Blind Intubation through Self-pressurized, Disposable Supraglottic Airway Laryngeal Intubation Masks

An International, Multicenter, Prospective Cohort Study

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ABSTRACT

Background: Supraglottic airway devices commonly are used for securing the airway during general anesthesia. Occasionally, intubation with an endotracheal tube through a supraglottic airway is indicated. Reported success rates for blind intubation range from 15 to 97%. The authors thus investigated as their primary outcome the fraction of patients who could be intubated blindly with an Air-Qsp supraglottic airway device (Mercury Medical, USA). Second, the authors investigated the influence of muscle relaxation on air leakage pressure, predictors for failed blind intubation, and associated complications of using the supraglottic airway device.

Methods: The authors enrolled 1,000 adults having elective surgery with endotracheal intubation. After routine induction of general anesthesia, a supraglottic airway device was inserted and patients were ventilated intermittently. Air leak pressure was measured before and after full muscle relaxation. Up to two blind intubation attempts were performed.

Results: The supraglottic airway provided adequate ventilation and oxygenation in 99% of cases. Blind intubation succeeded in 78% of all patients (95% CI, 75 to 81%). However, the success rate was inconsistent among the three centers ($P < 0.001$): 80% (95% CI, 75 to 85%) at the Institute of Anesthesia and Pain Therapy, Kantonsspital Winterthur, Winterthur, Switzerland; 41% (95% CI, 29 to 53%) at the Department of Anesthesiology and Intensive Therapy, Medical University of Lodz, Lodz, Poland; and 84% (95% CI, 80 to 88%) at the Institute of Anesthesiology, University Hospital Zurich, Zurich, Switzerland. Leak pressure before relaxation correlated reasonably well with air leak pressure after relaxation.

Conclusions: The supraglottic airway device reliably provided a good airway and allowed blind intubation in nearly 80% of patients. It is thus a reasonable initial approach to airway control. Muscle relaxation can be used safely when unparalyzed leak pressure is adequate. **(Anesthesiology 2017; 127:307-16)**

SECURING the airway and providing adequate oxygenation and ventilation is fundamental in patients having general anesthesia. Inability to intubate the trachea or oxygenate by mask can result in hypoxemia, aspiration, airway trauma, bradycardia, and even death. There are various methods of predicting difficult intubation, including the Mallampati oropharyngeal classification, thyromental distance, sternomental distance, mouth opening, and the Wilson risk score. Nonetheless, the incidence of unanticipated difficulties during intubation is about 6%.[1]

Several airway management guidelines recommend supraglottic airway devices as an alternative when intubation and ventilation fail.[2,3] Once an airway is secured with a supraglottic airway and ventilation restored, the trachea can be intubated through some types of supraglottic airway devices, if required. Intubation can be blind, meaning that the tube is inserted through the supraglottic airway without direct visualization of the tube within the larynx or pharynx or with fiberoptic guidance. The success rate of blind intubation has been reported to range between 15 and 97%, depending on the type of supraglottic airway, patient characteristics, and operator skill.[4–7] Although blind intubation

What We Already Know about This Topic

- When intubation and ventilation fail during anesthesia induction, insertion of a supraglottic airway device and intubation through the supraglottic airway device is a rescue plan to establish the airway. However, success rates ranging from 15 to 97% have been reported for blind intubation through a supraglottic airway.

What This Article Tells Us That Is New

- In this multicenter, prospective study, 99% of 1,000 patients with a supraglottic airway could be oxygenated and ventilated.
- Blind intubation succeeded in 78% of all patients, although the success rate significantly varied among the three centers (41, 80, and 84%), but when possible was easy, quick, and did not cause serious complications.

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is a common and helpful approach, the technique is associated with potentially serious outcomes, and guided techniques often are beneficial in patients with difficult airways.[2,3,8]

The Air-Qsp Self-Pressurizing Disposable Masked Laryngeal Airway (Mercury Medical, USA) is a recently introduced single-use supraglottic airway device. This device differs from most supraglottic airway devices in it has a self-inflating cuff, which usually provides sufficient tissue pressure to support positive pressure ventilation. This supraglottic airway is designed to permit blind or fiberoptic-guided tracheal intubation using most any commercially available tracheal tube.

Several studies, especially in pediatric patients, report that this supraglottic airway allows both blind and fiberoptic-guided intubation.[9–11] However, only a few small studies assess the suitability of the supraglottic airway as a conduit for blind intubation in adults.[4–6,12,13] Our goal was thus to evaluate the feasibility and clinical performance of the supraglottic airway in a large, multicenter cohort of surgical patients.

Our primary outcome was the fraction of patients who could be intubated blindly through a supraglottic airway. Second, we determined the ease with which the supraglottic airway was inserted; time to intubation; predictive risk factors for failed blind intubation; postoperative complications including sore throat, hoarseness, and cough; and change of airway leak pressure of the supraglottic airway before and after the use of muscle relaxation. In patients who could not be intubated blindly, we evaluated the supraglottic airway as a conduit for fiberoptic-guided intubation.

