

Title

Rescue of failed direct laryngoscopy. An analysis of the performance of rescue techniques during difficult airway management: Results from the multicentered perioperative outcomes group.

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Abstract

Introduction

The encountered difficult airway is a feared scenario to any laryngoscopist. Direct laryngoscopy remains a standard initial approach to intubation, however it is unknown what to do when direct laryngoscopy fails. Evidence suggests that various technologies may have benefit in this feared scenario, but they have never been comparatively evaluated in the scenario of routine clinical care.

Methods

We aim to conduct a retrospective observational study of the approach to failed direct laryngoscopy. Records from intubation details contained within the Multicenter Perioperative Outcomes Group will be analyzed to determine the primary success rate of five commonly employed strategies for the encountered difficult airway.

Introduction

Direct laryngoscopy is the primary intubation technique performed for routine airway management. In difficult airway scenarios, alternate tools may facilitate safe intubation. When direct laryngoscopy fails, it is unclear which techniques should be used to rescue the airway situation. According to the American Society of Anesthesiologists practice guidelines for difficult airway management; restoring ventilation becomes the priority when initial techniques have failed.¹ If ventilation is adequately restored, the guidelines suggest the use of alternate devices to maintain ventilation or secure the airway with a tracheal tube. However, these suggestions are based on closed claims analyses only. There is no empiric evidence regarding the relative performance of these various techniques in real world clinical experience. As repeated direct laryngoscopy attempts are associated with morbidity and mortality, it is imperative to determine the best tools to rescue a failed direct laryngoscopy scenario.^{2,3}

Several devices have been advocated for clinical use in the situation of failed direct laryngoscopy. The Glidescope video laryngoscope has been analyzed as a rescue device to demonstrate a success rate of 94% (224/239).⁴ When mask ventilation and intubation are both difficult, supraglottic airways restore ventilation in 94% of cases (16/17).⁵ In a large clinical trial the Pentax AWS facilitates successful intubation in 99% (268/270) of cases where direct laryngoscopy failed to achieve an adequate laryngeal view for intubation.⁶ A survey of preferred techniques amongst a large group of anesthesia providers advocates the use of a lighted stylet to rescue failed intubation.⁷ Other devices have been advocated as useful rescue tools in smaller case series.⁸⁻¹¹ As the majority of this evidence comes from isolated institutions and small case series, it is difficult to comparatively analyze these techniques. It is yet undetermined how the encountered difficult airway should be managed based on analysis of a broad-based practice across multiple centers.

We aim to determine the performance of various rescue techniques from a large database representing the diverse practice of airway management in the United States. First, we will describe the real-world use of variant rescue techniques across a national perioperative dataset of multiple centers and hundreds of anesthesiology providers. We hypothesize that video laryngoscopy achieves a higher success rate of tracheal intubation in the failed intubation scenario than alternative techniques including flexible fiberoptic intubation, lighted stylets, optical stylets, and supraglottic airways as a conduit to tracheal intubation.

Methods

The experimental design will be that of a multi-centered retrospective observational study. Institutional Review Board approval has been obtained from each contributing MPOG member to contribute and analyze de-identified data.** A requirement for written informed consent was waived for these purposes. Data have already compiled within this database, and have been de-identified of all protected health information with the exception of procedure date. The analysis will be based on the systematic evaluation of approximately 1.2 million electronic medical records from seven large tertiary care academic institutions.

To determine the success rate of rescued airways using any of the devices identified above, we will identify only those tracheal intubations where these devices were successfully employed following unsuccessful intubation attempt(s) using direct laryngoscopes. The primary automated query will attempt to identify all cases including attempts at direct laryngoscopy and use of alternative intubation techniques or cases with four or more direct laryngoscopy attempts. Airway management utilizing the studied devices will be recorded by reviewing the intubation narrative from the record as well as performing a search for the following words in the electronic record: “video”, “could not intubate”, “could not ventilate”, “lightwand” “fiberoptic” “video” “CMAC” “C-MAC” “stylet” “storz” “glidescope” “glide” “mcgrath” “shikani” “bullard” “bonfils” “aintree” “fiberoptic” “intubating LMA” “airq” “air-q” “gscope” “fast track” “fast trach” “cricothyrotomy” “trach” “lma” and “sga”. Each record will then be manually reviewed by two investigators (MA, DH, others) to assess whether the patient did indeed undergo initial direct laryngoscopy followed by an alternative intubation technique. If for some reason the patient chart, e.g. the intubation narrative, is unclear as to which device was used first, the case will be excluded from further analysis. Failure with a particular device is defined as switching to a different device or technique (surgical airway, wake up, mask or supraglottic airway alone).

