



# Survey of Laryngeal Mask Airway Usage in 11,910 Patients: Safety and Efficacy for Conventional and Nonconventional Usage

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A survey of laryngeal mask airway (LMA) usage was conducted to provide general information about safety and efficacy with special emphasis on controversial issues such as positive pressure ventilation (PPV), prolonged anesthesia, and laparoscopic and nonlaparoscopic intraabdominal surgery. During the 2-yr study period, of the 39,824 patients who underwent general anesthesia, 11,910 (29.9%) patient airways were managed with the LMA. Forty-four percent underwent PPV. Placement was successful in 99.81%, and in 23 patients the LMA was abandoned in favor of the tracheal tube (TT). Use of the LMA for any intraabdominal procedure was considered nonconventional and occurred in 2222 (18.7%) patients. On 579 occasions procedures

lasted >2 h. A total of 44 critical incidents were documented. Eighteen (0.15%) were related to the airway and none required intensive care management. There were 26 critical incidents not related to the airway which resulted in two admissions to the intensive care unit and one death. There were three cases of failed tracheal intubation managed with the LMA. This survey demonstrates that the LMA technique is safe and effective for both spontaneous and controlled ventilation. Use of the LMA for gynecologic laparoscopy, gynecologic laparotomy, and procedures >2 h also appears safe.

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The laryngeal mask airway (LMA) has been the subject of several comprehensive reviews (1,2). The popularity of the LMA stems from its perceived benefits over other airway devices (3), and several studies have reported that the overall success rate for the technique is high and the complication rate low (4-6). The LMA, however, is often misused (7) and there is continued debate about the frequency of failed placement (8) and need for further data about critical incidents, such as aspiration of gastric contents, particularly in view of suggestions that the LMA may interfere with lower esophageal sphincter function (9,10). Specific concerns have also been expressed about the safety of the device for positive pressure ventilation (PPV), prolonged anesthesia (>2 h), and laparoscopic and nonlaparoscopic intraabdominal surgery (2,9,11).

In 1991, our group conducted an immediately retrospective survey of LMA usage in 2359 patients (4), and data have continued to be collected as part of an ongoing audit of anesthesia practice. We considered that an analysis of 11,910 subsequent cases might provide further useful information relevant to the above issues. The primary aim of this study was therefore to assess the safety and efficacy of the LMA in a variety of conventional and nonconventional clinical settings, focusing on the above areas of controversy. Secondary aims were to identify any recurrent patterns associated with failure of the technique or critical incidents, determine any changing patterns of LMA usage and to provide information about the frequency of use in failed endotracheal intubation.

## Methods

The survey was performed during the period January 1, 1992, to December 31, 1993, in two hospitals in Reading, UK (the Royal Berkshire Hospital and the Battle NHS Trust Hospital). These hospitals provide a wide range of surgical services, but there is no obstetric anesthesia and only occasional ear, nose, and throat and dental surgery. Ethical committee approval was

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not considered necessary for the project since this was a survey of current practice, but retrospective permission was obtained to publish the patient-generated data.

Data for the survey were obtained from an ongoing computerized audit of anesthesia practice adapted from the Bloomsbury Anesthetic Audit System. In both hospitals, standardized data sheets were completed by the anesthesia staff using hand-held computers for all patients undergoing surgical procedures. Clinical information obtained included age, sex, ASA grade, surgical speciality, operation type and category (elective or nonelective), duration of surgery, grade of anesthesiologist (senior or junior), and primary mode of ventilation. An open data field was available for documentation of failed usage and critical incidents. A critical incident was defined as any adverse incident which was potentially or actually harmful to the patient. The severity of critical incidents was graded as follows: 1) potentially adverse outcome; 2) actual adverse outcome—full recovery; 3) major adverse outcome—permanent morbidity or mortality. Critical incidents were divided into those related to the airway and those which were not. Use for any intraabdominal procedure was considered nonconventional.

The data were downloaded at weekly intervals onto a Uniplex database by a trained clerk and was subsequently analyzed using Microsoft Excel 5. Only data about LMA usage were analyzed in detail. No attempt was made to compare the LMA with other forms of airway management. Patients were excluded from the analysis if LMA prototypes were used (12). Any admission to the intensive care unit (ICU) resulting from LMA usage was also documented, as was the outcome of any critical incident. The factual accuracy of the data was assessed by retrospective comparison of the data fields with the anesthetic records of 50 randomly selected patients included in the study. Statistical analysis was with  $\chi^2$  test. Significance was taken as  $P < 0.05$ .

## Results

The LMA data base had less than 1% factual errors and 98.7% of the data fields were complete. During the 2-yr study period, 39,824 patients underwent general anesthesia, of whom 11,910 (29.9%) were managed with the LMA. Usage rates increased from 27.1% (5437/20,071) in 1992 to 32.8% (6473/19,753) in 1993 ( $\chi^2 = 152, P < 0.001$ ).