Materials and Methods

We recruited an international, multicenter cohort between July 2013 and June 2016. With approval from institutional review boards at participating sites (Institutional Review Board of the University of Zurich, Zurich, Switzerland, and the Institutional Review Board of the University of Lodz, Lodz, Poland), we enrolled 1,000 adults having elective surgery who required endotracheal intubation. Patients were recruited at three hospitals: the Institute of Anesthesia and Pain Therapy, Kantonsspital Winterthur, Winterthur, Switzerland (KSW); Department of Anesthesiology and Intensive Therapy, Medical University of Lodz, Lodz, Poland (Lodz); and Institute of Anesthesiology, University Hospital Zurich, Zurich, Switzerland (USZ). Patients were *a priori* allocated to study centers, and the study was registered at ClinicalTrials.gov (NCT01906060) before starting.

Participating patients were between 18 and 85 yr old, weighed between 50 and 100 kg, had an American Society of Anesthesiologists (ASA) physical status between I and III, and were expected to be extubated immediately after surgery. We excluded patients who had pharyngeal, laryngeal, or tracheal pathology including tracheostomy, airway infections, psychiatric disorders or had an indication for rapid sequence induction. We also excluded women who were pregnant or breastfeeding.

Protocol

Qualifying patients consented during a preanesthesia visit at least 1 day before surgery. During this visit, the airway was assessed and documented: mouth opening in centimeters (interincisor gap measured with the mouth fully open; in patients with edentulism, we used the intergingival distance), thyromental distance in centimeters (measured along a straight line from the thyroid notch to the lower border of the mandibular mentum with the head fully extended), Mallampati score I to IV (visibility of oropharyngeal structures in the sitting position without phonation), cervical mobility 0 to 90° (range of motion from full extension to neutral position), decreased mandibular protrusion yes/no (graded as the capacity to bring the lower incisors in front of the upper incisors or inability to perform this maneuver), retrognathia yes/no (location of the mandible behind the frontal plane of the maxilla), abnormal neck anatomy yes/no (any history of C-spine surgery or congenital malformation), and big tonsils yes/no (any medical history).

On the day of surgery, patients were premedicated as clinically appropriate. Standard monitoring included electrocardiography, arterial blood pressure (invasive or noninvasive), and oxygen saturation. Patients were positioned supine, and the head was placed in neutral position, allowing passive cervical mobility. Patients were preoxygenated for at least 3 min, per clinical routine, and anesthesia was induced with fentanyl and propofol or thiopental.

After loss of muscle tone and the eyelash reflex, patients were ventilated with a face mask for at least 2 min. A jaw-thrust maneuver was performed to ensure adequate depth of anesthesia, and an unlubricated supraglottic airway of the appropriate size (3.5 for patients weighing between 50 and 70 kg or 4.5 for patients weighing 70 to 100 kg) was inserted. Intubations were performed by several anesthesiologists, including both attendings and residents. All intubation attempts were supervised by one of five skilled investigators, each of whom was familiar with the supraglottic airway and the blind intubation technique.

The supraglottic airway was connected to the anesthesia machine ventilator. Successful insertion of the supraglottic airway was confirmed by adequate appearance of the capnography waveform and ability to deliver adequate tidal volumes. Leak pressure was determined by setting the fresh gas flow adjusted to 3 l/min and progressively adjusting the expiratory valve to increase circle-system pressure in 5-mmHg steps to a maximum pressure of 30 mmHg.[14,15] The pressure that provoked audible air escape from the oropharynx was considered the leak pressure.[14,15] Thereafter, a nondepolarizing muscle relaxant such as rocuronium or atracurium was given. After 3 min of intermittent ventilation and absence of palpable twitches in response to supramaximal train-of-four 1-Hz stimulation of the ulnar nerve at the wrist, patients were deemed fully paralyzed. The leak pressure test was then repeated.

For the initial blind intubation attempt, a conventional endotracheal tube from any producer was lubricated and introduced *via* the supraglottic airway. Endotracheal tubes up to 7.5 mm inner diameter were used with the size 3.5 supraglottic airway, whereas tubes up to 8.5 mm were used with the size 4.5 supraglottic airway. Endotracheal tubes were inserted gently to a depth of 22 to 24 cm from the lips. If mild resistance

was encountered, minor adjustments, like lifting the mandible and twisting the tube, were allowed but proved impossible to standardize. If severe resistance was encountered, the tube was removed and the intubation attempt considered a failure. The endotracheal tube was then connected to the anesthesia circuit, the cuff inflated, and a single breath given. If correct placement was confirmed *via* auscultation and capnography, waveform ventilation continued *via* the endotracheal tube. If esophageal placement was apparent, the endotracheal tube was removed. If the initial intubation attempt failed, the supraglottic airway was repositioned (by pushing it deeper into the pharynx or pulling it back) and/or cervical mobility was adjusted as deemed necessary by the attending anesthesiologist. Another blind intubation attempt was then attempted.