To enable description of the patient population, elements of the airway exam and history will be identified from the preoperative history (e.g. history of difficult intubation, radiation to the neck) and the physical examination completed on the day of surgery (Mallampati score, neck range of motion, thyromental distance, mouth opening, jaw protrusion). This will be limited to sites contributing preoperative information.

Patient inclusion criteria

All adult patients (>18 years of age), who had tracheal intubation attempted initially with direct laryngoscopy, and alternated to one of the five mentioned rescue strategies.

Patient exclusion criteria

All patients who were successfully intubated with a direct laryngoscope alone.

Use of DL as the rescue technique with primary use of video laryngoscopy, flexible fiberoptic laryngoscopy, a supraglottic airway as a conduit to intubation, or an optical/lighted stylet

All pediatric patients < 18 years of age

Records that inadequately document the nature of the rescue technique utilized.

Primary outcome

Rescue success rate of failed direct laryngoscopy utilizing video laryngoscopy, flexible fiberoptic laryngoscopy, a supraglottic airway as a conduit to intubation, optical stylet, or lighted stylet. Each patient meeting inclusion criteria will be categorized into exactly one of the identified groups (video laryngoscopy, flexible fiberoptic intubation, lighted stylet, optical stylet, and supraglottic airways). Each patient will be recorded as a success or failure based upon the ability of the initial rescue technique to result in a successful tracheal intubation, regardless of number of attempts used. If the provider switches to a different rescue technique, or reverts back to direct laryngoscopy, the case will be recorded as a failure for the initial rescue technique. If there is adequate statistical power, we can evaluate the success rate of each device type temporally to assess whether national trends demonstrate an increase or decrease in use of value of a given device type.

Secondary outcome

Overall rescue success rate with the above devices in the setting of failed direct laryngoscopy AND difficult or impossible mask ventilation.

Data source

Intubation data will be retrieved using a combination of structured data element retrieval and free text searching. Data will be retrieved from preoperative history and physical examination for sites that provide this data. The intubation narrative and mask ventilation details from the intraoperative record for each included case.

Statistical analysis

Statistical analysis will be performed using SPSS version 19. An intention-to-treat analysis will be used, with the initial rescue technique being used to separate patients into five rescue technique groups: video laryngoscopy, flexible fiberoptic intubation, lighted stylets, optical stylets, and supraglottic airways.

To determine if there is a statistically significant difference among the proportions of successful tracheal intubations and the four identified groups a chi-square will be used. If the

result has a p-value of <0.05 and the video laryngoscopy is shown to have the highest successful intubation rate, then the primary research hypothesis is true. If the p-value is <0.05 but the video laryngoscopy is shown not to have the highest successful intubation rate or if the p-value is >0.05 than the primary research hypothesis is false. To determine if the successful tracheal intubation rate with the above devices in the setting of failed direct laryngoscopy AND difficult or impossible mask ventilation (secondary outcome), the data will be re-categorized based upon the stated outcome and chi-square test will be used. A p-value of <0.05 will be considered statistically significant. Center level effects will be incorporated as fixed effects using a dummy variable for each center.

Descriptive analysis will also be performed between the five identified groups and anthropometric characteristics as well as simple demographic information. All categorical data elements will be assessed using a chi-square analysis to determine if there is a statistically significant difference amongst the five identified groups. All continuous data elements will be assessed for normality. If the data are deemed to be parametric, a one-way between-groups analysis of variance will be performed to determine if there is any difference in means between the five identified groups and the continuous covariate of interest. If the data are deemed to be non-parametric a Kruskal-Wallis Test will be performed. A p-value of <0.05 will be considered statistically significant and indicate there is a difference amongst the five identified groups.

Power analysis

A retrospective power analysis will be performed after an initial data retrieval to assess whether adequate sample size is achieved to confirm a negative result.

