Predictors and Clinical Outcomes from Failed Laryngeal Mask Airway Unique™

A Study of 15,795 Patients

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ABSTRACT

Background: Although the estimated risk of life-threatening adverse respiratory events during supraglottic airway device use is rare, the reported rate of events leading to failure of the airway device is 0.2–8%. Little is known about the risk-adjusted prediction of Laryngeal Mask Airway failure requiring rescue tracheal intubation and its impact on patient outcomes.

Methods: All adult patients in whom a laryngeal mask airway (*LMA Unique*™, *uLMA*™; LMA North America, Inc., San Diego, CA) was used in ambulatory and nonambulatory anesthesia settings were included. The primary outcome was *uLMA*™ failure, defined as an airway event requiring *uLMA*™ removal and tracheal intubation. The secondary outcomes were the incidence of difficult mask ventilation and unplanned hospital admissions.

Results: Of the 15,795 cases included in our study, 170 (1.1%) experienced the primary outcome of *uLMA*™ failure. More than 60% of patients with *uLMA*™ failure experienced significant hypoxia, hypercapnia, or airway obstruction, whereas 42% presented with inadequate ventilation related to leak. Four independent risk factors for failed *uLMA*™ were identified: surgical table rotation, male sex, poor dentition, and increased body mass index. A 3-fold increased incidence of difficult mask ventilation was observed in patients with *uLMA*™ failure. Among outpatients with *uLMA*™ fail-

What We Already Know about This Topic

- Failure of supraglottic airway is not rare, but little about the risk factors for failure and its impact on respiration and patient outcomes.

What This Article Tells Us That Is New

- Laryngeal mask airway failure occurred in 1.1% of an adult surgical population of more than 15,000 patients, resulting in adverse respiratory events and unplanned hospitalization. Mask ventilation was difficult in 5.6% of patients with laryngeal mask airway failure.

ure, 13.7% had unplanned hospital admission, 5.6% of whom needed intensive care for persistent hypoxemia.

Conclusions: The study supports the use of the *uLMA*™ as an effective supraglottic airway device with a relatively low failure rate. However, there are clinically relevant consequences of *uLMA*™ failure, as evidenced by the high rate of acute respiratory events and need for unplanned hospital admissions.

SINCE the invention of the laryngeal mask airway (LMA) in 1981 and the subsequent introduction to clinical practice in 1988, its use during general anesthesia has gained popularity in the operating room with well-documented success.[1–3] However, just as with general anesthesia with tracheal intubation, LMAs are not without patient risks. The fourth National Audit Project of the Royal College of Anesthetists and Difficult Airway Society[4] reviewed complications of airway management that led to death, brain damage, the need for an emergency surgical airway, unanticipated intensive care unit admission, or prolongation of intensive

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◇ This article is featured in "This Month in Anesthesiology." Please see this issue of ANESTHESIOLOGY, page 9A.

◆ This article is accompanied by an Editorial View. Please see: Asai T: Complications with supraglottic airways: Something to worry about or much ado about nothing? ANESTHESIOLOGY 2012; 116:1183–5.

care unit stay.[4,5] The estimated incidence of these life-threatening complications with supraglottic airway device use for anesthesia was 1 in 46,174 (95% CI; 1 in 34,684 to 1 in 69,051). In comparison, adverse respiratory events, such as significant airway obstruction and laryngospasm during *Classic LMA*™ (LMA North America, Inc., San Diego, CA) use, are seen more frequently,[6,7] with reported rates of 0.15–7%. The incidence of *Classic LMA*™ failure ranges from 0.19 to 4.7%.[6–8] However, there is a paucity of data on independent risk factors for supraglottic airway device failure reflecting a gap in current knowledge. Within our institution, a standardized LMA, the *LMA Unique*™ (*uLMA*™; LMA North America, Inc., San Diego, CA) is used to manage planned intraoperative cases. There are no previous large observational studies of the *uLMA*™ in the literature, and data on failure rates are derived from small trials comparing the *uLMA*™ with other airway devices. The *uLMA*™ failure rates in these studies range from 0 to 2.5%.[9,10] This variability in reported rates of adverse respiratory events and LMA failure supports the need for examining these rates in a large observational study setting and identifying independent risk factors for the failure. Clinical decisions regarding the choice of *uLMA*™ *versus* endotracheal tube may be informed by knowledge of these risk factors.

To further characterize perioperative risk factors for *uLMA*™ device failure requiring an acute rescue tracheal intubation, we conducted this retrospective observational study at our quaternary care facility. We hypothesized that patient factors and intraoperative characteristics exist that place patients at increased risk of *uLMA*™ failure.

