Failure of the Laryngeal Mask Airway Unique™ and Classic™ in the Pediatric Surgical Patient

A Study of Clinical Predictors and Outcomes

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ABSTRACT

Background: Although predictors of laryngeal mask airway failure in adults have been elucidated, there remains a paucity of data regarding laryngeal mask airway failure in children.

Methods: The authors performed a retrospective database review of all pediatric patients who received a laryngeal mask anesthetic at their institution from 2006 to 2010. Device brands were restricted to LMA Unique™ (Cardinal Health, Dublin, OH) and LMA Classic™ (LMA North America, San Diego, CA), and primary outcome was laryngeal mask failure, defined as any airway event requiring device removal and tracheal intubation. Potential risk factors were analyzed with both univariate and multivariate techniques and included medical history, physical examination, surgical, and anesthetic characteristics.

Results: Of the 11,910 anesthesia cases performed in the study, 102 cases (0.86%) experienced laryngeal mask failure. Common presenting features of laryngeal mask failures included leak (25%), obstruction (48%), and patient intolerance such as intractable coughing/bucking (11%). Failures occurred before incision in 57% of cases and after incision in 43%. Independent clinical associations included ear/nose/throat surgical procedure, nonoutpatient admission status, prolonged surgical duration, congenital/acquired airway abnormality, and patient transport.

Conclusions: The findings of the study support the use of the LMA Unique™ and LMA Classic™ as reliable pediatric supraglottic airway devices, demonstrating relatively low failure rates. Predictors of laryngeal mask airway failure in the pediatric surgical population do not overlap with those in the adult population and should therefore be independently considered.

What We Already Know about This Topic

- A recent large adult study revealed a 1.1% incidence of laryngeal mask airway failure and identified surgical table rotation, male sex, poor dentition, and obesity as the independent risk factors
- There remains a paucity of data regarding laryngeal mask airway failure in children

What This Article Tells Us That Is New

- This study evidenced that laryngeal mask airway failures occur in 0.86% of 11,910 pediatric anesthesia cases with its planned use and are independently associated with ear/nose/throat procedures, admission status, prolonged surgical duration, airway abnormalities, and patient transport

THE laryngeal mask supraglottic airway device is used increasingly as a means of intraoperative airway management since its development in the 1980s.[1,2] Based on early successes, the laryngeal mask has gained widespread use in both the adult and pediatric populations.[3,4] Demonstrated advantages of the laryngeal mask compared with tracheal intubation include smaller hemodynamic changes[2,5,6] and reduced incidence of postoperative complications such as coughing, laryngospasm, soft-tissue trauma, and sore throat.[2,5,7] Demonstrated risks of the laryngeal mask

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compared with tracheal intubation include reduced levels of airway protection, increased risk of gastric insufflation, and increased incidence of hypoxemia.[2,4,5,8]

Optimal use of extraglottic airways, including the laryngeal mask, remains poorly defined using real-world data. Patterns of use over different geographic regions and the reported incidence of failures and complications vary widely.[9–11] In the adult population, a recent observational study of over 15,000 cases revealed a 1.1% incidence of laryngeal mask failure, defined as intubation after laryngeal mask removal, with 62% of patients having significant airway complications.[12] This observational study had adequate statistical power to elucidate independent risk factors for laryngeal mask failure and noted that surgical table rotation, male sex, poor dentition, and increased body mass index (BMI) were independent predictors of laryngeal mask failure.[12]

In children, however, similar data are scarce. Recent pediatric laryngeal mask studies report adverse event frequency ranging from 0 to 10%.[8,13–17] These data are limited by a focus on specific surgical procedures or by small sample size resulting in simplistic univariate or underpowered multivariate analyses. In addition, although data on adverse events are presented, laryngeal mask failure requiring endotracheal intubation is sparsely reported. The largest study of pediatric laryngeal mask complications published more than 15 yr ago included 1,400 patients, and there were no failures requiring replacement of the laryngeal mask with an endotracheal tube (ETT).[3] In addition, no multivariate, risk-adjusted analysis was performed to predict complications. In another study of 704 pediatric laryngeal mask insertions, only eight patients required endotracheal intubation, resulting in a grossly overfit multivariate analysis.[8] Collectively, the only risk factors for pediatric laryngeal mask failure previously identified in the peer-reviewed literature are provider experience, patient age, and type of surgery.[16,17] However, these risk factors are not based on adequately powered multivariate analyses in a broad and representative pediatric surgical population.

In order to identify specific independent clinical factors associated with laryngeal mask failure, a study is warranted that examines laryngeal mask use in children, allowing previously identified associations to be studied in a more generalizable pediatric surgical population. We therefore conducted an observational study at our tertiary care facility, describing the incidence of LMA Unique™ (*u*LMA™) and LMA Classic™ (cLMA™) failure in a general pediatric surgical population. We hypothesized that specific perioperative characteristics exist that increase risk of laryngeal mask failure and sought to characterize these risk factors *via* robust, adequately powered multivariate analyses.

Materials and Methods

Institutional Review Board approval (University of Michigan, Ann Arbor, Michigan) for this retrospective, observational study was obtained, and signed patient consent was waived, as no care interventions were mandated, and protected health information was not used or maintained after data collection. Through our electronic health record (Centricity® General Electric Healthcare, Waukesha, WI), preoperative, intraoperative, and postoperative data are documented by anesthesiology residents, attending staff, and certified registered nurse anesthetists. As is mandatory at our tertiary care academic medical center, documentation includes a structured, electronic preoperative history and physical on all patients using anesthesiology services. Within each history and physical, all clinical parameters are stored as discrete database elements. In addition, a structured predefined pick-list is typically used by the clinician to enter information, in order to make the database readily searchable for specific clinical findings (appendix 1). Additional demographic and laboratory data are acquired *via* an automated, validated, electronic interface from the hospital information system.