If both blind intubation attempts failed, we attempted fiberoptic-guided intubation when a scope was available. When correct tracheal placement of the tube was confirmed (after whichever insertion method), the supraglottic airway was removed according to the manufacturer's recommendations with the use of their special stylet. If a fiberoptic scope was unavailable, the trachea was intubated with direct laryngoscopy. Anesthetic management during intubation and thereafter was not specified by protocol and was thus up to each clinician.

Measurements

Success rate, defined as successful blind intubation within a maximum of two attempts, served as our primary outcome. Secondary outcomes included the following:

- Time for supraglottic airway insertion, defined as time between insertion of the supraglottic airway into the mouth and detection of end-tidal carbon dioxide from the supraglottic airway.
- Time for blind intubation, defined as time between insertion of the tube within the supraglottic airway and ending with detection of end-tidal carbon dioxide from the endotracheal tube.
- Airway leak pressure before and after muscle relaxation.
- Postoperative hoarseness, assessed 2 h after extubation and the next morning. Hoarseness was rated as none, noticed by patient only, apparent to an observer, or aphonia.[16]
- Postoperative cough, assessed 2 h after extubation and the next morning. Cough was rated as none, mild (less than a common cold), moderate (similar to a common cold), or severe (more than a common cold).[16]
- Postoperative sore throat, assessed 2 h after extubation and the next morning. Sore throat was rated as none, mild (less than a common cold), moderate (similar to a common cold), or severe (more than a common cold).[16]
- Any obvious complications related to airway management, including bleeding, airway trauma, dental fracture, aspiration, or bronchospasm.

Statistical Analysis

We descriptively compared patients at three hospitals on demographic, baseline, and airway variables using standard descriptive statistics. Summary statistics are presented as percentage of patients, means ± SDs, or medians [Q1, Q3] as appropriate.

Primary Analysis. The success rate of blind intubation through the supraglottic airway was estimated as the proportion of patients in whom an endotracheal tube was inserted successfully into the trachea within two attempts. The corresponding 95% CI was estimated with the exact method. We conducted a binomial test to compare the success rate and the null proportion of 70%. We also assessed with a chi-square test whether the success rate was different across the three participating hospitals. The success rate was reported by hospital with 98.3% exact CI (Bonferroni correction). For informational purposes, we summarized first and second attempt rates, time for insertion of the supraglottic airway mask, and time for blind intubation of the tube.

Secondary Analyses. Potential risk factors for blind intubation failure including age, sex, weight, body mass index, mouth opening, thyromental distance, cervical mobility, decreased mandibular protrusion, retrognathia, abnormal neck anatomy, enlarged tonsils, difficult intubation history, ASA physical status, Mallampati score, supraglottic airway size, and endotracheal tube size were calculated. Potential factors were compared in patients who were and were not successfully intubated with *t* or Wilcoxon tests for continuous variables and chi-square or Fisher exact tests for categorical variables.

All of these factors were considered in a model constructed *via* a backward selection procedure with alpha-to-stay criterion of 0.10. In addition, the ability of the final model to predict the successful intubation was estimated with a multivariable logistic regression and summarized with odds ratios and area under the receiver operating characteristic curve. The final model was subjected to bootstrap resamples for minimizing overfitting bias and for internal validation. The calibration of our final model was assessed graphically by plotting the bootstrapped calibration curve observed proportions against the predicted probabilities arising from the model with smoothing. Best cut-points were sought to jointly maximize sensitivity and specificity. The corresponding sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were estimated with standard normal theory for proportions.

The relationship between tightness during leak test before and after relaxation was measured by Pearson correlation. We also evaluated the extent to which dichotomous leak pressure (20 or greater *vs.* less than 20 mmHg) was affected by muscle relaxation. Overall sensitivity, specificity, PPV, and NPV, as well as accuracy were estimated; 95% CIs for these quantities were estimated with standard normal theory for proportions.

Sample Size

A total number of 1,000 patients was *a priori* defined to be sufficient to provide strong evidence about successful blind intubation within a reasonable time frame. We assumed a proportion of success of 0.7. The margin of error (*i.e.*, the "radius" or one half

Table 1. Summary of Demographics, Baseline Characteristics, and Airway Assessments (N = 1,000)