The mean (SD) age was 43.4 yr (21.3) and the male:female ratio was 4958:6952. ASA grades of the patients were grade I, 61.8%; grade II, 26.2%; grade III, 6.9%; grade IV, 0.43%; and grade V, 0.03%. Spontaneous ventilation occurred in 6674 patients (56.0%) and 5236 (44.0%) underwent PPV. Anesthesiologists were

Table 1. Age Range for Laryngeal Mask Airway Usage

Age of patient (yr)	Total	Percent
0-1	120	1
2-5	502	4.2
6-15	531	4.5
16-65	8067	67.7
66-80	1644	13.8
>81	418	3.5
Unknown	628	5.3
Total	11,910	

graded as senior, 8456 (71.1%); junior, 3226 (27.1%); and unknown, 228 (1.9%). Of the procedures, 83.5% were elective. Although not measured in the survey, all senior and most junior staff had considerable experience with the LMA. Data about the age range, speciality, and duration of operation are presented in Tables 1-3. Surgery lasted over 2 h in 579 patients, and 332 had their ventilation controlled.

Nonconventional usage was documented in 2222 (18.7%) patients (Table 4). Demographic details were similar to conventional usage patients, but 2168 (97.6%) were females. Of nonconventional uses, 95% were for gynecology and included 1469 laparoscopic procedures and 644 laparotomies, including 404 abdominal hysterectomies. Ventilation was controlled in 77.4% of patients undergoing gynecologic laparoscopy and 97% of patients undergoing laparotomy.

The LMA was successfully used in 11,887/11,910 patients (99.81%). In 23 patients (0.19%), the LMA was abandoned in favor of the tracheal tube. The reason for this was an inadequate seal ( $n = 14$ ) and failed placement ( $n = 9$ ). There were no demographic or surgical factors associated with failed placement. Inadequate seal was associated with attempted PPV.

There were a total of 44 (0.37%) critical incidents, of which 18 were related to the airway (Table 5). Regurgitation occurred in four patients (0.03%), vomiting in two patients (0.017%), and aspiration occurred once (0.009%). Laryngospasm and bronchospasm occurred in eight (0.07%) and three (0.025%) patients, respectively. Of the 18 "critical airway" incidents there was only one actual adverse outcome: a 68-yr-old ASA grade I female undergoing spontaneous ventilation anesthesia for elective excision of lipoma who aspirated gastric contents during the procedure. No patient required intensive care management or suffered permanent morbidity secondary to a critical airway incident. Of the 26 other critical incidents, there were two in which the adverse outcome required ICU admission. There was one death secondary to a cardiac arrest in a 97-yr-old female undergoing orthopedic surgery for a fractured femur. There were no documented episodes of myocardial

**Table 2. Surgical Speciality**

Speciality	Total	Percent
General surgery	3331	28.0
Gynecology	3219	27.0
Orthopedics	2343	19.7
Urology	1058	8.9
Ophthalmology	865	7.3
Bronchoscopy	377	3.2
Ear, nose, and throat	361	3.0
Vascular	196	1.6
Radiology	78	0.6
Dental	63	0.5
Others	19	0.2
Total	11,910	

**Table 3. Operation Time for Laryngeal Mask Airway Usage**

Operation time (min)	Total	Percent
0-30	5970	50.1
31-60	3205	26.9
61-120	1626	13.6
120-150	185	1.6
150-180	91	0.8
>180	303	2.5
Unknown	530	4.5
Total	11,910	

**Table 4. Nonconventional Uses of the Laryngeal Mask Airway**

	Total	Percent
Nonconventional		
Gynecologic laparoscopy	1469	12.3
Total abdominal hysterectomy	404	3.4
Gynecologic laparotomy	240	2.0
Laparoscopic cholecystectomy	65	0.55
Open cholecystectomy	20	0.17
Colectomy	14	0.12
Elective abdominal aortic aneurysm	7	0.06
Anterior resection	3	0.03
Total		
Nonconventional	2222	18.7
Conventional	9688	81.3
Combined	11,910	

ischemia, but seven patients had cardiac arrest during surgery (Table 6). There was no significant pattern linking critical incidents with sex, age, ASA grade, surgical speciality or category, or grade of anesthesiologist. Critical incidents occurred in 0.16% of conventional and 0.14% of nonconventional LMA usage. A slightly more frequent percentage of patients undergoing PPV had "critical airway" incidents compared with spontaneous ventilation (0.21% vs 0.11%), but this was not significant ( $\chi^2 = 2.2, P < 0.5$ ). There were no critical airway incidents for anesthesia lasting over 2 h.

**Table 5. Critical Incidents Associated with Laryngeal Mask Airway Use and Severity Grade**

Critical incident	Severity grade <sup>a</sup>			Total
	1	2	3	
Airway				
Regurgitation	4			4
Vomiting	2			2
Aspiration of gastric contents		1		1
Bronchospasm	3			3
Laryngospasm	8			8
Gastric dilation				0
Cardiovascular				
Hypotension	9	2		11
Arrhythmia	6			6
Arrest	6		1	7
Others	2			2
Total	40	3	1	44
Admission to intensive care unit				2

<sup>a</sup>Severity grade: 1 = potentially adverse outcome; 2 = actual adverse outcome, full recovery; 3 = major adverse outcome, permanent morbidity or mortality.