As is also mandatory in our institution, structured electronic intraoperative records are maintained for each surgical patient as part of the perioperative clinical information system. Within each intraoperative record, specific prompts are provided, such as caregiver sign-in or sign-out times, anesthetic intervention details, and patient positioning. In addition, hemodynamic data including minute-to-minute vital signs and mechanical ventilation parameters are acquired from automated, validated electronic physiologic monitors (Solar 9500™, General Electric Healthcare) and recorded in the intraoperative record. Through a consistent recording of these structured notes and intraoperative records on all surgical patients, a means of standardized documentation of intraoperative care—as well as access to a large-scale, searchable database—has been established.

Patient Population

By using a research copy of this electronic database, all data for this study were obtained using search parameters. This included a review of all pediatric patients (aged <18 yr) who underwent general anesthesia with a laryngeal mask from January 1, 2006 to December 31, 2010, at our institution, across hospital-based and outpatient sites, and including repeat procedures on some patients. These dates were selected because during this time period, laryngeal masks used in our institution were restricted to the LMA Unique™ disposable laryngeal mask (Cardinal Health, Dublin, OH) and the LMA Classic™ reusable laryngeal mask (LMA North America, San Diego, CA).

Independent Variables

Variables evaluated for each patient (tables 1–3) were selected on the basis of a detailed literature review that identified preoperative and intraoperative factors associated with adverse respiratory events. As suggested by prior literature, anthropometric and patient history factors included sex,[12,17] age,[8,17–21] BMI,[12,19,22] smoke exposure,[12,23,24] asthma,[25,26]

Table 1. Perioperative Patient Characteristics and Univariate Analyses

Potential Risk Factor Category			Successful Laryngeal Mask N = 11,808 (% of 11,808)	Failed Laryngeal Mask N = 102 (% of 102)	*P* Value	Odds Ratio (95% CI)	% Cases with Complete Data
Anthropometric data	Male sex		6,835 (58)	59 (58)	0.993	1.0 (0.7–1.5)	100.0
	Age	0–6 months	66 (0.6)	2 (2.0)	0.114	0.3 (0.08–1.4)	99.8
		6–12 months	218 (2.0)	6 (6.0)	0.018	0.4 (0.2–0.9)	
		12–24 months	880 (7.5)	11 (11)	0.520	0.8 (0.4–1.6)	
		2–12 yr	7,024 (60)	47 (46)	0.069	(0.9–2.3)	
		>12 yr	3,598 (31)	36 (35)		Reference	
	BMI	Normal	6,324 (66)	54 (65)		Reference	89.6
		Overweight	1,445 (15)	12 (15)	0.931	0.9 (0.5–1.8)	
		Obese	450 (4.7)	5 (5)	0.585	0.5 (0.1–2.1)	
		Severe obese	1,418 (15)	15 (18)	0.464	1.2 (0.7–2.2)	
Medical history	Admission status	Outpatient	10,173 (86)	73 (72)		Reference	100.0
		Admit	743 (6.3)	8 (8)	0.275	0.7 (0.3–1.4)	
		Inpatient	892 (8)	21 (21)	<0.001	0.3 (0.2–0.5)	
	Smoke exposure		263 (2.2)	0 (0.0)	0.127	0.98 (0.98–0.98)	99.8
	Asthma		1,839 (16)	15 (15)	0.802	0.9 (0.5–1.6)	99.8
	URI within 4 weeks		1,147 (10)	17 (17)	0.019	1.9 (1.1–3.1)	99.8
	Gastroesophageal reflux disease		1,171 (10)	11 (11)	0.777	1.1 (0.6–2.1)	99.8
	Obstructive sleep apnea		309 (3)	3 (3)	0.842	1.1 (0.4–3.6)	99.7
	Congenital/acquired airway abnormality		521 (4)	13 (13)	<0.001	3.2 (1.8–5.7)	100.0
	Prior difficult mask ventilation		13 (0.1)	0 (0.0)	0.737	1.0 (1.0–1.0)	100.0
	Prior difficult intubation		74 (0.6)	0 (0.0)	0.423	1.0 (1.0–1.0)	100.0
Surgical characteristics	Patient positioning	Lateral	1,336 (11)	13 (13)	0.848	1.1 (0.6–1.9)	99.1
		Lithotomy	1,137 (10)	5 (5)	0.102	0.4 (0.2–1.2)	
		Prone	83 (0.7)	0 (0)	0.383	0.9 (0.9–0.9)	
		Supine	9,143 (78)	84 (82)		Reference	
	Patient transport		1,703 (17)	23 (24)	0.067	1.5 (1.0–2.5)	84.4
	Surgical table rotation		1,848 (18)	7 (9)	0.031	0.4 (0.2–0.9)	85.5
	Surgical/procedural CPT code			(Detailed separately)			96.0
	Surgical duration, min	0–29.99	6,131 (52)	32 (33)		Reference	100.0
		30–59.99	3,418 (29)	28 (29)	0.080	1.6 (0.9–2.6)	
		60–89.99	1,441 (12)	21 (21)	<0.001	2.8 (1.6–4.9)	
		90–119.99	476 (4)	8 (8)	0.002	3.2 (1.5–7.0)	
		120–149.99	201 (2)	8 (8)	<0.001	7.6 (3.5–16.8)	
		>150	77 (1.0)	1 (1.0)	0.356	2.5 (0.3–18.4)	
Anesthetic characteristics	Junior caregiver		1,902 (16)	15 (15)	0.699	0.9 (0.5–1.6)	99.9
	Laryngeal mask size			(Detailed separately)			99.0
	Weight-matched laryngeal mask size		7,987 (68)	73 (72)	<0.001	N/A	100.0
	Current difficult mask ventilation (if performed)*		(N = 9,014) 4 (0.04)	(N = 80) 1 (1.2)	<0.001	28 (3.2–258)	100.0

* As a mask ventilation was performed in 77% of patients before laryngeal mask placement for the current case, statistical analysis was performed within this subpopulation only for this variable.