Factor	Overall (N = 1,000)	KSW (n = 401)	Lodz (n = 100)	USZ (n = 499)
Age, yr	54 [37, 67]	58 [41, 70]	52 [36, 65]	51 [35, 66]
Sex, female	51%	52%	71%	47%
Weight, kg	74 ± 13	74 ± 13	75 ± 13	74 ± 13
Body mass index, kg/m^2	25 [23, 28]	25 [23, 28]	26 [24, 30]	25 [23, 28]
Mouth opening, cm	5 [4, 5]*	5 [5, 5]	5 [5, 6]*	5 [4, 5]
Thyromental distance, cm	6 [6, 7]	6 [6, 7]	7 [6, 8]	6 [6, 7]
Cervical reclination, degree	45 [40, 45]	45 [45, 45]	40 [40, 45]	45 [35, 45]
Decreased mandibular protrusion	2%	3%	0%	2%
Retrognathia	4%	5%	1%	3%
Abnormal neck anatomy	12%	18%	0%	8%
Big tonsils	< 1%	< 1%	0%	< 1%
Difficult intubation history	1%	1%	0%	1%
ASA				
I	39%	32%	47%	44%
II	53%	60%	48%	49%
III	7%	8%	5%	7%
Mallampati score				
I	49%	49%	60%	46%
II	42%	42%	37%	43%
III	9%	10%	3%	10%
IV	< 1%	0%	0%	1%
Supraglottic airway size				
3.5	45%	49%	54%	41%
4.5	55%	51%	46%	59%
Tube size				
6.5	< 1%	0%	0%	< 1%
7.0	50%	54%	60%	46%
7.5	9%	0%	38%	10%
8.0	41%	46%	2%	44%

Summary statistics are presented as % of patients, mean ± SD, or median [Q1, Q3], respectively.

*Number of missing values = 2.

ASA = American Society of Anesthesiologists; KSW = Institute of Anesthesia and Pain Therapy, Kantonsspital Winterthur, Switzerland; Lodz = Department of Anesthesiology and Intensive Therapy, Medical University of Lodz, Poland; USZ = Institute of Anesthesiology, University Hospital Zurich, Switzerland.

the width) of the 95% CI with 1,000 patients was 0.028, which we considered to be sufficient. SAS software, version 9.4 for Windows (SAS Institute, USA) was used for all statistical analyses.

Results

A total of 401 patients were enrolled at KSW, 100 patients at Lodz, and 499 patients at USZ. Demographic characteristics, baseline characteristics, and airway assessments are summarized in table 1.

Among 1,000 enrolled patients, the supraglottic airway was inserted successfully within two attempts in 994 (99%). The six failures were due to persistent air leak in five patients and inability to insert the supraglottic airway within the oral cavity in one patient. The insertion of the supraglottic airway was rated as very easy for 69% of the patients, easy for 18%, somewhat difficult for 11%, very difficult for 1%, and impossible for 0.1%. The median time for insertion was 21 s [Q1, Q3: 16, 28] (min, max: 4, 90) for patients in whom the supraglottic airway was inserted successfully.

Blind intubation through the supraglottic airway laryngeal intubation mask was successful in 781 patients within two attempts, resulting in an overall success rate of 78% (95% CI, 75 to 81%). The successful rate was not different between patients with normal and abnormal airway anatomy (decreased mandibular protrusion, retrognathia, abnormal neck anatomy, and/or big tonsils); the corresponding estimated successful

Table 2. Primary Analysis: Estimated Success Rate of Blind Intubation through the Disposable Supraglottic Airway Self-inflating Laryngeal Intubation Mask

No. Patients	No. Successes	Success Rate (95% CI)*
Overall (N = 1,000)	781	78.1% (75.4–80.6%)
KSW (n = 401)	321	80.1% (74.9–84.6%)
Lodz (n = 100)	41	41.0% (29.4–53.4%)
USZ (n = 499)	419	84.0% (79.7–87.7%)
At first attempt (N = 1,000)	687	68.7% (65.7–71.6%)
At second attempt (N = 313)	94	30.0% (25.0–35.1%)

*Exact CI is reported. 95% CI is reported for all patients; 98.3% CI is reported for each individual hospital (Bonferroni correction, 0.05/3).

KSW = Institute of Anesthesia and Pain Therapy, Kantonsspital Winterthur, Switzerland; Lodz = Department of Anesthesiology and Intensive Therapy, Medical University of Lodz, Poland; USZ = Institute of Anesthesiology, University Hospital Zurich, Switzerland.

rates were 79% (670/848; 95% CI, 76 to 82%) for normal and 73% (111/152; 95% CI, 66 to 80%) for abnormal; $P = 0.10$. However, the success rate was inconsistent among the three centers ($P < 0.001$): 80% (95% CI, 75 to 85%) at KSW, 41% (29 to 53%) at Lodz, and 84% (80 to 88%) at USZ (table 2).

The success rate of blind intubation was 74% (136/184) for patients rated as having very easy supraglottic airway placement, 83% (568/686) for patients with easy placement, 63% (69/109) for patients with somewhat difficult placement, 70% (7/10) for patients with very difficult placement, and 9% (1/11) for patients with impossible placement. The ease of supraglottic airway placement was associated significantly with success of blind intubation; the estimated odds ratio for successful blind intubation was 1.75 (1.48 to 2.08) for each one-category decrease in the ease of supraglottic airway placement (1 to 5: very easy to impossible). Among the 781 patients who were intubated successfully, 687 patients were intubated on the first attempt and 94 on the second. The first attempt success rate was 69% (95% CI, 66 to 72%), and the second attempt success rate was 30% (95% CI, 25 to 35%). With a maximum of two attempts, our overall success rate was 78% (95% CI, 75 to 81%). Insertion of the endotracheal tube was rated very easy for 52% of the patients, easy for 14%, somewhat difficult for 11%, very difficult for 2%, and impossible for 22%. The median time for successful endotracheal intubation was 26 s [Q1, Q3: 20, 33] (min, max: 4, 74).