Variables to be collected

Preoperative data elements requested

Risk Factor	source	definition
Age (in years) ^o	Caseinfo.age_in_years	
Body Mass Index (kg/m ²) ^o	Preop ID 70253	
Male sex	Caseinfo.sex	
Weight in kg	Preop ID 70264	
Height in inches	Preop ID 70258	
History of difficult intubation	Preop ID 70080	
Unstable cervical spine	Preop ID 70083	Marked as unstable, in c-collar, halo traction, etc
Limited neck extension	Preop ID 70083	
Edentulous	Preop ID 70003	Includes upper and lower dentures
Neck radiation changes	Preop ID 70062	Radiation
Limited thyromental distance	Preop ID 70004	
Limited jaw protrusion	Preop ID 70005	
Severely limited jaw protrusion	Preop ID 70005	
Limited mouth opening	Preop ID 70009	
Mallampati III or IV	Preop ID 70006 or 70007	Standard or extended

Table 2: Intraoperative data elements requested

Element	source
Intubation view note	Intraop ID 50208
Intubation number of attempts	Intraop ID 50118
Failed intubation	Intraop ID 50117
View at laryngoscopy	Intraop ID 50119
Intubation device / blade	Intraop ID 50115, 50207
Mask ventilation grade	Intraop ID 50113
Difficult intubation (yes/no)	Intraop ID 50101
Video laryngoscopy view	Intraop ID 50100
LMA usage	Intraop ID 50142, 50209
Free text search for terms	<p>“video”, “could not intubate”, “could not ventilate” “awoken” “lightwand”, “stylet”, “cmac” “storz” “glidescope” “glide” “mcgrath” “shikani” “bullard” “bonfils” “aintree” “fiberoptic” “intubating LMA” “airq” “air-q” “gscope” “fast track” “fast trach” “cricothyrotomy” “trach” “sga” “lma”</p>

Management of missing data

Some participating centers do not have preoperative examination details available for analysis. We plan to describe the patient characteristics from the subset that do and report the null values for those cases. Inadequate information from the intubation narrative will result in an excluded case and be included in Figure 1 describing the patient sample

Discussion

The data derived from the proposed study will guide algorithms towards the appropriate rescue strategies during difficult airway management. First, it will advance the knowledge of airway management by describing the contemporary use of variant rescue techniques. The data is particularly valuable because it is based a large multicenter perioperative dataset reflecting years of evolving practice of airway management. The results will help to further determine the role of video laryngoscopy in the management of the general anesthesia population, and as a rescue means in case of a failed intubation using a direct laryngoscope.

Known limitations

- There are no consistent policies or procedures across the centers to establish consistent use of the devices. However, this lack of control in the data and processes is helpful because it reflects real world practice
- No data on provider experience with a given device or prevalence / availability of devices at a given institution
- No ability to establish whether rescue device was in the room already when intubation was attempted.
- No postoperative data for outcomes
- No ICU intubations included
- Physiologic data (spo2, etco2) only collected every 60 seconds and are not reliable enough during airway rescue to serve as an outcome measure
- Some centers do not have airway exam info in MPOG

References

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STROBE Statement

Checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	<p>(a) Indicate the study's design with a commonly used term in the title or the abstract</p> <hr/> <p>(b) Provide in the abstract an informative and balanced summary of what was done and what was found</p> <hr/>
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	<p>(a) <i>Cohort study</i>—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</p> <p><i>Case-control study</i>—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</p> <p><i>Cross-sectional study</i>—Give the eligibility criteria, and the sources and methods of selection of participants</p> <hr/> <p>(b) <i>Cohort study</i>—For matched studies, give matching criteria and number of exposed and unexposed</p> <p><i>Case-control study</i>—For matched studies, give matching criteria and the number of controls per case</p> <hr/>
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group

Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	<p>(a) Describe all statistical methods, including those used to control for confounding</p> <p>(b) Describe any methods used to examine subgroups and interactions</p> <p>(c) Explain how missing data were addressed</p> <p>(d) <i>Cohort study</i>—If applicable, explain how loss to follow-up was addressed</p> <p><i>Case-control study</i>—If applicable, explain how matching of cases and controls was addressed</p> <p><i>Cross-sectional study</i>—If applicable, describe analytical methods taking account of sampling strategy</p> <p>(e) Describe any sensitivity analyses</p>

Results

Participants	13*	<p>(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed</p> <p>(b) Give reasons for non-participation at each stage</p> <p>(c) Consider use of a flow diagram</p>
Descriptive data	14*	<p>(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders</p> <p>(b) Indicate number of participants with missing data for each variable of interest</p> <p>(c) <i>Cohort study</i>—Summarise follow-up time (eg, average and total amount)</p>
Outcome data	15*	<p><i>Cohort study</i>—Report numbers of outcome events or summary measures over time</p> <p><i>Case-control study</i>—Report numbers in each exposure category, or summary measures of exposure</p> <p><i>Cross-sectional study</i>—Report numbers of outcome events or summary measures</p>
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and

		their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.