Materials and Methods

After obtaining approval from the Institutional Review Board (University of Michigan, Ann Arbor, Michigan), we reviewed the prospective perioperative electronic clinical information available within the anesthesiology unit of our hospital system. Because no care interventions were mandated, signed patient consent was waived. Through this computerized database (Centricity; General Electric Healthcare, Waukesha, WI), preoperative, intraoperative, and postoperative data are documented routinely by anesthesiology residents, attending staff, and certified registered nurse anesthetists. As is mandatory in our institution, structured electronic preoperative history and physical notes are recorded for each surgical patient. All clinical elements (*e.g.*, cardiac symptoms, history of sleep apnea) are stored as discrete database elements. In addition, a structured, predefined pick-list is used by the clinician to enter information to make the database readily searchable for specific clinical findings (appendix). Within each intraoperative record, patient data such as mask ventilation grade, intubation ease, and vital signs are uniquely stored as binary or continuous data. Through a consistent recording of these data, a searchable database for observational research has been established and recently used in multiple large-scale clinical studies.[11,12]

From this prospectively populated computerized database, a search query was performed to obtain all relevant data

for this study. Inclusion criteria were adult (≥18 yr) patients who underwent general anesthesia with a planned *uLMA*™ from January 1, 2006, to October 30, 2009. This period was chosen because intraoperative data relevant to this study were collected using the Anesthesia Information Management System during the period. The study included use of *uLMA*™ in patients in both ambulatory and nonambulatory settings. Exclusion criteria were children, instances in which the laryngoscopy was performed before *uLMA*™ placement, and when the *uLMA*™ removal was related to a change in surgical plan.

For each patient included in the study, a number of variables were evaluated based on a thorough literature review of all frequently used perioperative assessment tools shown to be associated with a difficult airway and upper airway obstruction. Airway-related variables included modified Mallampati class 3–4,[12–14] reduced thyromental distance estimated less than 6 cm,[11,12] reduced mouth opening estimated less than 3 cm,[13] inability to protrude lower incisors anterior to upper incisors,[11,13] qualitatively assessed thick neck,[12,15] beard presence,[13] clinically estimated reduced cervical spine mobility,[14,15] and clinically assessed poor dentition defined as edentulous, having dentures, or having missing, loose, or broken teeth.[13,15] Preoperatively recorded patient characteristics were analyzed for each patient, including age, body mass index, sex, and obstructive sleep apnea.[11–13] Age and sex previously have been shown to be associated with differences in upper airway resistance.[12,16] Recent upper respiratory tract infections, asthma, chronic obstructive pulmonary disease, and current smoking also were assessed both individually and collapsed as one variable because hyperreactive airways have been shown to be associated with an increased incidence of adverse respiratory events with LMA anesthesia.[3,17]

Because anesthesia provider experience has been shown to be associated with an increased incidence of tracheal intubation failure,[18] this variable was included in the analysis: novice caregivers were defined as interns, nonanesthesia rotators, and clinical anesthesia year-1 residents, who typically have less than 1 yr of clinical anesthesia experience. Experienced caregivers included all clinical anesthesia year-2 or year-3 residents, anesthesiology fellows, anesthesiology attending physicians, and certified registered nurse anesthetists. Intraoperative characteristics related to surgical positioning were evaluated because they have been studied previously with LMA anesthesia[19]; these characteristics included nonsupine patient positioning and any case in which the surgical table was rotated. Nonsupine positions included lithotomy, lateral, sitting, and prone. Finally, on the basis that mask ventilation and *uLMA*™ are both considered to be rescue techniques to be used in the event of each other's failure, we evaluated the relationship between *uLMA*™ failure and difficult mask ventilation, defined as mask ventilation that was inadequate, unstable, impossible, or required two providers.[20] Difficult mask ventilation was included in a separate univariate analysis because not all patients in the study un-
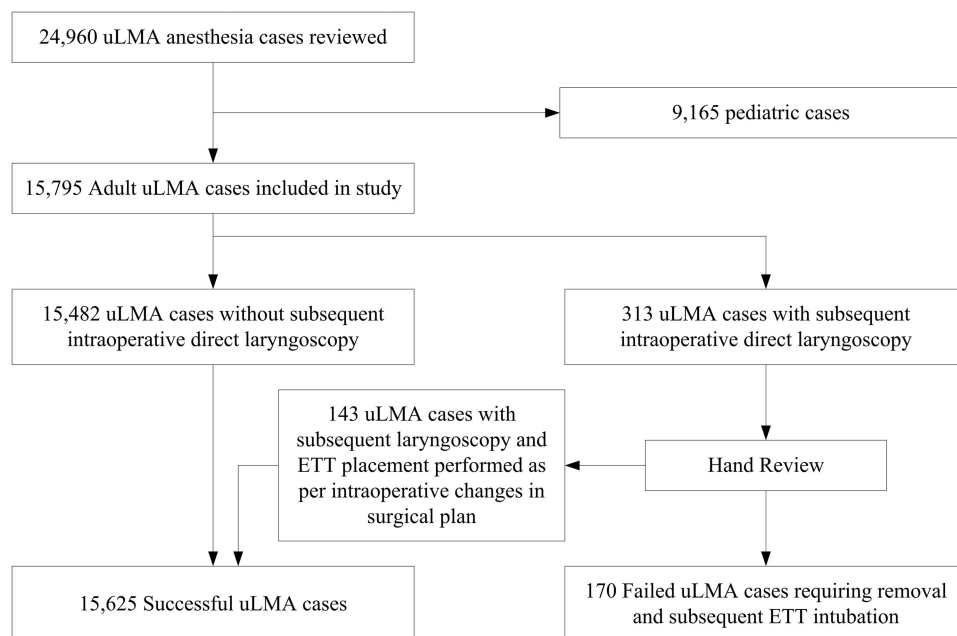
Fig. 1. Patient inclusions and exclusions. The number of patients excluded because of each exclusion criterion is shown. ETT = endotracheal tube; *uLMA = Laryngeal Mask Airway Unique™*.

