PCRC Proposal Cover Sheet

Title of Study or Project:	The Frequency of Difficult Tracheal Intubation in Obstetric Patients: A Report from the Multicenter Perioperative Outcomes Group Research Consortium
Primary Institution:	Brigham and Women's Hospital
Principal Investigator:	Sharon Reale MD
Co-Investigators:	Melissa E Bauer DO, Thomas Klumpner MD, Sachin Kheterpal MD, Leif Saager MD, David Healy MD, Nadir El Sharawi MBBS MSc, Jill Mhyre, MD, Brian Bateman MD MSc
Type of Study:	Retrospective Observational
IRB Number/Status:	IRB approval has been obtained for MPOG and informed consent will be waived
Hypothesis:	The frequency of difficult and failed tracheal intubation in parturients undergoing cesarean delivery is higher than that of women undergoing general surgical procedures. Risk factors for difficult tracheal intubation in parturients can be identified.
Number of Patients/Participants:	The MPOG database will be queried for all obstetric patients aged 15-44 who received a general anesthetic for cesarean delivery. Women aged 15-44 undergoing non-obstetric surgeries will also be included as a comparison group.
Power Analysis:	A convenience sample of all obstetric patients in the MPOG database who received a general anesthetic for cesarean delivery will be included.
Proposed statistical test/analysis:	To determine the frequency of difficult tracheal intubation for cesarean delivery, all cases meeting inclusion criteria for difficult tracheal intubation will be pooled across institutions. Point estimates and 95% confidence intervals will be calculated based on cases of cesarean section with general anesthesia and difficult tracheal intubation divided all cases of cesarean section with general anesthesia, during the study period. In order to compare the frequency of difficult tracheal intubation in general anesthesia for cesarean delivery against the frequency of difficult tracheal intubation for non-pregnant women between the ages of 15-44, we will perform a McNemar test (given the matched data) to determine whether these frequencies are significantly different. To determine risk factors for difficult tracheal intubation in pregnant parturients, we will compare those patients who underwent general anesthesia for cesarean delivery and were found to have a difficult tracheal intubation against those who were not found to have a difficult tracheal intubation. Univariate associations between each predictor and the risk of difficult tracheal intubation will be assessed using the chi-square or the Fisher's exact test. If there are >50 patients found to have a difficult tracheal intubation, multivariable modeling will be used to assess independent predictors of difficult tracheal intubation. Backwards stepwise logistic regression will be performed, with a p value of <0.05 for inclusion in the final model. Model fit statistics will be performed including measures of discrimination (c-statistic) and calibration (Hosmer-Lemeshow test). If 3 or more risk factors for difficult tracheal intubation are identified, a weighted risk factor score will be created to attempt to predict the likelihood of difficult tracheal intubation. Receiver operating curves and odds ratios will be created to assess the clinical value of the risk factor score.
Resources (Brief summary of resources for data collection, personnel, financial):	The MPOG database will be queried for the specified Concept IDs. Statisticians will perform statistical analyses to determine the overall frequency of difficult tracheal intubation in cesarean delivery. This will be compared to the frequency of difficult tracheal intubation in an age-matched cohort of women undergoing non-obstetric surgery. Logistic regression will be used to identify independent predictors of difficult tracheal intubation in cesarean delivery patients.

The Frequency of Difficult Tracheal Intubation in Obstetric Patients: A Report from the Multicenter Perioperative Outcomes Group Research Consortium

Sharon Reale MD, Melissa E Bauer DO, Thomas Klumpner MD, Sachin Kheterpal MD, Leif Saager MD, David Healy MD, Nadir El Sharawi MBBS MSc, Jill Mhyre MD, and Brian Bateman MD MSc

Introduction

The incidence of difficult tracheal intubation in the obstetric population has been estimated to range from 0.2-3%, approximately eight times higher than the general population.[1-5] There appears to have been little change in the frequency of difficult tracheal intubation in obstetrics over the last 30 years.[4] However, the studies that have examined the rates of difficult tracheal intubation in obstetrics have come from countries other than the United States or smaller centers. Furthermore, the high frequency of difficult tracheal intubation reported for obstetric patients, coupled with the risk of aspiration with general anesthesia and the potential benefits of neuraxial anesthesia (e.g., lack of fetal exposure to anesthetics, maternal participation in birth), has led to increased rates of neuraxial anesthesia use,[6] which may have impacted on observed rates of difficult tracheal intubation in this population. Video laryngoscope availability and use has also proliferated in recent years, which may also have affected rates of difficult tracheal intubation.[7]