Patients who were intubated successfully were younger and leaner, had a smaller mouth opening, had more mobility, and were less likely to have abnormal neck anatomy and history of difficulty intubation (table 3, left). Only age, body mass index, mouth opening, and cervical mobility were retained in our multivariable model (table 3, right). However, the predictive ability of the model was moderate to weak with area under the receiver operating characteristic curve of 0.63 (95% CI, 0.59 to 0.67).

Table 3. Secondary Analysis: Estimated Association between Successful Blind Intubation *via* the Supraglottic Airway Mask and Potential Risk Factors (N = 1,000)

	Univariable Analysis			Multivariable Analysis*	
Factor	Successful (N = 781)	Unsuccessful (N = 219)	*P* Value†	Estimated OR (98.75% CI)	*P* Value‡
Age, yr	53 [35, 66]	58 [46, 70]	< 0.001§	0.94 (0.89–1.00)‖	0.01
Sex, female	52%	47%	0.17#		
Weight, kg	74 ± 13	76 ± 13	0.05**		
Body mass index, kg/m^2	25 [22, 28]	26 [24, 29]	< 0.001§	0.94 (0.89–0.98)	0.001
Mouth opening, cm	5 [4, 5]††	5 [5, 6]††	0.03§	0.79 (0.63–0.99)	0.01
Thyromental distance, cm	6 [6, 7]	6 [6, 7]	0.26§		
Cervical reclination, degree	43 ± 8	41 ± 7	< 0.001§	1.11 (0.98–1.28)†	0.04
Decreased mandibular protrusion	2%	4%	0.12		
Retrognathia	4%	2%	0.14#		
Abnormal neck anatomy	10%	17%	0.005#		
Big tonsils	< 1%	0%	0.99		
Difficult intubation history	1%	3%	0.03		
ASA			0.06#		
I	40%	36%			
II	53%	53%			
III	6%	11%			
Mallampati score			0.26		
I	50%	43%			
II	41%	47%			
III	9%	9%			
IV	< 1%	0%			
Supraglottic airway size			0.16		
3.5	46%	41%			
4.5	53%	59%			
Tube size			0.10		
6.5	< 1%	0%			
7.0	51%	47%			
7.5	8%	12%			
8.0	41%	40%			

Summary statistics are presented as % of patients, mean ± SD, or median [Q1, Q3], respectively.

*Age, body mass index, mouth opening, and cervical reclination were retained in our final model *via* a backward model selection procedure. †Fisher exact test, unless specified. ‡The significance criterion was 0.0125 (*i.e.*, 0.05/4, Bonferroni correction). §Wilcoxon rank sum test. ‖Estimated OR of having successful intubation for every five-unit increase in the predictor. #Pearson chi-square test. **Student's *t* test. ††Number of missing values = 1.

ASA = American Society of Anesthesiologists; OR = odds ratio.

The bias-corrected (based on bootstrap resampling) estimate of predictive discrimination was 0.625. The estimate of the maximum calibration error in predicting successful intubation was 0.02 and the corrected Brier score was 0.17, which are satisfactory. The appendix shows a linear calibration function estimate. The ideal calibration curve lies on the 45° line from the origin. The overfitting-corrected calibration is reasonable everywhere. To use this model to predict successful intubation, we need to calculate a linear predictor (LP) value for a patient using the equation LP = 3.87 – 0.012 × age (yr) + 0.02 × cervical mobility (°) – 0.065 × body mass index (kg/m^2) – 0.23 × mouth opening (centimeters). Successful intubation would be predicted for an LP greater than the cutpoint of 1.28, for which sensitivity and specificity were maximized, which corresponded with age of 62 yr, cervical mobility of 45°, body mass index of 25 kg/m^2, and mouth opening of 5 cm. At this cutpoint, the estimated sensitivity was 0.58 (95% CI, 0.55 to 0.62), specificity was 0.63 (95% CI, 0.57 to 0.70), PPV was 0.85 (95% CI, 0.82 to 0.88), NPV was 0.30 (95% CI, 0.26 to 0.34), and accuracy was 0.60 (95% CI, 0.56 to 0.63), respectively.

Leak pressure before relaxation was reasonably well correlated with leak pressure after relaxation (Pearson correlation coefficient 0.81; 95% CI, 0.79 to 0.83; fig. 1). Among 580 patients who had leak pressures less than 20 cm H_2O after relaxation, 498 (84%) had leak pressures less than 20 cm H_2O before relaxation as well (specificity, 0.85; 95% CI, 0.83 to 0.89). Similarly, 84% of patients who had leak pressures 20 cm H_2O or greater after relaxation had pressures 20 cm H_2O or greater before relaxation (sensitivity, 0.84; 95% CI, 0.80 to 0.87). Measures of discrimination, including sensitivity, specificity, PPV, NPV, and accuracy were all high (table 4).