derwent an assessment of mask ventilation with *uLMA™* placement. The presenting features of the airway events leading to *uLMA™* failures were extracted by individual chart review. Data on *uLMA™* size (relative to patient sex and weight), airway event type (inability to ventilate because of leak or airway obstruction), presence of adverse respiratory event (significant desaturation, hypercapnia, or increased peak inspiratory pressures), and prelaryngoscopy airway event management (reinsertion of *uLMA™* or use of succinylcholine) were collected. For the purposes of defining a significant adverse respiratory event, the following variables were used. Desaturation was defined as $SpO_2 \leq 85\%$, hypercapnia was defined as $EtCO_2 \geq 50$ mmHg, and increased peak inspiratory pressure was defined as peak inspiratory pressure ≥ 25 cm H_2O on two consecutive readings, each 1 min apart, with *uLMA™* in place.

Outcomes

The primary outcome was *uLMA™* failure, defined as any acute airway event occurring between insertion of *uLMA™* and completion of surgical procedure that required *uLMA™* removal and rescue endotracheal tube placement. This definition was chosen as the primary outcome measure because it encompassed all possible characteristics of a clinically significant airway event (from inadequate ventilation to severe desaturation, hypercapnia, and airway obstruction) associated with a failed *uLMA™* for which an acute airway intervention was clinically indicated. Cases involving the primary outcome were identified initially in our database by noting any case in which a direct laryngoscopy was performed after *uLMA™* placement. These case records were then manually reviewed by two investigators (MM and SKR) to exclude

cases in which the *uLMA™* replacement was performed in response to a change in surgical management (fig. 1). The secondary outcome measures of this study were the incidence of difficult mask ventilation in patients with failed *uLMA™* and frequency of unplanned hospital admission. Unplanned admissions were defined as patients originally planned to undergo ambulatory procedures who required admission to the hospital.

Statistical Analysis

Our data analysis was carried out with SPSS® version 15.0 (SPSS Inc., Chicago, IL). Univariate analyses comparing patients with and without *uLMA™* failure were conducted for each data field variable, with *P* values calculated using Pearson chi-square or Fisher exact tests for categorical variables and Student *t* tests for continuous variables.

Because no previous adjusted models were available for LMA failure, all studied variables were included in a nonparsimonious logistic regression model to evaluate the strength of any univariate association and reduce the risk of missing important variables. Collinearity diagnostics and Pearson correlations were conducted on all pairs of variables to assess for independence. Condition indices more than 30 were used to identify covariates that are highly correlated with one another before building the logistic regression model.[21] The Omnibus test was used to evaluate the goodness of fit by the presence of statistically significant differences between the explained and unexplained variance within the model.[22] The resultant chi-square statistic value is a measure of the relationship between observed and expected frequencies. A *P* value of <0.05 in this test denotes that the null hypothesis is rejected.[22] The predictive value of the resulting regression

model was then evaluated using a receiver operating characteristic area under the curve.[23] The area under the curve represents the fractions of outcomes, both positive and negative, that are accurately predicted by the model. All variables deemed to be significant in the logistic regression model ($P < 0.05$) were established as independent predictors. Adjusted odds ratios with 95% CI were then used to describe the individual effect size of each independent variable on *uLMA™* failure.[24] Finally, the frequency of unplanned admissions and difficult mask ventilation were evaluated between patients with and without *uLMA™* failure.

