Incidence, Predictors, and Outcome of Difficult Mask Ventilation combined with Difficult Laryngoscopy

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Introduction

Each year, nearly 30 million procedures are performed in the United States with general anesthesia, regional anesthesia, deep sedation, or conscious sedation. Due to early data demonstrating the significant risk of depressed oxygenation or ventilation associated with sedation, The Joint Commission and Centers for Medicare and Medicaid Services (CMS) now require standardized pre-procedural risk assessment processes that evaluate the risk for cardiopulmonary compromise.Ref##

Unfortunately, the current airway risk assessment tools in widespread use are focused on one specific aspect of a difficult airway: difficult intubation. A patient centered definition of the difficult airway would include difficulty in mask ventilation or laryngoscopy since each technique serves as a primary rescue technique for the other.Ref## Recent data have demonstrated that the incidence and risk factors for difficult mask ventilation are distinct from difficult laryngoscopy predictors.Ref## A particularly dangerous clinical situation arises when a patient demonstrates difficult mask ventilation and difficult intubation. This is particularly true when conscious sedation is performed by a non-anesthesiologist. There are limited single center data exploring the incidence, predictors, or outcomes of patients that are difficult to intubate and difficult to mask ventilate.Ref##

Using a prospectively collected multicenter database of more than 1 million patients undergoing procedures requiring a structured airway assessment by a trained airway expert, we sought to identify the incidence, independent predictors, and outcomes of difficult mask ventilation combined with difficult intubation. These data will define a

modern airway exam focused on a holistic definition of the difficult airway. This airway exam may improve the risk assessment and airway management plan for the millions of patients undergoing procedures each year. Most importantly, CMS now requires that management and quality assurance of all anesthesia services, including conscious sedation by non-anesthesiologists, be consistently managed by a single leader. Our data will be the first multicenter data to guide the anesthesia service director's documentation and quality assurance efforts.

Materials and Methods

University of Michigan institutional review board approval (Ann Arbor, MI) was obtained for this observational study. Signed patient consent was waived because no patient care interventions were involved in the conduct of the study and all protected health information was destroyed after data collection was completed.

Patient population

All adult patients (age ≥ 18 years) undergoing a general anesthetic at one of four MPOG institutions (University of Michigan, University of Colorado Denver, Oregon Health and Science University, and University of Tennessee) over an six year period from 2006 to 2012. All cases without an attempt at mask ventilation and direct laryngoscopy were excluded from the data collection and analysis, including planned awake fiberoptic intubations and elective primary use of videolaryngoscopy. Patients with multiple procedures during the study period will have each procedure included as a distinct data point.

Data collection

Data were acquired from the Multicenter Perioperative Outcomes Group (MPOG) database, a consortium of medical centers using observational data to assess and improve perioperative outcomes. The detailed methodology of the MPOG group is discussed elsewhere, but will be summarized briefly. Ref## For each patient, a detailed anesthesia preoperative history and physical is documented by an anesthesia provider using a perioperative clinical information system (Centricity® from General Electric Healthcare,

Waukesha, WI). This history and physical includes discrete data elements regarding patient anthropomorphic details, airway physical exam information, and other general patient clinical information (Table 1, Appendix 1). For each discrete data element, a user may easily select from pre-defined pick lists for each item (Appendix 1), or may choose to enter free-text information if they feel that the pick-list options do not accurately describe the clinical situation.

Each intraoperative record is documented using the perioperative clinical information system as well. At the four participating institutions, clinicians describe the ease or difficulty of mask ventilation in the intraoperative record using a previously described four point scale (Table 2). [7] Grade 3 is defined as mask ventilation that is inadequate to maintain oxygenation, unstable mask ventilation, or mask ventilation requiring two providers. Grade 4 mask ventilation is defined as impossible mask ventilation noted by absence of end tidal carbon dioxide measurement and lack of perceptible chest wall movement during positive pressure ventilation attempts despite airway adjuvants and additional personnel. The use of neuromuscular blockade or the type of blockade (depolarizing or non-depolarizing) does not affect the designation of impossible mask ventilation. Direct laryngoscopy view is documented using a structured pick list of the Cormack-Lehane scale. [11] In addition, all other intraoperative clinical documentation regarding airway adjuvants, number of intubation attempts, and alternative or advanced airway management techniques is entered into the intraoperative record of the perioperative clinical information system. A detailed airway physical exam with discrete data elements for cervical spine mobility, dentition, neck anatomy, thyromental distance, jaw protrusion, mouth opening, and Mallampati oropharyngeal

classification (as modified by Samsoon and Young[8]) is incorporated into the anesthesia history and physical.

Outcomes

The primary outcome was difficult mask ventilation combined with difficult intubation. Difficult mask ventilation is defined as grade 3 or 4 mask ventilation. Difficult intubation was defined as a grade III or IV Cormack-Lehane direct laryngoscopy view[11], or more than 3 attempts intubation attempts recorded. Secondary outcomes included the ultimate airway management technique (ie, direct laryngoscopy, rigid indirect laryngoscopy, flexible fiberoptic intubation, case performed with laryngeal mask airway, patient awakened, emergency surgical airway access, etc), grade view of direct laryngoscopy if performed, and number of laryngoscopy attempts. For each case meeting search criteria of difficult mask ventilation and difficult laryngoscopy, the entire intraoperative record was individually reviewed by two of the study investigators (SK, RF, DH, AFB) in order to independently confirm the ultimate airway management technique and number of laryngoscopy attempts.