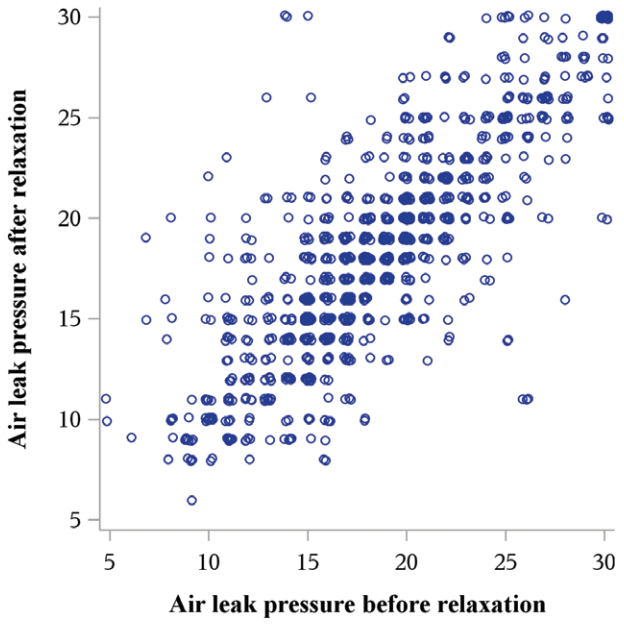

Fig. 1. Scatter plot of air leak pressure (cm H_2O) before and after relaxation (N = 989). Estimated Spearman correlation was 0.81 (95% CI, 0.79 to 0.83).

A total of 11 patients who did not have air pressure measured due to persistent leaks were excluded from this analysis.

Only 3% of patients experienced cough 2 h after extubation, and 4% reported cough on the first postoperative morning. A total of 23% of patients reported a sore throat at 2 h, and 13% continued to report a sore throat on the first postoperative morning. A total of 27% and 12% of patients reported hoarseness at 2 h and on the first postoperative morning, respectively (table 5 and fig. 2).

Discussion

Previous smaller studies reported that ventilation through this supraglottic airway device was adequate in 88 to 100% of patients.[4–6,12,13] However, we found that insertion of the supraglottic airway and subsequent adequate ventilation and oxygenation was successful in 994 of 1,000 patients, representing a convincing success rate of 99%. Insertion of the supraglottic airway required just 21 s, which confirms previous findings reporting insertion times between 15 and 27 s.[6,17] Furthermore, insertion was rated as easy or very easy in 87% of the patients. We thus conclude that this supraglottic airway is generally easy to use, quickly inserted, and nearly always provides an adequate airway in general surgical patients.

First-attempt blind intubation success through the supraglottic airway was 69% in our study, confirming previous findings reporting first-pass blind intubation success rates ranging between 57 and 70%.[6,12,17,18] With a maximum of

Table 4. *Post Hoc* Analysis: Measures of Discrimination for Using Air Leak (Air Leak Pressure < 20 cm H_2O) before Relaxation to Predict Air Leak after Relaxation (N = 989*)

	Air Leak Pressure after Relaxation	
	< 20 (N = 580)	≥ 20 (N = 409)
Air leak pressure before relaxation		
< 20 (N = 564)	498	66
≥ 20 (N = 425)	82	343
Measure of discrimination† (95% CI)		
Sensitivity	0.84 (0.80–0.87)	
Specificity	0.86 (0.83–0.89)	
Positive predictive value	0.81 (0.77–0.84)	
Negative predictive value	0.88 (0.86–0.91)	
Accuracy	0.85 (0.83–0.87)	

Results presented as number for cell counts.

*A total of 11 patients did not have air pressure measured due to persistent leak. †Sensitivity: proportion of patients with air leak pressure ≥ 20 cm H_2O before relaxation out of patients who had air leak pressure ≥ 20 cm H_2O after relaxation, *i.e.*, 343/409. Specificity: proportion of patients with air leak pressure < 20 cm H_2O before relaxation out of patients who had air leak pressure < 20 cm H_2O after relaxation, *i.e.*, 498/580. Positive predictive value: proportion of patients with air leak pressure ≥ 20 cm H_2O after relaxation out of patients who had air leak pressure ≥ 20 cm H_2O before relaxation, *i.e.*, 343/425. Negative predictive value: proportion of patients with air leak pressure < 20 cm H_2O after relaxation out of patients who had air leak pressure < 20 cm H_2O before relaxation, *i.e.*, 498/564. Accuracy: proportion of patients with same air leak pressure category before and after relaxation, *i.e.*, (498 + 343)/989.

two attempts, our overall success rate was 78%, which was well within the wide 24 to 97% range reported previously.[4–6,12,13,17] It seems likely that the wide range reported previously reflects methodologic differences, including the fact that some studies allowed up to three blind intubation attempts or were restricted to specific patient populations. And although hard to quantify, operator skill levels surely contributed to varying success rates. As importantly, previous studies included only 60 to 180 patients which provides limited statistical power. In contrast, the 1,000 patients we enrolled provide tight bounds on our estimate: 78% (95% CI, 75 to 81%).