Sample size estimation was performed to define the limits of data analysis. Based on *uLMA™* failure rates as great as 2.5%, a sample size of 5,000 patients (125 failed *uLMA™* events) would allow evaluation of at least 12 covariates in a logistic regression model with minimal risk of over-fitting.[25]

Results

Of the 15,795 adult *uLMA™* cases performed between 2006 and 2009 at a single quaternary care facility, 313 cases were identified in which a laryngoscopy was performed during an *uLMA™* anesthetic. Through a subsequent manual review, 143 cases were excluded from the *uLMA™* failure group because tracheal intubation was performed in response to changes in the surgical plan. Thus, 170 (1.1%) patients experienced the primary outcome of a failed *uLMA™*, defined as an acute airway event necessitating *uLMA™* removal and subsequent tracheal intubation.

On univariate analysis, the following variables had a significantly higher frequency in patients with *uLMA™* failure, as described in table 1: advanced age, increased body mass index, male sex, reduced thyromental distance, thick neck, poor dentition, smoking, and surgical table rotation. Hyperreactive airway, sleep apnea, increased modified Mallampati score, reduced mouth opening, reduced neck movement, limited jaw protrusion, beard presence, novice caregiver, and nonsupine patient positioning were not associated with *uLMA™* failure on univariate analyses.

Event analyses of failed *uLMA™* cases revealed the following findings (table 2). The event occurred early (induction to incision) in 104 cases (61.1%, 95% CI 53.7–68.2%), during table rotation in 27 cases (15.9%, 95% CI 10.7–22.3%), and during maintenance of anesthesia in the remaining 39 cases. Although 47.7% of cases involved use of *uLMA™* outside the recommended size for body weight range, there were no difference in the frequency of failed *uLMA™* relating to choice of size by patient sex or body weight (table 1). There was no documented attempt to reinsert an *uLMA™* in 61%, one attempt at reinsertion in 25%, and two or more attempts in the remaining cases. Among the 27 instances of *uLMA™* failure relating to table rotation, surgical procedures involving the head and neck were observed in nine cases. Inadequate ventilation secondary to leak was observed in 72 patients (42.3%, 95% CI 35.1–50.2%). Significant adverse respiratory events manifesting as desatu-

ration, hypercapnia, or increased peak inspiratory pressures were seen in 106 patients (62.3%, 95% CI 54.6–69.7%). Severe desaturation (SpO_2 less than 85%, more than 1 min) was seen in 22.4% of failed *uLMA™* cases. Gastric contents were observed in the *uLMA™* in three patients. In eight instances, laryngospasm was denoted in the anesthetic record as the cause of airway obstruction, requiring active treatment with succinylcholine. An additional 44 patients had airway obstruction, stridor, increased peak inspiratory pressures, bronchospasm, coughing, bucking, hiccups, grunting or phonating.

On multivariate analysis, collinearity diagnostics did not demonstrate any condition indices greater than 30. Four independent predictors of *uLMA™* failure were identified on logistic regression analysis: surgical table rotation (adjusted odds ratio 5.00, 95% CI 3.12–8.02), male sex (adjusted odds ratio 1.74, 95% CI 1.23–2.45), poor dentition (adjusted odds ratio 1.58, 95% CI 1.00–2.49), and increased body mass index (adjusted odds ratio 1.06 per unit body mass index increase, 95% CI 1.03–1.09) (table 3). The model was evaluated using the omnibus test of model coefficients, which demonstrated a chi-square value of 106 with 17 degrees of freedom and a *P* value of <0.001. Receiver operating characteristic curve analysis demonstrated an area under the curve of 0.708 (95% CI 0.667–0.748).

Of the 15,795 adult *uLMA™* cases studied, mask ventilation was attempted in 1,089 cases (6.9% of study patients), as shown in figure 2. Of 1,005 control group patients, the overall incidence of difficult mask ventilation in patients without a failed *uLMA™* was 1.9% (19 of 1,005), whereas the incidence of difficult mask ventilation in patients with a failed *uLMA™* was 5 of 84 (5.6%, *P* value = 0.013, unadjusted odds ratio 3.3, 95% CI 1.24–8.73).

Finally, it was noted that 13,170 (83.4%) of the *uLMA™* cases performed were conducted in the ambulatory setting. There was a lower frequency of *uLMA™* failure in ambulatory anesthesia compared with in-patient settings (0.99 *vs.* 1.48%, *P* value = 0.03). Of the cases involving a failed *uLMA™*, 131 of 170 were performed in the ambulatory setting, 18 (13.7%, 95% CI 8.4–20.8%) of which resulted in an unplanned hospital admission. In addition, 2 of the 170 failed *uLMA™* cases (one inpatient and one outpatient) subsequently required unplanned intensive care unit admission for persistent hypoxemia.

The quality of data output for this study was verified through a method of systematic sampling (every tenth case) and manual chart audits for data completeness and accuracy. For all data fields, the completion rate was noted to be 99% or greater for all but two variables, body mass index (98.9% completion rate) and modified Mallampati score (87.5%). Missing data analysis demonstrated a significantly lower rate of *uLMA™* failure in patients with missing modified Mallampati score (0.55 *vs.* 1.15%; *P* value = 0.02).