Obstetric anesthesia provides a unique circumstance where difficult airway management is an emergent situation for not one, but two, patients. Given the potential maternal and neonatal morbidity associated with difficult or failed intubation, it is important to predict patients in whom intubation will be difficult. This may be particularly challenging given that Mallampati scores have been reported to change throughout labor.[8] However, higher Mallampati scores have been shown to be a risk factor for failed intubation in obstetrics.[5] Furthermore, studies have variably shown obesity, age, and emergency surgery status to be a risk factor for difficult tracheal intubation in obstetrics.[2,3,5,9-11]

This study aims to provide an updated estimate of the frequency of difficult tracheal intubation in obstetrics in the United States, leveraging the large number of cesarean delivery records contained in the MPOG database. We will determine whether the frequency of difficult tracheal intubation continues to be higher in obstetric patients in contemporary practice. We also aim to elucidate risk factors for difficult tracheal intubation, in order to inform risk stratification based on factors that may be unique to obstetric patients.

Methods

This is a multicenter, retrospective, observational study utilizing the Multicenter Perioperative Outcomes Group (MPOG) database. MPOG is a consortium of institutions founded in 2008 with a shared data set to facilitate the investigation of perioperative outcomes. Institutional Review Board approval has been obtained for each MPOG center and informed consent will be waived.

We will first define the frequency of difficult tracheal intubation for obstetric patients having a cesarean delivery between January 1, 2000 and July 1, 2018 at all MPOG sites. To determine the frequency of difficult tracheal intubation, the MPOG database will first be queried for all female patients between the ages of 15-44 who had general anesthesia for cesarean delivery using applicable procedure codes and a previously described list of search terms for cesarean delivery.[12] The database will then be narrowed to those who experienced a difficult tracheal intubation by identifying any of the following: observed or labeled difficult tracheal intubation, direct or video laryngoscopy view >/= 3, intubation attempts >/= 3, fiberoptic intubation through an existing airway device, emergency surgical airway, cricothyrotomy, or rescue laryngeal mask airway placement. The frequency of difficult intubation will be calculated by dividing the number of cases of difficult tracheal intubation by total number of patients receiving general anesthesia for cesarean delivery.

We will also compare the rate of difficult tracheal intubation to the rate of difficult tracheal intubation for age and gender matched controls undergoing non-obstetric surgery with general anesthesia with an endotracheal tube. These patients will be identified via the MPOG database by the following factors: female sex, age 15-44, general anesthesia with an endotracheal tube, and procedure codes consistent with hysterectomy, salpingectomy, tubal ligation, mastectomy, appendectomy, cholecystectomy, hernia repair, colectomy, discectomy, or laminectomy.

We will then define risk factors for difficult tracheal intubation. Potential risk factors that will be assessed include: age (categorized as <35, 35-39, >40), body mass index (BMI <25, 25-39.9, >40), Mallamapti score (I/II, III, IV), small hyoid to mentum distance (less than three fingerbreadths), subjectively limited jaw protrusion (yes/no), limited mouth opening (less than 3cm), altered neck anatomy (yes/no), cervical spine limitations (yes/no), and history of previous anesthetic problem (yes/no). In order to identify covariates for adjustment, a review of resulting cases will also identify: ASA class, race, institution (deidentified), emergency surgery, presence of preterm delivery, presence of multiple gestation, labor to cesarean status, induction of labor, and presence of pre-eclampsia or eclampsia.

Statistical Analysis

All cases meeting inclusion criteria for difficult tracheal intubation will be pooled across institutions to determine the frequency of difficult tracheal intubation for cesarean delivery. Point

estimates and 95% confidence intervals will be calculated based on the numerator (cases of cesarean delivery with general anesthesia with difficult tracheal intubation), divided by the denominator (all cases of cesarean section with general anesthesia) identified during the study period.

