure ventilation with either the LMA or tracheal tube. Data are shown as number (proportion), mean (SD) or median (IQR).

	Total	LMA	Tracheal tube
n	10	3	7
Incidence			
Total	1:6 571	1:11 877	1:4 297
Elective surgery	1:15 584	1:17 349	1:13 819
Unplanned surgery	1:563	1:933	1:489
Outcome			
Discharge: PACU to ward	4	2	2
Discharge: PACU to ICU	6	1	5
Hospital mortality	2	0	2
Hospital mortality attributable to pulmonary aspiration	0	0	0
Patients and procedures			
Female sex	1	1	0
Age; years	42 (25)	33 (20)	46 (28)
Patients < 14 years old	2	1	1
Patients > 65 years old	3	0	3
Body weight; kg	67 (22)	66 (21)	70 (24)
Patients > 100 kg	0	0	0
Unplanned surgery	6	1	5
Duration of surgery; min	70 (46–110)	70 (60–70)	110 (45–120)
Duration of surgery < 1 h	4	1	3
Local/regional anaesthesia	0	0	0
ASA physical status	2 (1–3)	1 (1–2)	3 (1–4)
ASA physical status I or II	6	3	3
Major abdominal surgery	4	0	4
Laparoscopy	0	0	0

PACU, post-anaesthesia care unit; ICU, intensive care unit.

Table 1 Characteristics of patients receiving positive pressure ventilation with either the LMA or tracheal tube. Data are shown as number (proportion), mean (SD) or median (IQR).

	LMA	Tracheal tube	p	Standardised difference
n	35 630	30 082		
Female sex	16 902 (47.4%)	14 771 (49.1%)	< 0.001	0.03
Age; years	45.2 (18.3)	49.7 (20.1)	< 0.001	0.24
Patients < 14 years old	723 (2%)	1 408 (4.7%)	< 0.001	0.15
Patients > 65 years old	5 895 (16.5%)	8 272 (27.5%)	< 0.001	0.26
Body weight; kg	70 (14.7)	69 (17.7)	< 0.001	0.08
Patients > 100 kg	979 (2.7%)	1 100 (3.7%)	< 0.001	0.05
Unplanned surgery	933 (2.6%)	2 444 (8.1%)	< 0.001	0.25
Duration of surgery; min	40 (20–60)	60 (30–90)	< 0.001	0.43
Duration of surgery < 1 h	28 405 (79.7%)	18 224 (60.6%)	< 0.001	0.42
Local/regional anaesthesia	1 888 (5.3%)	3 075 (10.2%)	< 0.001	0.19
ASA physical status	1 (1–2)	2 (1–2)	< 0.001	0.45
ASA physical status 1 or 2	33 064 (92.8%)	23 802 (79.1%)	< 0.001	0.40
Major abdominal surgery	1 727 (4.8%)	5 010 (16.6%)	< 0.001	0.39
Laparoscopy	861 (2.4%)	3 174 (10.6%)	< 0.001	0.34

	OR	p	Adjusted OR	p
Unplanned surgery	27.74 (7.82–98.33)	< 0.001	30.52 (8.55–108.89)	< 0.001
Male sex	8.38 (1.06–66.12)	0.044	8.6 (1.09–67.95)	0.041
Patients < 14 years old	0.24 (0.08–0.72)	0.011	0.21 (0.07–0.64)	0.006
Patients > 65 years old	1.37 (0.53–3.56)	0.52		
Duration of surgery < 1 h	2.51 (1.02–6.13)	0.044		
ASA physical status 1 or 2	2.8 (1.14–6.85)	0.024		
Major abdominal surgery	5.84 (1.65–20.7)	0.006		

Table 3 Variables associated with pulmonary aspiration in patients receiving positive pressure ventilation with either the LMA or tracheal tube. Data are shown as number (95% CI).

impact on mortality and morbidity, apart from two cases of ICU admission with a length of stay < 24 h.

In the present study, both incidence and outcome of pulmonary aspiration were similar to those previously reported. Our incidence of pulmonary aspiration was 1:6571: this value is very close to that reported in the most recent paper (1:7103) [22], and it is within the range of values that have been reported in the last 20 years (from 1:3216 to 1:14 139) [22–25]. Similarly, our low incidences of mortality and morbidity attributable to pulmonary aspiration are in keeping with those reported in previous studies [22–26].

We found that unplanned surgery and male sex were associated with an increased risk of pulmonary aspiration, as previously reported [24, 26]. It is less clear whether an age of < 14 years has a 'protective effect'. A possible explanation for this could be a selection bias of paediatric patients, due to the fact that children are usually admitted for elective surgery at Poliambulanza Foundation Hospital because there is a paediatric hospital in the same urban area. There were no reported incidents of pulmonary aspiration in the 9653 cases of elective major abdominal surgery and laparoscopy, 2517 of which were performed with LMA. Despite this finding, we cannot prove that the LMA is safe for use for elective laparoscopy and major abdominal surgery as these procedures pose a low risk for pulmonary aspiration provided that the surgery is planned, whether an LMA or tracheal tube is used.