Anesthesia services are provided by anesthesiology attending staff with assistance from certified registered nurse anesthetists, anesthesia residents, and fellows-in-training. In general, both mask ventilation and intubation are attempted initially by the anesthesiology resident or certified registered nurse anesthetist present in the room. All clinical decisions regarding airway management are made by the attending staff. The attending could choose to perform an awake fiberoptic intubation, rapid sequence

induction, or videolaryngoscopy at their discretion, thereby eliminating an attempt at mask ventilation or direct laryngoscopy. Mask ventilation is generally performed without a harness using a clear disposable mask (King Systems Corporation, Noblesville, IN). Laryngoscopy was performed using a fiberoptic direct laryngoscopy handle and blade (Heine Inc Dover, NH).

Statistical Analysis

Statistical analysis was performed using SPSS® Version 195 (SPSS Inc, Chicago, Illinois). Patients were classified into the outcome of either having a difficult mask ventilation combined with difficult intubation or not. First, descriptive analyses were performed on all independent covariates (table 1) variables and the outcome. Categorical data were assessed using either the chi-square or Fischer's Exact Test as appropriate. Odds ratios and 95% confidence intervals will be reported. Continuous data elements will be first be analyzed for outliers and each outlier will be addressed by either confirmation that the value was correct or by making the value a missing data element. After each outlier has been properly addressed, the data will be assessed for normality. Parametric data will be analyzed using the student's t-test. Non-parametric data will be analyzed using the Mann-Whitney U test. A p-value of <0.05 will be considered statistically significant.

To determine independent predictors of difficult mask ventilation combined with difficult intubation a binary logistic regression model will be used. Prior to building the model, collinearity diagnostics will be run to determine if any two covariates are highly correlated with one another. If the condition index is >30, it will be determined that high

collinearity exists between variables and a Pearson Correlation matrix will be constructed to determine which covariates are highly correlated. A pair-wise correlation of >0.70 will be considered highly correlated and the covariates will either be collapsed into one concept or one of the variables will be used in the logistic regression model. All remaining variables were entered into a non-parsimonious binary logistic regression full model fit with the occurrence of the primary outcome, difficult mask ventilation combined with difficult intubation, as the dependent dichotomous outcome. The model's fit will be assessed using the Omnibus Test for Model Coefficients and the Hosmer and Lemeshow Test. All variables deemed to be significant in the full model fit ($p < 0.05$) will be established as independent predictors. Effect size will be reported with adjusted odds ratios and 95% confidence intervals will be reported for all independent predictors. The resulting model's predictive value was evaluated using a receiver-operating-characteristic area-under-the-curve, or c-statistic. Each independent predictor was assessed for effect size using adjusted odds ratios.

An unweighted risk scale assigning one point to each risk factor was created using the independent risk factors. In addition, a weighted prediction score based on the β coefficient of the independent predictors was derived from the logistic regression model. The weighted points were calculated by taking the specific β coefficient for each independent predictor divided by the lowest β coefficient of all the independent predictors, multiplied by two, and rounded to the nearest integer. Each patient received a weighted risk score based on the sum of the points for each predictor they possessed. The unweighted and weighted prediction score were compared using the c-statistic. If the confidence intervals of the unweighted and weighted risk scores cross one another,

the unweighted risk score will be used. The risk score will be divided into risk groups based on the distribution of outcomes in each individual risk score. After the groups have been determined, the lowest risk group will be considered the reference group and each additional risk group will be compared against the reference group to determine the increase in odds for having the outcome of difficult mask ventilation combined with difficult intubation based on the risk score characteristics. Odds ratios were derived for the unweighted risk score. The secondary outcomes will be assessed using a chi-square or Fischer's Exact Test as appropriate.

Power analysis

Previous studies have demonstrated a difficult mask ventilation combined with difficult intubation incidence of 0.30%[3]. We are assuming that approximately 80,000 patients will meet study inclusion criteria, resulting in approximately 240 cases demonstrating the primary outcome. A population of 240 events would allow inclusion of 16 – 24 independent variables in a multivariate analysis while minimizing the impact of model over-fitting. [3,14]

Areas for PCRC discussion / limitations

- target journal – JAMA, hoping to provide insight into standard airway exam for all conscious sedation and anesthesia provider
- how to handle video laryngoscopy – include or exclude?