Table 1. Patient and Anesthetic/Surgical Characteristics

Risk Factor	Successful LMA (n = 15,625)	Failed LMA (n = 170)	P Value*	% Cases with Complete Data
Patient history				
Age, yr	47	56	<0.001	100.0
Body mass index, kg/m^2	26.9	29.3	<0.001	98.9
Male gender	7,387 (47)	108 (64)	<0.001	100.0
Hyperreactive airway†	4,167 (27)	55 (32)	0.10	100.0
Asthma	1,671 (11)	15 (8.8)	0.43	100.0
COPD	468 (3)	7 (4.1)	0.39	100.0
URI	378 (2.4)	4 (2.4)	1.00	100.0
Current smoker	2,265 (15)	35 (21)	0.03	100.0
Sleep apnea	641 (4)	9 (5)	0.44	100.0
Physical examination				
Modified mallampati score (3–4)	1,463 (11)	19 (12)	0.62	87.5
Reduced thyromental distance <6 cm	1,021 (7)	3 (2)	0.012	100.0
Reduced mouth opening <3 cm	334 (2.1)	5 (2.9)	0.47	100.0
Reduced neck movement‡	51 (0.3)	2 (1.2)	0.06	100.0
Thick neck	1,003 (6)	23 (14)	<0.001	100.0
Limited jaw protrusion‡	1,169 (8)	13 (8)	0.94	100.0
Poor dentition‡	1,509 (10)	34 (20)	<0.001	100.0
Beard	1,663 (11)	19 (11)	0.82	100.0
Anesthetic technique				
Novice caregiver§	5,936 (38)	69 (41)	0.49	100.0
uLMA size				
3	1,127 (7)	7 (4)		
4	8,986 (58)	71 (42)		
5	4,910 (31)	78 (46)		
uLMA size by body weight‖ (recommended/nonrecommended)				
3	249 (2)/878 (6)	3 (2)/4 (2)	0.184	
4	3,720 (24)/5,266 (34)	24 (14)/47 (28)	0.207	
5	3,504 (22)/1,406 (9)	50 (29)/28 (16)	0.153	
uLMA size by patient sex (men/women)				
3	69 (0.4)/1,058 (7)	0 (0)/7 (4)	0.499	
4	2,265 (14)/6,721 (43)	20 (12)/51 (30)	0.567	
5	4,779 (31)/131 (0.8)	77 (45)/1 (0.6)	0.449	
Surgical details				
Surgical table rotated during case	470 (3)	27 (16)	<0.001	100.0
Nonsupine patient positioning	5,044 (32)	46 (27)	0.14	99.7
Lithotomy	4,490 (29)	41 (24)		
Lateral	202 (1.3)	3 (1.8)		
Sitting	98 (0.6)	0 (0)		
Prone	64 (0.4)	0 (0)		
Other	191 (1.2)	1 (0.6)		

Data are presented as n (%) unless otherwise indicated. All 15,795 patients were included in the regression model.

* P values calculated using Pearson chi-square or Fisher exact test for categorical variables and Student t test for continuous variables.
† Defined as a past medical history of asthma, chronic obstructive pulmonary disease, upper respiratory tract infection within the past 4 weeks, or currently smoking. ‡ Refer to appendix of pick-list choices for specific definitions. All airway variables are estimations. § Defined as interns, nonanesthesia rotators, or first year clinical anesthesia residents conducting uLMA placement; experienced caregivers included all levels of more senior residency or nurse anesthetists. ‖ Appropriate choice of uLMA size derived from package insert of device. Data are presented as recommended/nonrecommended size.

COPD = chronic obstructive pulmonary disease; uLMA = Laryngeal Mask Airway Unique™; URI = upper respiratory infection.

Discussion

The incidence of uLMA™ failure was 1.1% among 15,795 adult patients undergoing general anesthesia. We identified four independent predictors of uLMA™ failure: intraoperative surgical table rotation, male sex, poor dentition, and increased body mass index. Failed uLMA™ was associated with an approximately 3-fold increased incidence of difficult mask ventilation among patients with attempted mask ventilation. Unplanned hospital admission was seen in 13.7% of ambulatory patients with uLMA™ failure, and 5.6% of admissions needed intensive care for hypoxemia.