Several investigators report that fiberoptic-guided intubation through a supraglottic airway was successful in all patients, even after several failed blind intubation attempts.[5,19] In contrast, another study reported that fiberoptic-guided intubation failed in 4 of 19 patients, again after previous failed blind intubations.[6] Fiberoptic-guided intubation was attempted in 21 of our patients after two failed blind intubation attempts. A total of 19 of 21 attempts were successful, resulting in a success rate of about 90%. However, this fraction is derived from a small number of patients and may well vary in different populations or in patients with different characteristics.

Various risk scores for difficulties during ventilation and intubation have been proposed.[1] We identified four independent factors that predicted failed blind intubation: older age, increased body mass index, increased mouth opening, and reduced cervical mobility. Although these findings may help to predict unsuccessful blind intubation, the model needs to be confirmed in an independent population. More

Table 5. Adverse Events at 2 h after Extubation and POD 1 Morning for Patients Who Were Intubated Successfully *via* the Supraglottic Airway at First Attempt, Second Attempt, and Who Were Not Intubated Successfully

Adverse Event	Overall (N = 1,000)	Successful at First Attempt (n = 687)	Successful at Second Attempt (n = 94)	Unsuccessful (n = 219)
Cough				
2 h				
No	973 (97)	676 (98)	91 (97)	206 (94)
Mild	24 (2)	10 (1)	3 (3)	11 (5)
Moderate	2 (< 1)	0 (0)	0 (0)	2 (1)
Severe	1 (< 1)	1 (< 1)	0 (0)	0 (0)
Any (*vs.* no)	27 (3)	11 (2)	3 (3)	13 (6)
POD 1				
No	958 (96)	663 (97)	94 (100)	201 (92)
Mild	39 (4)	22 (3)	0 (0)	17 (8)
Moderate	3 (< 1)	2 (< 1)	0 (0)	1 (< 1)
Severe	0 (0)	0 (0)	0 (0)	0 (0)
Any (*vs.* no)	42 (4)	24 (3)	0 (0)	18 (8)
Sore throat				
2 h				
No	772 (77)	535 (78)	69 (73)	168 (77)
Mild	183 (18)	122 (18)	18 (19)	43 (20)
Moderate	44 (4)	29 (4)	7 (7)	8 (4)
Severe	1 (< 1)	1 (< 1)	0 (0)	0 (0)
Any (*vs.* no)	228 (23)	152 (22)	25 (27)	51 (23)
POD 1				
No	872 (87)	616 (90)	76 (81)	180 (82)
Mild	116 (12)	67 (10)	15 (16)	34 (16)
Moderate	12 (1)	4 (1)	3 (3)	5 (2)
Severe	0 (0)	0 (0)	0 (0)	0 (0)
Any (*vs.* no)	128 (13)	71 (10)	18 (19)	39 (18)
Hoarseness				
2 h				
No	733 (73)	512 (75)	73 (78)	148 (68)
Noticed by patient	137 (14)	84 (12)	13 (14)	40 (18)
Noticed by observer	130 (13)	91 (13)	8 (9)	31 (14)
Any (*vs.* no)	267 (27)	175 (25)	21 (22)	71 (32)
POD 1				
No	878 (88)	606 (88)	80 (85)	192 (88)
Noticed by patient	97 (10)	65 (9)	8 (9)	24 (11)
Noticed by observer	25 (3)	16 (2)	6 (6)	3 (1)
Any (*vs.* no)	123 (12)	81 (12)	14 (15)	27 (12)

POD = postoperative day.