BMI = body mass index; CPT = Current Procedural Terminology; N/A = not applicable; URI = upper respiratory tract infection.

recent upper respiratory infection (URI),[7,8,20,25,27,28] gastroesophageal reflux disease,[29–31] obstructive sleep apnea,[19,32] congenital or acquired airway abnormalities,[27,33–40] and history of difficult airway.[41,42] Surgical-related factors included procedure type (classified by Current Procedural Terminology code),[3,19–21,43,44] surgical duration,[45–47] patient positioning,[48] and surgical table rotation.[12] Anesthetic factors included laryngeal mask size,[3,49] laryngeal mask size–weight

Table 2. Surgical/Procedural CPT Code Ranges and Univariate Analysis

Potential Surgical Risk Factor Category			Successful Laryngeal Mask (Complete Data N = 11,331)	Failed Laryngeal Mask (Complete Data N = 102)
Surgical/procedural CPT code range	10021–10022	General	5 (0.04%)	0 (0%)
	10040–19499	Integumentary system	1,217 (11%)	4 (4%)
	20000–29999	Musculoskeletal system	2,526 (22%)	21 (22%)
	30000–32999	Respiratory system*	467 (4%)	13 (13%)
	33010–37799	Cardiovascular system	443 (4%)	11 (11%)
	38100–38999	Hemic and lymphatic systems	181 (2%)	0 (0%)
	39000–39599	Mediastinum and diaphragm	0 (0%)	0 (0%)
	40490–49999	Digestive system	551 (5%)	5 (5%)
	50010–53899	Urinary system	1,261 (11%)	6 (6%)
	54000–55899	Male genital system	664 (6%)	8 (8%)
	55920–55980	Reproductive system and intersex	0 (0%)	0 (0%)
	56405–58999	Female genital system	86 (1.0%)	0 (0%)
	59000–59899	Maternity care and delivery	1 (0.009%)	0 (0%)
	60000–60699	Endocrine system	2 (0.02%)	0 (0%)
	61000–64999	Nervous system	322 (3%)	0 (0%)
	65091–68899	Eye and ocular adnexa	1,071 (9%)	5 (5%)
	69000–69979	Auditory system *	124 (1%)	2 (2%)
	70010–79999	Radiology	2,069 (18%)	20 (21%)
	90281–99607	Medicine	346 (3%)	2 (2%)

* Classified in multivariate analysis as ENT surgical procedure; all other procedures classified as non-ENT.
CPT = Current Procedural Terminology; ENT = ear/nose/throat.

matching,[45,50,51] anesthesia caregiver experience,[16,52] and current intraoperative difficult mask ventilation (if performed before laryngeal mask placement).[12] To adjust for unmeasured confounders related to procedure or patient complexity, admission status was also studied. Specific definitions of patient history variables, as appearing within the pick-list choices in our institution's preoperative History and Physical document, are detailed in appendix 1.

Primary and Secondary Outcomes

Within this population, the primary outcome was laryngeal mask failure, defined by the abandonment of the laryngeal mask and subsequent tracheal intubation. Such cases were initially identified as all cases in which direct laryngoscopy was performed or an ETT was placed after use of the laryngeal mask. These cases were then reviewed manually by two reviewers (M.M. and B.H.) to determine whether a subsequent tracheal intubation was indeed performed and to ensure reclassification of cases in which the laryngeal mask was removed secondary to a change in surgical plan rather than anesthetic management (fig. 1). In addition, cases involving a laryngeal mask device used as a rescue airway, and cases in which a laryngeal mask was replaced with an ETT reflecting a communication failure between the anesthesia and surgical teams (*e.g.*, requiring breath holds for radiologic imaging) rather than a clinical failure, were excluded.

After identifying all cases in which a laryngeal mask failure occurred, the salient characteristics of each case were reviewed to identify secondary outcomes. This included the timing of the primary outcome relative to surgical incision, as well as presenting features of laryngeal mask failure. Presenting features were determined by both reviewers through evaluation of the anesthesia record and other electronic health record documentation, to determine whether the laryngeal mask failure presented as inadequate seal, upper or lower airway obstruction, or other presenting feature, as detailed in appendix 2. To validate this analysis, laryngeal mask failures were classified independently by each reviewer; in cases where a disagreement existed, consensus was obtained after a discussion of the case and further record review.

Statistical Analysis

For purposes of statistical analysis, age was treated as a binned concept, with ranges based on relative changes in airway anatomy with growth and development; for multivariate analysis, age was further dichotomized into age less than 2 yr and age 2 yr or more. BMI was binned