The incidence of failed uLMA™ in our study is consistent with previously reported Classic LMA™ failure rates in large observational studies[8] and surveys of 0.1–4.7%.[6] This relatively low failure rate supports the safety of uLMA™ for intraoperative airway management. Life-threatening complications relating to supraglottic airway device use are esti-

Table 2. Airway Event Characteristics

Airway event type	
Inadequate ventilation	
due to leak	72 (42.4)
Airway obstruction	51 (30)
Other presentation	44 (25.9)
Suspected aspiration	3 (1.7)
Adverse respiratory events	
uLMA failures with adverse	
respiratory event	106 (62.4)
uLMA failures with just	
desaturation	7
uLMA failures with just	
hypercapnia	29
uLMA failures with just	
elevated PIP	18
uLMA failures with	
desaturation,	
hypercapnia, and	
elevated PIP	12
uLMA failures with	
desaturation,	
hypercapnia, but no	
elevated PIP	5
uLMA failures with	
desaturation, elevated	
PIP, but no hypercapnia	14
uLMA failures with	
hypercapnia, elevated	
PIP, but no desaturation	21
uLMA failures with no	
adverse respiratory event	64 (37.6)
Airway event management	
Succinylcholine	8
Reinsertion of uLMA	
0 attempts	104
1 attempt	43
≥2 attempts	23

Desaturation was defined as $Spo_2 \leq 85\%$ on two consecutive readings, each 1 min apart, with *uLMA* in place. Hypercapnia was defined as $EtCO_2 \geq 50$ mmHg on two consecutive readings, each 1 min apart, with *uLMA* in place. Elevated PIP was defined as peak inspiratory pressure ≥ 25 cm H_2O on two consecutive readings, each 1 min apart, with *uLMA* in place.

PIP = peak inspiratory pressure; *uLMA = Laryngeal Mask Airway Unique™*.

mated to be extremely rare occurrences.[4] In our study, all of the *uLMA™* failures were associated with airway events. Although a significant fraction (approximately 40%) of *uLMA™* failures in our study presented as inability to ventilate relating to leaks, almost two thirds of *uLMA™* failures were associated with an adverse respiratory event, manifesting as desaturation, hypercapnia, or increased peak inspiratory pressures. The higher frequency of these adverse respiratory events may reflect the influence of high prevalence of obesity in the study population.

Consistent with previous studies on difficult airway, increased body mass index was demonstrated to be an independent predictor of *uLMA™* failure. However, this finding also contrasts with current literature in support of LMA us-

age in comparison with tracheal intubation in obese patients.[26] Despite this finding, the *Classic LMA™* has been demonstrated as a valuable tool in managing an unanticipated difficult airway in obese patients.[1] Our study also demonstrates an independent increase in *uLMA™* failure risk for male patients, independent of *uLMA™* size and body weight. This finding is consistent with the increased incidence of increased upper airway resistance in men compared with women, leading to upper airway narrowing, obstruction, and obstructive sleep apnea.[16,27,28] Of the airway measures evaluated in our study, absence of normal dentition was identified as an independent predictor of *uLMA™* failure, and because all but one of these patients had missing rather than damaged teeth, this association is likely attributable to the reduced oropharyngeal support for the *uLMA™*. None of the other evaluated airway variables were associated significantly with the primary outcome on adjusted analyses. Of the anesthetic technique risk factors assessed in our study, it was interesting to note that no significant association between anesthesia provider experience and *uLMA™* failure risk existed. This finding may suggest the relative technical ease of supraglottic airway device placement and management, as supported by literature documenting *uLMA™* success even among early clinical trials.[9,10]

Of the surgical risk factors assessed in our study, nonsupine patient positioning was not determined to predict *uLMA™* failure, consistent with a review of previous studies demonstrating the feasibility of *uLMA™* anesthesia in nonsupine positioned patients.[19,29] Intraoperative surgical table rotation was the most significant risk factor independently associated with *uLMA™* failure. The results may reflect displacement of the *uLMA™* position during untwisting of the circuit connection, during reattachment of the circuit to the *uLMA™*, rotation of the table with *uLMA™* connected, or intraoperative dislodgement of the *uLMA™*. In addition, surgical procedures on the head and neck were seen in one-third of *uLMA™* failures related to table rotation, suggesting that surgical factors may have played a small but important role.

When considering the medical setting in which *uLMA™* cases were performed, it was noted that most took place in an ambulatory setting, although the *uLMA™* failure rates across inpatient settings were marginally greater. The high (13.7%) incidence of unplanned hospital admission for patients after *uLMA™* failure may signify the need to improve preoperative prediction of this complication, lending support to the rationale for this study.

The univariate relationship between failed *uLMA™* and difficult mask ventilation could not be further evaluated by adjusted techniques because of the small proportion of patients with difficult mask ventilation included in the study. Despite this, the 3-fold overall increase in incidence of difficult mask ventilation in patients with failed *uLMA™* is of concern. This finding could suggest a common tendency to airway closure in these patients or simply be a reflection of the high incidence of laryngospasm associated with *uLMA™*