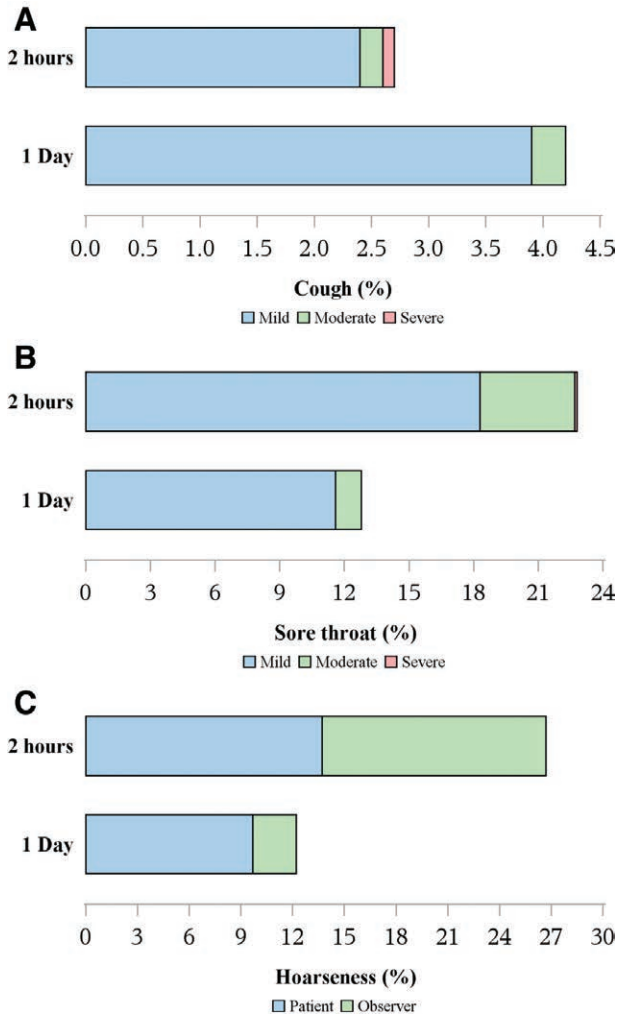

Fig. 2. Incidence of adverse events: (*A*) cough (mild/moderate/severe), (*B*) sore throat (mild/moderate/severe), and (*C*) hoarseness (noticed by patient/noticed by observer) at 2 h after extubation and 1 day after surgery.

importantly, none of the identified factors—or all of them combined—seems likely to be sufficiently predictive to provide clinically useful guidance. In this respect, our results are similar to previous models, which also fail to provide clinically useful guidance. Or, to put this another way, even in patients with the lowest chance of success, there is little reason not to attempt blind intubation since the process is easy and low risk.

Anesthesiologists usually try to keep peak ventilation pressure less than 20 mmHg during positive pressure ventilation with a supraglottic airway to avoid gastric inflation and associated risk of pulmonary aspiration of gastric contents. In contrast, pressures near 20 mmHg may be needed to provide adequate lung inflation. Supraglottic airways should thus have a leak pressure at or exceeding 20 mmHg. Our results show that muscle relaxation generally has little influence on leak pressure. Consequently, patients who have a leak pressure exceeding 20 mmHg while unparalyzed usually maintain a similarly high leak pressure after being paralyzed. We thus conclude that muscle relaxation usually can be used safely in patients who have an adequate unparalyzed leak pressure. Conversely, inducing muscle relaxation will not normally improve leak pressure with this supraglottic airway device.

A concern about blind intubation is that it might cause tissue injury.[20,21] However, we did not observe any serious complications, including any kind of major airway trauma, substantive bleeding, laryngospasm, or obvious aspiration of gastric contents. Furthermore, the incidence and also severity of minor complications like sore throat, coughing, and hoarseness were low. It therefore appears that blind intubation through this supraglottic airway device is reasonably safe.

The overall success rate differed between the three study centers. The overall success rate in USZ was 84%, compared with 80% in KSW and only 41% in Lodz. Overall, we did not control tube size and head positioning in this pragmatic trial. Only after seeing the divergent results in Lodz did we appreciate these two differences, which may or may not provide some explanation (less experience seems a more likely cause.) A consequence of our pragmatic, multicenter design is reduced internal validity—and enhanced generalizability. Because the results for each center are presented separately, the reader can select those most applicable to their practice.

The investigators at USZ and KSW had substantial experience with blind intubation through a laryngeal mask before starting the study, whereas the investigators in Lodz previously were unfamiliar with the technique. Perhaps as a consequence, investigators in Lodz more often used smaller endotracheal tubes, which may reduce the efficacy of the supraglottic airway as a conduit for blind intubation. Minor adjustments like lifting the mandible and twisting the tube were allowed during initial blind intubation attempt but proved impossible to standardize. During the second intubation attempt, investigators also were allowed to minimally reposition the supraglottic airway, maintain minimal cervical mobility of patient's head, or apply cricoid pressure, whatever clinically appropriate. These small interventions were not controlled by the study protocol and not recorded, but the skill with which they were implemented may have affected success rates at the three participating hospitals. Furthermore, the investigators in Lodz placed the patient on a Troop Elevation Pillow (CR Enterprises, LLC, USA), which lifted the head higher than the standard rectangular intubation pad that was used at the USZ and KSW.

We only excluded patients with serious contraindications against use of a supraglottic airway or blind intubation. We thus conclude that this supraglottic airway can be used successfully in 99% of the general surgical population. The success rate might well be lower in patients with difficult airways. In contrast, it seems likely that the success rate we report for blind intubation applies to most patients in whom the supraglottic airway can be inserted.

In summary, 99% of patients could be ventilated and oxygenated with this supraglottic airway device. Blind intubation *via* the supraglottic airway was less successful at 78%, but when possible was easy and quick and did not cause serious complications. Blind intubation through a supraglottic airway cannot be recommended as a first-line intubation technique in the regular clinical setting, but might be helpful in clinical scenarios with difficulties during ventilation and intubation. The use of muscle relaxation agents did not extensively change air leakage pressure and can therefore be used safely when unparalyzed leak pressure is adequate.

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Competing Interests

The authors declare no competing interests.

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Appendix. Linear Calibration Function Estimate