Table 3. Laryngeal Mask Size/Size–Weight Matching and Univariate Analyses

Laryngeal Mask Size	Overall Failure Rate for Size (%, *P* Value *vs.* Entire Population)	Successful Laryngeal Mask (Complete Data N = 11,808)			Failed Laryngeal Mask (Complete Data N = 102)		
		Total	Not Size–Weight Matched	Too Large (TL) / Too Small (TS)	Total	Not Size–Weight Matched	Too Large (TL) / Too Small (TS)
1	0/27 (0.0) *P* > 0.999	27 (0.2%)	14/27 (52 %)	TL: N/A TS: 14/14 (100%)	0 (0.0%)	0	TL: N/A TS: 0
1.5	11/448 (2.5) *P* < 0.001	437 (3.7%)	162/437 (37%)	TL: 14/162 (9%) TS: 148/162 (91%)	11 (11 %)	0/11 (0%)	TL: 0 TS: 0
2	27/3,443 (0.78) *P* = 0.585	3,416 (29%)	555/3,416 (16%)	TL: 198/555 (36%) TS: 357/555 (64%)	27 (27%)	2/27 (6.7%)	TL: 2/2 (100%) TS: 0/2 (0%)
2.5	22/3,053 (0.72) *P* = 0.345	3,031 (26%)	1,145/3,031 (38%)	TL: 646/1,145 (56%) TS: 499/1,145 (44%)	22 (22%)	8/22 (36%)	TL: 5/8 (63%) TS: 3/8 (37%)
3	24/2,761 (0.87) *P* = 0.933	2,737 (23%)	1,103/2,737 (40%)	TL: 185/1,103 (17%) TS: 918/1,103 (83%)	24 (24%)	13/24 (46%)	TL: 3/13 (23%) TS: 10/13 (77%)
4	9/1,730 (0.52) *P* = 0.101	1,721 (15%)	679/1,721 (40%)	TL: 97/679 (14%) TS: 582/679 (86%)	9 (9.0%)	4/9 (44%)	TL: 1/4 (25%) TS: 3/4 (75%)
5	8/327 (2.4) *P* = 0.002	319 (2.7%)	43/319 (14%)	TL: 43/43 (100%) TS: N/A	8 (7.9%)	1/8 (13%)	TL: 1/1 (100%) TS: N/A
Unknown	1/121 (0.83) *P* = 1.000	120	N/A	TL: N/A TS: N/A	1	N/A	TL: N/A TS: N/A
Total	102/11,910 (0.86) *P* = N/A	11,808	3,701 (31%)	TL: 1,183/3,701 (32%) TS: 2,518/3,701 (68%)	102	28/102 (27%)	TL: 12/28 (43%) TS: 16/28 (57%)
Not size–weight matched total	28/3,729 (0.75) *P* = N/A	3,701/11,808 (31%)		TL: 1,183/3,701 (32%) TS: 2,518/3,701 (68%)	28/102 (27%)		TL: 12/28 (43%) TS: 16/28 (57%)

N/A = not applicable.

into Centers for Disease Control and Prevention pediatric age- and sex-specific classifications for normal weight, overweight, obese, and severe obesity; for multivariate analysis, BMI was further dichotomized into obese (BMI ≥95th age-based percentile) *versus* nonobese.[53,54] Surgical duration was treated as a binned continuous concept, with ranges divided into 30-min epochs. Surgical procedure type was classified by Current Procedural Terminology code, which was then binned by organ system; for multivariate analysis, Current Procedural Terminology code organ system was further dichotomized into ear/nose/throat (ENT) *versus* non-ENT. As detailed in appendix 1, congenital or acquired airway abnormalities encompassed a range of congenital syndromes (*e.g.*, Pierre-Robin, Treacher Collins) and acquired pathologies (*e.g.*, subglottic stenosis, tracheomalacia). History of a difficult airway was divided into two concepts: difficult mask ventilation and difficult intubation. Likewise, as surgical procedures on occasion involved anesthetic induction and laryngeal mask placement in a separate induction bay followed by transport with a laryngeal mask in place to the procedure destination (*e.g.*, patients who underwent magnetic resonance imaging scan), surgical table rotation was expanded into two mutually exclusive concepts: patient transport and surgical table rotation. Patient transport was defined as room-to-room transport with an LMA in place, whereas surgical table rotation occurred within an operating room, not involving room-to-room transport.

For purposes of multivariate analysis, admission status was dichotomized into outpatient *versus* inpatient or admit day of procedure. Similarly, positioning was dichotomized into supine *versus* nonsupine; all laryngeal masks were placed supine before further positioning. Laryngeal mask size was also treated as a binned concept, binned across all *u*LMA™ and *c*LMA™ sizes available; for multivariate analysis, laryngeal mask size was dichotomized into small (size ≤2) and large (size >2). Laryngeal mask size–weight matching was based on a comparison of each patient's weight to the manufacturer-specified weight range for the final (and often only) size used during each case. Anesthesia caregiver experience was dichotomized as "junior" and "experienced" caregiver. Junior caregivers were defined as nonanesthesiology rotators, interns, and clinical anesthesiology year-1 residents, all who typically have less than 1 yr of clinical anesthesia experience; experienced caregivers included all clinical anesthesiology residents year-2 and beyond, anesthesiology fellows,