Contraindications to use of the LMA

One issue is that the criteria used to exclude selection of the LMA are based mainly on opinion and not evidence. There appears to be a consensus that the main contraindication to use of the LMA is the risk of regurgitation of gastric contents, as the LMA does not provide an airtight seal around the larynx [13]. Nevertheless, concern about aspiration with the LMA is not strongly supported by outcome data. Reported risk factors for regurgitation and pulmonary aspiration with the LMA include oesophagitis, gastritis, gastric or duodenal ulcer, pyloric stenosis, intestinal obstruction, hiatus hernia, history of reflux or gastric surgery, obesity, injury, opioid administration,

prolonged anaesthesia, upper abdominal surgery, pregnancy, positive pressure ventilation and low respiratory system compliance [13–18, 27]. Should all patients with any of these conditions therefore be excluded from having an LMA? We evaluated the LMA's safety using a small list of definite clinical conditions as contraindications. Our choices for excluding the LMA were based upon documented risk factors and reflected our opinion about which were most important. We are confident that these contraindications were well known by the anaesthetists and they were strictly observed at Poliambulanza Foundation Hospital. This is supported by the almost universal use of tracheal tubes in surgical procedures where there were contraindications to the LMA. Objectively defined and consistently applied contraindications to the LMA may provide anaesthetists with protection from claims related to use of the LMA.

The risk of pulmonary aspiration was limited to non-fasted patients, patients with intestinal obstruction, patients who were pregnant and those who had undergone unplanned surgery. The last of these was a relative contraindication if the pre-operative fasting period was considered adequate, and the LMA was chosen in 933 unplanned procedures. Finally, the prone position and airway surgery were considered to be contraindications to the LMA because of difficulty in airway management in the event of complications during surgery. Although there are studies that show that the LMA can be effective in these conditions [28–30], data about safety are lacking.

Study limitations

The present study is a retrospective analysis of prospectively collected data. As for all observational studies, some cases may have been missed in a non-random manner. The study groups differed with respect to most of the considered variables and this is shown in Table 1. In the clinical setting, the LMA was not used for high-risk patients. The odds ratio for aspiration in patients in whom the LMA was used was < 1 in the univariate analysis, which is consistent with selection of patients with a lower risk of aspiration. The odds ratio increased when the propensity score was considered in the multivariate analysis, suggesting that patient selection did play a part

in how cases of aspiration were distributed between the LMA and tracheal tube groups. It is impossible to know whether the propensity score accounted for all of the important covariates in calculating the adjusted odds ratio. Since the anaesthetists who performed the anaesthetic filled out the data cards, the incidence of complications may have been underestimated. In the present study, reporting bias should be limited by only considering clinically relevant episodes. In our hospital, monitoring with pulse oximetry begins before induction of anaesthesia and it continues until discharge from the recovery room. Clinical evaluation and monitoring data are visible at all times to all medical staff and nurses. This should compel anaesthetists to report episodes of dyspnoea or hypoxia, as well as cases of aspiration of gastric or bilious contents from the LMA or tracheal tube. Moreover, interviews with departmental anaesthetists were carried out to pick up cases of pulmonary aspiration that had not been reported in the patient's chart. The definition of aspiration required signs of regurgitation and new pulmonary symptoms or signs. This limited the analysis to cases of clinically evident pulmonary aspiration and should reduce detection bias. Indeed, patients with clinically relevant aspiration usually show dyspnoea and/or hypoxia that should be independent of LMA or tracheal tube use.

Power analysis

Pulmonary aspiration is an infrequent event, making it very difficult to perform controlled randomised trials or prospective epidemiological studies with optimal statistical power [31]. The power of the present study was 0.69 when calculated by comparing the crude incidence of pulmonary aspiration with the LMA and tracheal tube (significance level 0.05, one-sided test). However, study groups were not matched, and comparison of the incidence of pulmonary aspiration between the LMA and tracheal tube may be meaningless. The absence of matching between groups was managed by regression adjustment with a propensity score. With this approach the uncertainty about odds ratios can be evaluated with 95% confidence intervals.

From our data, the incidence of pulmonary aspiration in patients with tracheal intubation undergoing mechanical ventilation during elective surgery was 1:13 819. In order to show an increase of 25% for pulmonary aspiration with the LMA compared to tracheal intubation, 3 075 472 patients per group would need to be randomised. The evaluation of the risk of pulmonary aspiration is likely to remain based on observational studies [31] and only meta-analysis is likely to be able to give conclusive evidence. Unfortunately, only limited data are available about pulmonary aspiration with the LMA: a survey involving 11 910 patients and a meta-analysis involving

12 901 patients [32, 33]. Our study increases the level of evidence.

We conclude that the LMA did not increase the risk of incurring signs or symptoms of pulmonary aspiration compared with the tracheal tube in selected patients undergoing mechanical ventilation. In particular, using an LMA in properly selected patients was not associated with pulmonary complications (hypoxia, new radiograph findings or auscultatory findings) or ICU admission. Institutional contraindications for LMA may have contributed to the results, and they aid in defining evidence-based limitations to clinical use of the LMA.

Acknowledgements

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