References

1. Practice guidelines for management of the difficult airway: an updated report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Anesthesiology 2003; 98: 1269-77

2. Yentis SM: Predicting trouble in airway management. Anesthesiology 2006; 105: 871-2

3. Kheterpal S, Han R, Tremper KK, Shanks A, Tait AR, O'Reilly M, Ludwig TA: Incidence and predictors of difficult and impossible mask ventilation. Anesthesiology 2006; 105: 885-91

4. Calder I, Yentis SM: Could 'safe practice' be compromising safe practice? Should anaesthetists have to demonstrate that face mask ventilation is possible before giving a neuromuscular blocker? Anaesthesia 2008; 63: 113-5

5. Langeron O, Masso E, Huraux C, Guggiari M, Bianchi A, Coriat P, Riou B: Prediction of difficult mask ventilation. Anesthesiology 2000; 92: 1229-36

6. Yildiz TS, Solak M, Toker K: The incidence and risk factors of difficult mask ventilation. J Anesth 2005; 19: 7-11

7. Han R, Tremper KK, Kheterpal S, O'Reilly M: Grading scale for mask ventilation. Anesthesiology 2004; 101: 267

8. Samsoon GL, Young JR: Difficult tracheal intubation: a retrospective study. Anaesthesia 1987; 42: 487-90

9. Bennett JA, Abrams JT, Van Riper DF, Horrow JC: Difficult or impossible ventilation after sufentanil-induced anesthesia is caused primarily by vocal cord closure. Anesthesiology 1997; 87: 1070-4

10. Gentili ME: Is difficult mask ventilation only correlated to the physical status of the patient? Anesthesiology 2001; 94: 935

11. Cormack RS, Lehane J: Difficult tracheal intubation in obstetrics. Anaesthesia 1984; 39: 1105-11

12. Barash PG, Cullen BF, Stoelting RK: Clinical anesthesia, 5th Edition. Philadelphia, Lippincott Williams & Wilkins, 2006, pp 334-52, 421-52

13. Rassi A, Jr., Rassi A, Little WC, Xavier SS, Rassi SG, Rassi AG, Rassi GG, Hasslocher-Moreno A, Sousa AS, Scanavacca MI: Development and validation of a risk score for predicting death in Chagas' heart disease. N Engl J Med 2006; 355: 799-808

14. Harrell FE, Jr., Lee KL, Matchar DB, Reichert TA: Regression models for prognostic prediction: advantages, problems, and suggested solutions. Cancer Treat Rep 1985; 69: 1071-7

15. Adnet F: Difficult mask ventilation: an underestimated aspect of the problem of the difficult airway? Anesthesiology 2000; 92: 1217-8

16. el-Ganzouri AR, McCarthy RJ, Tuman KJ, Tanck EN, Ivankovich AD: Preoperative airway assessment: predictive value of a multivariate risk index. Anesth Analg 1996; 82: 1197-204

17. Benyamin RM, Wafai Y, Salem MR, Joseph NJ: Two-handed mask ventilation of the difficult airway by a single individual. Anesthesiology 1998; 88: 1134

18. Chou HC, Wu TL: Large hypopharyngeal tongue: a shared anatomic abnormality for difficult mask ventilation, difficult intubation, and obstructive sleep apnea? Anesthesiology 2001; 94: 936-7

19. Conlon NP, Sullivan RP, Herbison PG, Zacharias M, Buggy DJ: The effect of leaving dentures in place on bag-mask ventilation at induction of general anesthesia. Anesth Analg 2007; 105: 370-3

20. Durga VK, Millns JP, Smith JE: Manoeuvres used to clear the airway during fibreoptic intubation. Br J Anaesth 2001; 87: 207-11

21. Garewal DS, Johnson JO: Difficult Mask Ventilation. Anesthesiology 2000; 92: 1199-200

22. Liang Y, Kimball WR, Kacmarek RM, Zapol WM, Jiang Y: Nasal ventilation is more effective than combined oral-nasal ventilation during induction of general anesthesia in adult subjects. Anesthesiology 2008; 108: 998-1003

23. Takenaka I, Aoyama K, Kadoya T: Mandibular protrusion test for prediction of difficult mask ventilation. Anesthesiology 2001; 94: 935

24. Burkle CM, Walsh MT, Pryor SG, Kasperbauer JL: Severe postextubation laryngeal obstruction: the role of prior neck dissection and radiation. Anesth Analg 2006; 102: 322-5

25. Shiga T, Wajima Z, Inoue T, Sakamoto A: Predicting difficult intubation in apparently normal patients: a meta-analysis of bedside screening test performance. Anesthesiology 2005; 103: 429-37

26. Yentis SM: Predicting difficult intubation--worthwhile exercise or pointless ritual? Anaesthesia 2002; 57: 105-9

27. Avorn J: In defense of pharmacoepidemiology--embracing the yin and yang of drug research. N Engl J Med 2007; 357: 2219-21

Table 1: Preoperative data elements requested

Risk Factor	source	definition
Age (in years)°	Caseinfo.age_in_years	
Body Mass Index (kg/m^2)°	Preop ID 70253	
Male sex	Caseinfo.sex	
Sleep apnea	Preop ID 70122	Prescribed CPAP (using or not), stops breathing at night
Snoring	Preop ID 70012	Yes
Presence of beard	Preop ID 70008	Does not include moustache
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
Thick neck	Preop ID 70062	Subjective assessment, not measured
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
Mask ventilation grade	Intraop ID 50113
Difficult intubation (yes/no)	Intraop ID 50101