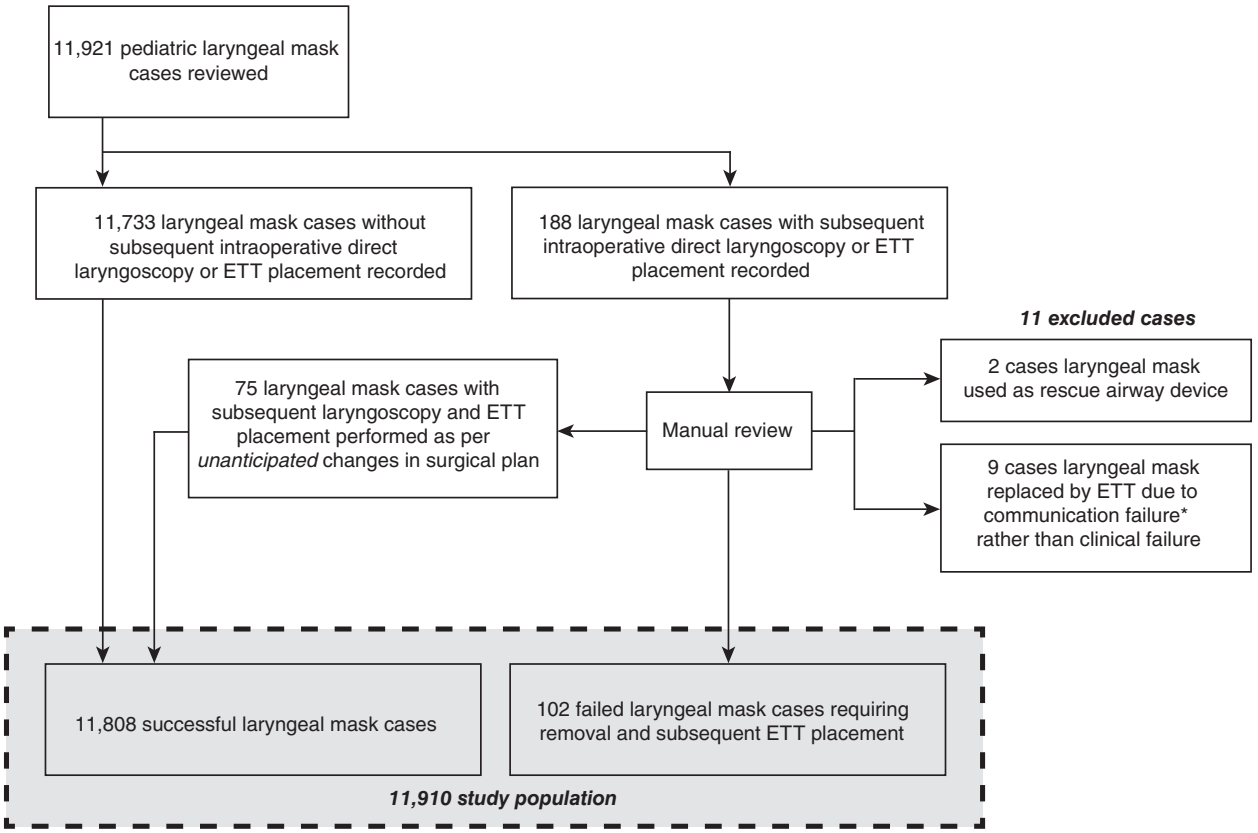

Fig. 1. Patient inclusions, exclusions, and primary outcome. * Communication failures between anesthesia and surgical team included radiologic procedures requiring breath holds (4), surgical procedures with anticipated planned laparoscopy (1), and surgical procedures where laryngeal mask device obstructed surgical exposure (4). ETT = endotracheal tube.

anesthesiology attending physicians, and certified registered nurse anesthetists.

All analyses were performed using SPSS® version 20.0 (SPSS Inc., Chicago, IL). Basic descriptive statistics were calculated for all data-field variables listed in tables 1–3. Univariate analysis was conducted for each variable, with *P* values calculated using Pearson chi-square or Fisher exact tests for categorical variables and Student *t* tests for continuous variables. For purposes of multivariate analysis, collinearity diagnostics and Pearson correlations were conducted on all variable pairs to assess for independence. This was performed by evaluating the condition index of the entire group of independent variables to identify covariates that were highly correlated. The condition index of the independent variables in this dataset was less than 30, so all variables were eligible for entry into the multivariate model. To minimize the risk of overfitting, a semiparsimonious logistic regression model analysis was performed.

All variables considered to be significant in the full model fit ($P < 0.05$) were established as independent predictors. Odds ratios were then used to assess each variable for effect size, comparing the likelihood of a failed laryngeal mask among patients with and without each risk factor. The predictive value of the resulting regression model was then evaluated using the c-statistic. Finally, a sensitivity analysis was performed in which a multivariate regression model was developed in identical manner although excluding all cases in which laryngeal masks were not size–weight matched.

Power Analysis

Before data acquisition, a power analysis was performed in order to determine sample size requirements. Based on a *c*LMA™/*u*LMA™ failure rate of 1%, a multivariable analysis including up to 10 risk factors (nine included in our study) would require approximately 100 primary outcomes to be observed, and thus 10,000 anesthesia cases available for analysis. Based on previous work[19] and knowledge of the annual procedural volume at the study center, at least 10,000 anesthesia cases were expected for analysis. This *a priori* power analysis was documented and presented at a departmental clinical research peer-review committee.

Results

Of the 11,921 pediatric anesthesia cases performed with a *u*LMA™ or *c*LMA™ as a primary airway-management plan from 2006 to 2010 at our tertiary care facility (compared with 62,227 tracheal intubations), 188 cases were noted to

have an intraoperative direct laryngoscopy and/or placement of an ETT. Through manual review, we reclassified 75 anesthesia cases during which the laryngeal mask was replaced due to unanticipated changes in the surgical plan unrelated to anesthetic management. In addition, 11 anesthesia cases in which the laryngeal mask was used as a rescue airway, or was replaced due to a communication rather than clinical failure, were excluded from the study. Thus, we report a primary outcome of laryngeal mask failure to have occurred in 102 individually reviewed cases among 11,910 anesthetics (tables 1–3 and fig. 1). This corresponded to a laryngeal mask failure rate of 0.86%, or approximately 1 in every 117 cases.

Of the 11,910 anesthesia cases, 10,643 cases (89.4%) were performed within our pediatric hospital under the supervision of attendings with extensive pediatric training; of these 10,643 cases, 94 involved a failed laryngeal mask (failure rate 0.88%). Of the remaining 1,267 cases performed at adult locations—under the supervision of attendings less commonly having extensive pediatric training—8 failures occurred (0.63%). In addition, of the 11,808 anesthesia cases with a successful use of a laryngeal mask, only 31 received nondepolarizing neuromuscular blockade (0.26%). Of the 102 laryngeal mask failures, none received nondepolarizing neuromuscular blockade before replacement with an ETT.

Regarding univariate analysis of laryngeal mask sizes, overall failure rates were noted to be significantly increased for sizes 1.5 and 5; other sizes showed no significantly increased failure rate (table 3). Among successful laryngeal mask anesthetics, the majority (92%) involved sizes 2 to 4, and the majority (68%) involved proper size–weight matching per manufacturer's recommendations. Among failed laryngeal mask anesthetics, a similar majority (82%) involved sizes 2 to 4, and a similar majority (73%) involved proper size–weight matching. With size–weight mismatches, successful laryngeal mask anesthetics involved laryngeal masks smaller than specified more often than larger (68 *vs.* 32%); this was also true for failed laryngeal mask anesthetics (57 *vs.* 43%).