Table 3. Independent Risk Factors for *Laryngeal Mask Airway Unique*™ Failure

Risk Factor	P Value	Adjusted Odds Ratio	95% Confidence Interval	
			Lower	Upper
Surgical table rotation*	0.000	5.000	3.117	8.020
Body mass index*	0.000	1.058	1.032	1.086
Men*	0.002	1.736	1.230	2.451
Poor dentition*	0.049	1.579	1.001	2.490
Reduced thyromental distance	0.052	3.144	0.991	9.975
Age	0.056	1.010	1.000	1.021
Thick neck	0.116	1.508	0.904	2.517
Reduced neck movement	0.123	3.334	0.721	15.413
Hyperreactive airway	0.201	1.254	0.886	1.774
Modified Mallampati score	0.302	0.762	0.455	1.277
Beard	0.325	0.772	0.460	1.293
Nonsupine position	0.346	0.835	0.575	1.214
Limited jaw protrusion	0.601	0.848	0.457	1.574
Experienced provider	0.627	0.923	0.668	1.275
Sleep apnea	0.646	0.847	0.417	1.721
Reduced mouth opening	0.679	1.253	0.430	3.648

Detailed definitions of all data elements are available in the appendix.

* Any variable with a *P* value <0.05 was established as an independent predictor of failed *Laryngeal Mask Airway Unique*™.

failure. In either case, the study findings are provocative and add to the knowledge on the relationship between failed *uLMA*™ and difficult mask ventilation.

It should be noted that data obtained from this study have several limitations. First, because this study was observational in nature, no specific care protocol was enforced regarding the decision to use, manage, or remove an *uLMA*™ and replace it with a more secure airway. Consequently, our primary outcome was dependent on the clinical judgment of the attending anesthesiologist rather than any objective measure, and we cannot be certain that the criteria for *uLMA*™ removal and subsequent tracheal intubation were similar for all providers involved. We have addressed this limitation by using a rigorous manual review of the chart to separate surgical causes from airway event-driven *uLMA*™ failures. We did not record how the *uLMA*™ was secured; it usually is

taped. The size of *uLMA*™ relative to patient sex and body weight was outside the recommended range in a significant number of patients, and this may have influenced the risk of *uLMA*™ failure. However, we were unable to demonstrate a weight- or gender-based relationship to *uLMA*™ failure in these patients. In rare cases, *ProSeal*™ LMAs (LMA North America, Inc., San Diego, CA) or other types of supraglottic airway devices may have been used for research purposes. When these are used for research purposes, the departmental expectation is a notation to that effect in the medical record. None of the patients who experienced *uLMA*™ failure had a notation that an alternate study LMA had been placed.

Although such events are rare, it should be noted that an unknown number of adverse respiratory events under *uLMA*™ anesthesia may have been managed by deepening
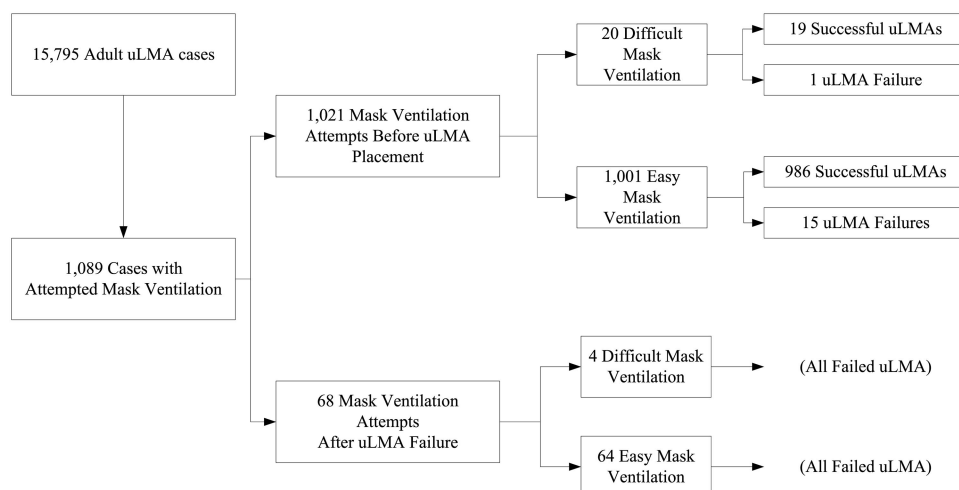

Fig. 2. Flow chart describing the ease of mask ventilation in patients with *Laryngeal Mask Airway Unique*™ (LMA North America, Inc., San Diego, CA) use. *uLMA* = *Laryngeal Mask Airway Unique*™.

the plane of anesthesia or by administration of muscle relaxants with subsequent clinical improvement, rather than *uLMA*™ replacement with a endotracheal tube. These cases were not concluded to be *uLMA*™ failures for purposes of this study, although they represent potential risks to patients. Next, because of the paucity of current data available regarding the preoperative and intraoperative characteristics of a failed *uLMA*™, variables included in this study were limited to our own hypotheses of potential risk factors. In addition, we limited the analyzed variables to prevent regression model over-fitting.[25] It should be noted that an unmeasured selection bias existed for the patient population, which may have influenced the primary choice of *uLMA*™ over a endotracheal tube. Depth of anesthesia may have been an important factor that was not assessed in this study. We routinely do not collect data on processed electroencephalogram, so weight-based dosage analysis is likely to have errors relating to individual variability in determining thresholds for anesthesia and laryngeal reflex suppression.