Rare complications, such as tongue cyanosis, vocal cord paralysis, hypoglossal nerve palsy, parotid swelling, and dental trauma were not reported.

There were three cases of failed tracheal intubation in which the airway was secured with the LMA. Approximately 25,000 patients were managed with the tracheal tube giving an incidence of 1:8300 for airway rescue.

## Discussion

This survey adds to the growing body of evidence from large scale studies (5,6,13-17) that the LMA is a safe and effective form of airway management both for spontaneous and controlled ventilation. It also confirms that very high success rates and low complication rates are achievable. The failure rate of 0.19% compares with that of Van Damme (5) who had problems with placement in 0.24% of 5000 outpatient surgical cases, but contrasts with those of Rose and Cohen (18) who reported a failure rate of 4.7% in 634 patients. These differences may reflect suboptimal LMA usage or differing criteria for successful use. The failure rate for conventional tracheal intubation in Rose and Cohen's study of 18,500 patients was 0.3% (18). Recently, the size 5 LMA became available in the United States, and it is possible that this, and more widespread use of the size 4 LMA in adult females, may reduce the incidence of functionally unacceptable leak (19).

Table 6. Details of Patients Who Had a Cardiac Arrest

Age	Sex	Surgery	ASA grade	Classification	User grade	Mode	Etiology	Outcome
79	M	Urology	II	Elective	Senior	PPV	Unknown (nonairway)	Survived
74	M	General	V	Nonelective	Senior	PPV	Hemorrhage	Survived
31	F	Gynecology	II	Elective	Senior	PPV	Peritoneal traction	Survived
30	M	Ophthalmology	I	Elective	Senior	PPV	Extraocular muscle traction	Survived
97	F	Orthopedics	II	Nonelective	Junior	SV	Unknown (nonairway)	Died
3	M	General	III	Elective	Senior	SV	Testicular traction	Survived
39	F	Gynecology	I	Elective	Senior	PPV	Peritoneal traction	Survived

PPV = positive pressure ventilation; SV = spontaneous ventilation.

Composite data taken from observational studies has provided insight into the frequency of some critical incidents associated with LMA usage. Brimacombe and Berry (20), for instance, suggest the incidence of pulmonary aspiration of gastric contents is 2/10,000 based on a meta-analysis of observational studies in which the LMA was the main airway management technique through September 1993. A recent, large scale survey confirms this estimate (5), but underreporting cannot be excluded. Other critical events have been less well documented although Haden et al. (14) found a 0.9% incidence of difficult placement and laryngospasm using audit data collected from more than 5655 LMA cases. Van Damme reported that 1.5% (77/5000) of patients briefly registered an oxygen saturation of <90%, and that the LMA was subsequently abandoned in 0.16% (8/5000) (5). Critical anesthetic events are consistently underreported (21,22), but only one aspiration of gastric contents was documented in the current series giving an incidence of 0.84/10,000. The fact that there were no admissions to the ICU from critical airway incidents supports this finding. The incidence of laryngospasm and bronchospasm was also lower than in other series (6).

Our data provide further evidence that the LMA may have a role in gynecologic laparoscopy (23,24). In the audited hospitals, the LMA is the preferred airway for elective gynecologic laparoscopy. Our data also suggest that LMA usage for gynecologic laparotomy and prolonged procedures may be acceptable. Prospective trials are required to confirm this suggestion. There are insufficient data to comment on its safety for nongynecologic intraabdominal surgery, but we cannot recommend LMA usage for open or laparoscopic cholecystectomy or elective abdominal aortic aneurysm repair in normal circumstances.

The frequency of other critical incidents was less than that reported prior to the availability of the LMA. In a cross-sectional study of complications of inhaled anesthesia in 16,995 patients conducted before the release of the LMA, the incidence of arrhythmias was 2.2% and myocardial ischemia 0.2% (25). The incidences compare with 0.09% and 0% for the current study. The extent to which these data reflect patient selection, underreporting, inadequate monitoring, use

of different anesthetics, or lesser cardiovascular stimulation by the LMA versus endotracheal intubation (3) could not be determined from these data. The incidence of cardiac arrest in this series was 0.06% and would be considered relatively high, but the overall mortality rate was low (0.009%). Four of the seven cardiac arrests were brief asystolic events which were directly related to surgical stimulation. One was secondary to massive hemorrhage and the other two occurred in elderly patients.

Finally, Benumof (26) has suggested that the immediately life threatening "cannot intubate, cannot ventilate" situation occurs in approximately 1:10,000 anesthetics. In the current survey this occurred on three occasions (1:8333) and the LMA proved successful in providing an airway. No patient required emergency surgical airway access. This lends further support for the inclusion of the LMA in the American Society of Anesthesiologist's guidelines for the management of the difficult airway (27).

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