Regarding laryngeal mask failure timing, 58 (57%) occurred before surgical incision and 44 (43%) after incision during the procedure. Manual review for the presenting features of laryngeal mask failure demonstrated an inadequate seal or leak as the primary symptom in 25 of 102 cases (25%). Forty-nine cases were attributable to obstruction; of these, 38 (37% of total) were identifiable as an upper airway event and 11 (10% of total) as a lower airway event. In 11 cases (11%), patient intolerance, manifested as intractable hiccoughing, bucking, or coughing, was the primary symptom. In the remaining 17 cases (17%), the failure manifested with some combination of the above features not specifically documented adequately for classification. These results are detailed in table 4.

Specific etiologies of the laryngeal mask failure could be elucidated in a subset of patients. Eight cases involved intractable hiccoughing or coughing, leading to unsatisfactory conditions for surgery or magnetic resonance imaging. In 30 cases (29%), laryngospasm was strongly suspected or confirmed. In eight cases, blood or lower airway secretions made ventilation difficult or impossible; all occurred during flexible bronchoscopy. In three of these cases, the patient was intubated for airway protection from severe epistaxis or concern for lower airway hemorrhage and transported to the intensive care unit intubated and sedated. Of the 11 lower airway events identified, only 1 case of bronchospasm was noted; the remaining 10 cases were attributable to either aspiration or secretions/mucous/blood in the lower airway (table 4). In five cases, the laryngeal mask was dislodged by a head coil for magnetic resonance imaging, radiation mask, or by the surgeon turning the head. Position changes were identified as a cause in four cases, most

Table 4. Laryngeal Mask Failure Presenting Feature Results

Presenting Feature	Total Events (N = 102)	Notes
Laryngeal mask leak	25 (25%)	Four documented as after patient position change Three documented as accidentally dislodged by operating room personnel*
Laryngeal mask obstruction/upper airway event	38 (37%)—Total 30 (29%)—Laryngospasm 8 (8%)—Unspecified	One documented as after patient position change
Lower airway event	11 (10%)—Total 3 (3%)—Aspiration 7 (6%)—Secretions/mucous/blood 1 (1%)—Bronchospasm	
Patient intolerance	11 (11%)	
Other	17 (17%)	One documented as prophylactic measure to secure unstable airway

* Including all caregivers in operating room (*e.g.*, anesthesia providers, surgeons, nursing staff, medical students, and many more).

commonly in turning the patient to a lateral position for caudal placement.

Univariate analysis demonstrated a wide variety of clinical characteristics to be associated with laryngeal mask failure (tables 1–3). The following variables were entered into a semiparsimonious logistic regression: ENT surgical procedure, inpatient/admit day of surgery admission status, surgical duration, congenital/acquired airway abnormality, patient transport, age less than 2 yr, small laryngeal mask size of 2 or less, nonsupine patient positioning, and URI within 4 weeks.

As noted in table 5, five independent predictors associated with laryngeal mask failure were identified: ENT procedure, inpatient/admit day of surgery admission status, prolonged surgical duration, congenital/acquired airway abnormality, and patient transport. The model was evaluated using the omnibus test of model coefficients, demonstrating a chi-square value of 61 with 9 degrees of freedom and a *P* value of less than 0.001. Receiver operating characteristic curve analysis demonstrated a c-statistic of 0.72 (95% CI, 0.66–0 .77). On a sensitivity analysis in which only cases with size–weight matched laryngeal masks were used, a chi-square value of 55 was obtained with 9 degrees of freedom and a *P* value of less than 0.001, with a c-statistic of 0.73 (95% CI, 0.66–0.79).

Discussion

Among 11,910 children undergoing general anesthesia with a planned laryngeal mask included in our study, the incidence of *u*LMA™ or *c*LMA™ failure was 0.86%, or 1 in every 117 cases. Fifty-seven percent of laryngeal mask failures occurred before incision and 43% occurred after incision. Presenting features of laryngeal mask failure included leak (25%), upper airway obstruction (37%), lower airway event (10%), patient intolerance (11%), and others (17%). We identified five independent clinical factors associated with laryngeal mask failure: ENT procedure, inpatient/admit day of surgery admission status, prolonged surgical duration, congenital/acquired airway abnormality, and patient transport. These data represent advances upon prior peer-reviewed literature, in which underpowered analyses limited to surgical subpopulations identified provider experience, patient age, and surgery type as risk factors.[16,17]

The low incidence of pediatric laryngeal mask failure in our study is consistent with prior literature, confirming its use as an airway-management device during general anesthesia.[8,12,14,16,43] Despite this, the potentially serious nature of adverse airway events is a risk the anesthesia caregiver must be mindful of, and factors associated with increased failure risk are identified by our study. In many instances, laryngeal mask failures in our study were accompanied by hypoxemia, hypotension, tachycardia, administration of succinylcholine and additional anesthetics, and prolongation of anesthesia time.

Among the independent clinical associations identified, 13 patients with a congenital or acquired airway abnormality experienced a laryngeal mask failure. In such instances, presenting features varied. These included leak (four cases), upper airway obstruction (five), aspiration (one), bronchospasm (one), patient intolerance (one), and other causes (one). Laryngeal mask failure timing also varied: eight occurred before surgical incision and five occurred after. Given these results, caution must be used with interpretation, as airway abnormalities encompassed a wide range of pathologies.