This study was subject to the limitations inherent within the electronic perioperative medical record from which our data were obtained. Because this electronic medical record is used primarily to manage clinical care, data outside the scope of this purpose are unable to be obtained. Within our medical record system, no rigorous validation of data entry exists, so this study is limited by the reliability of the data entry from which it has been derived. However, it should be noted that a robust data audit process was involved in verification of the accuracy of the data used in this study. Unplanned hospital admissions may have been for other indications that were not apparent in the medical record. Despite this limitation, the unplanned admission rates seen with *uLMA*™ failure were significantly higher than expected rates at our institution (~0.5%). The prediction model has modest discrimination, and additional work may need to be done to enhance the model's accuracy in the future. The validity of the model needs to be tested in an independent population to confirm generalizability of findings. Finally, because data from this study were drawn from a single quaternary care center, caution should be observed when applying results to patients nationally or internationally because anesthesia care delivery processes are variable across these regions. It is quite possible that other hospitals do not have the same rate of *uLMA*™ (or other supraglottic airway device) displacement when the operating table is rotated, and the 5-fold independent increase in risk raises the possibility of a system-level error in *uLMA*™ management during table rotation. In addition, it is potentially the one risk factor (unlike male gender, increased body mass index, and poor dentition) that the anesthesiologist can actively modify by increased attention to detail.

Despite these limitations, our data shed light on a largely unstudied clinical issue commonly encountered by anesthesia providers. Through identifying risk factors for intraoperative *uLMA*™ failure in a large patient sample, this study allows for a clinician's decision to use or refrain from using an *uLMA*™ to be drawn in part from evidence, rather than solely clinical intuition. In addition, our study has identified high-risk patient and operative characteristics that can serve to focus efforts of future prospective, randomized trials testing intraoperative therapies and management techniques.

In conclusion, we report that *uLMA*™ failures occur approximately once in every 93 anesthetic inductions and are independently associated with surgical table rotation, male sex, poor dentition, and increased body mass index. There are clinically relevant consequences of *uLMA*™ failure, as evidenced by the high rate of adverse respiratory events and the need for unplanned hospital admissions. Difficult mask ventilation was encountered in 5.6% of patients with *uLMA*™ failure, representing a 3-fold increase from patients with successful *uLMA*™.

Appendix 1. Preoperative Predictor Pick-list Choices

Preoperative Predictor	Pick-list Choices Included in Study
Hyperreactive Airway	
Asthma	Diagnosis: Allergen induced/aspirin induced/exercise induced/infection Induced/nocturnal/occupational/exacerbated by pregnancy/reactive airway disease/unknown
	Symptom frequency: Status asthmaticus/several episodes daily/daily/weekly/monthly/yearly/very infrequent/never
	Emergency room visits: Never/last 1 week/last 6 months/more than 6 months ago
	Hospitalization: Never/last 1 week/last 6 months/more than 6 months ago
Chronic obstructive pulmonary disease	Type: Bronchiectasis/bronchiolitis obliterans/chronic bronchitis/cystic fibrosis/emphysema/tracheal stenosis/unknown
	Severity: Mild/moderate (chronic bronchodilator use)/severe (oxygen)/very severe (oxygen dependent)
Upper respiratory infection	Within 4 weeks with fever
	Within 4 weeks without fever
Smoking	Current smoker
Sleep apnea	Treated by positive airway pressure
	Treated by surgery
	Diagnosed with sleep study but untreated
	Tested positive for Sleep Apnea
Elevated modified Mallampati score*	3
	4
Reduced thyromental distance	<6 cm
Reduced mouth opening	<3 cm
Reduced neck movement	Limited extension (estimated)
	Limited flexion (unable to obtain chin-chest contact)
	Known unstable
	Possibly unstable
Thick neck	Neck anatomy: Thick/obese
Limited jaw protrusion	Limited: Lower incisors can be advanced only to meet upper incisors
	Severely limited: Lower incisors cannot be advanced to meet upper incisors
Poor dentition	Edentulous
	Dentures upper partial
	Dentures upper complete
	Dentures lower partial
	Dentures lower complete
	Teeth missing/loose/broken
Beard	Yes

Structured anesthesia history and physical pick-list choices are provided as they appear in the clinical information system user interface. Only choices that were used to define a patient as possessing the predictor are listed. All acronyms are listed as they appear in the clinical information system pick-list.

* As modified by Samsoon and Young,[30] performed with patient sitting with head in neutral position, tongue out, without phonation.

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