Several procedural characteristics also demonstrated significant independent relationships with laryngeal mask

Table 5. Multivariate Analysis and Sensitivity Analysis

	Multivariate Analysis		Sensitivity Analysis (Included Only Size–Weight Matched Laryngeal Masks)	
Multivariate Potential Risk Factor	*P* Value	Adjusted Odds Ratio (95% CI)	*P* Value	Adjusted Odds Ratio (95% CI)
Surgical duration	<0.001	1.54 (1.31–1.81)	<0.001	1.59 (1.31–1.94)
Nonoutpatient admission status	0.003	2.06 (1.28–3.34)	0.042	1.85 (1.02–3.34)
ENT surgical procedure	0.006	2.54 (1.31–4.92)	0.005	2.85 (1.36–5.95)
Congenital/acquired airway abnormality	0.008	2.42 (1.25–4.67)	0.007	2.74 (1.31–5.73)
Patient transport	0.014	1.90 (1.14–3.18)	0.027	1.97 (1.08–3.60)
Age <2 yr	0.099	1.75 (0.90–3.41)	0.102	1.79 (0.89–3.60)
URI within 4 weeks	0.325	1.35 (0.75–2.43)	0.068	1.80 (0.96–3.39)
Small laryngeal mask size ≤2	0.668	1.12 (0.66–1.92)	0.221	1.46 (0.80–2.66)
Nonsupine positioning	0.875	0.96 (0.55–1.67)	0.979	0.99 (0.51–1.94)

ENT = ear/nose/throat; URI = upper respiratory tract infection.

failure. Surgical duration was noted to raise the risk of failure for each 30-min increase. These are the first data to describe the continuous relationship between surgical duration and laryngeal mask failure. It is possible that surgical duration incorporates some of the clinical effect of surgical complexity, but given that this risk factor was independent of admission status, and 43% of the failures were postincision, duration itself is likely a contributing factor. In addition, ENT surgical procedures were demonstrated to be an independent risk factor for laryngeal mask failure. Previous studies have similarly reported increased adverse respiratory events in head and neck surgeries using a laryngeal mask.[3,43] Finally, procedures involving patient transport demonstrated an independently increased risk of laryngeal mask failure. Laryngeal mask failure associated with transport occurred in radiologic procedures, where failures frequently followed dislodgement during radiologic imaging. This suggests potential for future studies investigating laryngeal mask failure during radiologic imaging; however, on the basis that no *a priori* analysis was performed, the authors do not wish to speculate further on etiologies for laryngeal mask failure associated with patient transport.

Although multivariate analysis did not demonstrate age less than 2 yr to be independently associated with laryngeal mask failure, univariate analysis demonstrated an association with increased failure risk. Previous studies have found younger ages to present increased risk of airway complications from a general anesthesia[8,19–21,25] and increased risk of laryngeal mask failure in specific procedural groups.[17,44] Our data suggest the need for heightened concern when considering laryngeal masks for younger children. On univariate analysis, smaller laryngeal mask sizes and sizes not weight-matched to manufacturer recommendations were more frequently noted to present with laryngeal mask failure (table 3). These results must also be interpreted with caution, however, as variations in success were observed across laryngeal mask sizes, and laryngeal masks which were not size–weight matched may have been the result of switching sizes due to an initially inadequate laryngeal mask. On multivariate analysis, smaller laryngeal mask sizes did not demonstrate an independent clinical association.

Although multivariate analysis did not demonstrate a history of URI within 4 weeks to be an independent association, univariate analysis found increased risk of laryngeal mask failure. In general, conditions contributing to increased airway reactivity, including recent URI, have resulted in increased risk of laryngospasm in children.[27,55] In addition, a recent URI has been associated with increased risk of laryngeal mask–related airway events[7,20] or any adverse respiratory event from general anesthesia.[25,27,28] Conversely, three studies have found lower risk of respiratory adverse events in children with an active or recent URI who were anesthetized using a laryngeal mask compared with ETT.[56–58] In our study, 29% of laryngeal mask failures reported were attributable to laryngospasm, suggesting that in children with potential for heightened airway reactivity, selection of a laryngeal mask should be made after careful consideration.

In addition, admission status was noted to be an independent risk factor for laryngeal mask failure. One can hypothesize that procedures requiring admission suggest increased perioperative risks already considered by the primary surgical team. Our study does not identify which unique characteristics prompting an admission contributed to the increased risk of laryngeal mask failure. Finally, it is notable that multiple characteristics studied were not associated with increased risk of laryngeal mask failure on univariate and/or multivariate analyses; these included sex, obesity, asthma, smoke exposure, gastroesophageal reflux disease, obstructive sleep apnea, positioning, table rotation, prior/current difficult mask ventilation/difficult intubation, and anesthesia-provider experience. Although junior caregivers were present in 1,917 cases, it was noted that the majority of cases were performed at pediatric locations (89.4%) under supervision from attending physicians with pediatric training; this majority may explain the relatively low incidence of laryngeal mask failure compared with prior literature, in which anesthesia may have been performed by anesthesia caregivers with less-extensive pediatric training.[8,13,15,17,43]

In comparison with a prior study performed at our institution examining risk factors for laryngeal mask failure in the adult population, we noted some unique features for the pediatric population.[12,59] Both populations note similar incidence of laryngeal mask failure (0.86% in pediatric population *vs.* 1.1% in adult population), and both studies note surgical table movement as an independent risk factor. Adult risk factors not observed in the current pediatric data include male sex, increased BMI, and poor dentition. In the pediatric population, airway examination characteristics were unreliably recorded due to patient cooperation difficulties. However, sex and BMI were reliably recorded characteristics which did not show significantly increased rates of failure. Such findings warrant further evaluation in future prospective, controlled studies.

Several limitations existed for this study. Given its observational nature, no specific protocol could be used to direct anesthesia caregiver decisions to replace the laryngeal mask with an ETT. As such, our primary outcome was reliant on clinical judgment of the anesthesia caregiver, and could not be based on any controlled measure. Each provider could choose to use the laryngeal mask for spontaneous unassisted ventilation, pressure support ventilation, or controlled ventilation. Patient selection bias also existed; similar cases may have been performed with an ETT instead of a laryngeal mask, or *vice-versa*. In addition, the search strategy focused on laryngeal mask cases which involved a subsequent tracheal intubation; cases in which an unstable laryngeal mask was adequately treated by other means of anesthetic

intervention were considered not to represent laryngeal mask failures. Patient risks likely existed during these cases, however, which were not characterized by this study. It should also be noted that laryngeal mask types in this study were restricted to the cLMA™ and uLMA™, both of which are first-generation laryngeal masks. Although second-generation supraglottic devices are increasingly prevalent, their safety and superiority have yet to be established,[4,60,61] with first-generation devices still comprising the majority of annual sales (67%) (Electronic mail personal communication with Chris DeShetler, Sales Specialist, Teleflex Corporation [parent company of LMA North America], San Diego, California, June 2013) and reflecting routine clinical practice at many organizations. Within our study, data regarding specific laryngeal mask type—cLMA™ or uLMA™—were not available, and variations in failure related to laryngeal mask type were not available.

In addition, study limitations existed intrinsic to the electronic record from which data were obtained. Given the primary goal of our electronic record was to manage care, data beyond this scope were unavailable. In addition, failures due to intraoperative surgical plan changes were excluded because the etiologies of clinical laryngeal mask failure *versus* communication failure are fundamentally different and cannot be evaluated in a single multivariate analysis. Finally, as data from this study were drawn from our single-tertiary care center, caution should be used when applying results of this study nationally or globally, as anesthesia care processes and patients are likely to vary across different regions.

Despite these limitations, our study offers new insight into anesthesia providers considering risks of a laryngeal mask airway in the pediatric population. Our data inform an anesthesia caregiver's decision to use a laryngeal mask for a particular patient and decrease dependence on anecdotal experience. In elucidating risk factors, our study identifies areas for further research. In conclusion, we report that laryngeal mask failures occur once in approximately every 117 anesthesia cases and are independently associated with ENT surgical procedures, admission status, prolonged surgical duration, congenital/acquired airway abnormalities, and patient transport.

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Appendix 1. Potential Risk Factor Pick-list Choices

Potential Risk Factor	Pick-list Choices Included in Study
Smoke exposure	*Tobacco*—second-hand smoke exposure/current smoker/former smoker
Asthma	*Asthma*—allergen induced/aspirin induced/exercise induced/infection induced/nocturnal/occupational/exacerbated by pregnancy/reactive airway disease/(unknown)
URI within 4 weeks	*URI*—within 4 weeks with fever/within 4 weeks without fever *Pneumonia*—current (rales, sputum, radiographic evidence)/within 30 days
Gastroesophageal reflux disease	*Other GI*—GERD *GI signs and symptoms*—reflux
Obstructive sleep apnea	*Sleep apnea*—treated by BIPAP/CPAP/prescribed BIPAP/CPAP but not using it/treated by surgery/tested positive for sleep apnea/diagnosed with sleep study but untreated
Congenital or acquired airway abnormality	*Congenital syndrome*—Angelman's/Beckwith–Wiedemann/chromosome 22 syndromes/cleft lip/cleft palate/cornelia de Lange/DiGeorge's/Goldenhaar's/Heterotaxy/Jeune/Pierre-Robin/Prader-Willi/Treacher Collins/Trisomy 18/Trisomy 21/Turner's/VACTERL Syndrome/(Custom free text entry, hand-reviewed) *ENT*—tracheomalacia/bronchomalacia/laryngomalacia/subglottic stenosis/paralyzed vocal cord
Prior difficult mask ventilation	*Previous Intraoperative Record*—mask ventilation grade 3/mask ventilation grade 4
Prior difficult intubation	*Previous Intraoperative Record*—Grade 3 laryngoscopic view/Grade 4 laryngoscopic view/(Custom free text entry indicating unsuccessful attempt, multiple attempts, or "difficult intubation")
Current difficult mask ventilation	*Current intraoperative record*—mask ventilation grade 3/mask ventilation grade 4

BIPAP = bilevel positive airway pressure; CPAP = continuous positive airway pressure; ENT = ear/nose/throat; GERD = gastroesophageal reflux disease; GI = gastrointestinal; URI = upper respiratory tract infection; VACTERL = vertebral anomalies, anal atresia, cardiovascular anomalies, tracheoesophageal fistula, renal anomalies, limb defects.

Appendix 2. Laryngeal Mask Failure Presenting Feature Definitions

Presenting Feature	Example Intraoperative Record Comments
Laryngeal mask leak	"Inadequate seal," "poor seal," "poor fit," "unable to fit," "unseated," "unable to seat," "not seated well," "audible breath sounds"
Laryngeal mask obstruction/upper airway event	"Obstruction," "obstructing," "stridor," "increased peak inspiratory pressure," "laryngospasm"
Lower airway event	1. Aspiration—"Gastric contents noted," "aspirate noted," "patient vomited," "bile seen," "bilious contents seen" 2. Secretions/mucous/blood—"secretions noted," "mucous noted," "blood in airway" 3. Bronchospasm—"bronchospasm," epinephrine or albuterol given in response to difficulty with laryngeal mask placement ("Wheezing" treated as nondiagnostic finding)
Patient intolerance*	"Coughing," "bucking," "hiccupping," "breath holding," "patient moving"
Other	Laryngeal mask failure not attributable to changes in surgical plan and not clearly documented; or not solely attributable to above causes

* Defined as any airway event in which intraoperative documentation clearly described patient poorly tolerating laryngeal mask, yet not clearly experiencing a laryngeal mask leak, obstruction/upper airway event/lower airway event.