Given the matched data, a McNemar test will be performed to determine if a significant difference exists between the frequency of difficult tracheal intubation in general anesthesia for cesarean deliveries compared to the frequency of general anesthesia for non-pregnant women between the ages of 15-44. If a difference is observed additional analysis will be performed to identify risk factors for difficult tracheal intubation in pregnant parturients. Bivariate associations between each predictor and the outcome of difficult tracheal intubation will be individually assessed using the chi-square or the Fisher's exact test, dependent on the number of events. If there are >50 patients found to have a difficult tracheal intubation, multivariable modeling will be used to assess independent predictors of difficult tracheal intubation. Backwards stepwise logistic regression will be performed, with a p value of <0.05 for inclusion in the final model. Model fit statistics will be performed including measures of discrimination (c-statistic) and calibration (Hosmer-Lemeshow test). The effect sizes will be reported using adjusted odds ratios and 95% confidence intervals for all the risk factors that are identified as independent predictors. The sample will not be split into a training and validation dataset given the expectation of relatively few cases of difficult tracheal intubation. If 3 or more risk factors for difficult tracheal intubation are identified, a weighted risk factor score will be created to attempt to predict the likelihood of difficult tracheal intubation. The beta coefficient for each risk factor from the logistic regression model will be used to determine the score using the method described by Schneeweiss et al.[13] Receiver operating curves and odds ratios will be estimated to assess the clinical value of the risk factor score.

Known Limitations

Limitations to this study will include those inherent to an observational study based on electronic health record data. Cases of difficult tracheal intubation may be missed if there is incomplete or missing data charted. Similarly, risk factors for difficult tracheal intubation may be incompletely identified if documentation is not complete for each case. It also may not be possible to determine provider experience level with each given device or attempt.

Furthermore, in can be difficult to use the number of attempts at intubation as a marker for difficult tracheal intubation at teaching hospitals if junior residents are making the initial attempts at laryngoscopy, and most MPOG sites are teaching hospitals. Institutional factors may also differ in determining whether direct vs. indirect laryngoscopy is attempted initially, potentially altering the ability to compare rescue device success rates. While the MPOG database consists of a large database of multiple institutions, the patient population may skew towards a higher acuity and may not be representative of community practices and rural areas.

Variables to be Collected

Frequency of Obstetric Difficult Tracheal Intubation and Risk Factors

Data Direct Elements

Name	Category	Criteria
Sex	Demographics	Female
Age	Demographics	15-44
Procedures	Procedures	**59510** (Routine obstetric care including antepartum care, cesarean delivery, and postpartum care) or **59618** (Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery) or **01961** (Anesthesia for cesarean delivery only) or **59515** (cesarean delivery only; including postpartum care) or **59514** (cesarean delivery only) or **59620** (Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery) or **59622** (Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care) or **01968** (Anes/anag cs deliv add-on)
Institution	Demographics	Institution
Emergency Status	Cases	Yes or No

Phenotype Browser Elements

Phenotype Name	Category	Criteria
Age (Years)	Demographics	15-44
ASA Class (cleaned)	Preoperative Exam	
Anesthesia Technique: General	Anesthesia Technique	Yes (1)
BMI	Demographics	
Race	Demographics	

Sex	Demographics	Female (1), Unknown (-1)

Concept Browser Elements

ID	Concept Name	Concept Type	Criteria
50101	Intubation- Observed to be difficult	Intraoperative Events, Interventions, and Observations	
90310	Difficult Intubation	Outcome Observations	
50119	Intubation Direct Laryngoscopy View	Intraoperative Events, Interventions, and Observations	>/= 3
50118	Intubation Number of Attempts	Intraoperative Events, Interventions, and Observations	>/= 3
50100	Intubation - Videolaryngoscopy View	Intraoperative Events, Interventions, and Observations	>/= 3
50134	Intubation Fiberoptic Existing Airway Device	Intraoperative Events, Interventions, and Observations	
90316	Emergency Surgical Airway	Outcome Observations	
50604	Airway – Cricothyrotomy	Intraoperative Events, Interventions, and Observations	
50209	Airway - Laryngeal Mask Airway placement note	Intraoperative Events, Interventions, and Observations	
70001	Airway - Mallampati Score -- Unspecified Exam Position	Preoperative Observations	
70004	Airway - Hyoid to Mentum	Preoperative Observations	
70005	Airway - Jaw Protrusion	Preoperative Observations	
70006	Airway - Mallampati Score -- Full Neck Extension	Preoperative Observations	
70007	Airway - Mallampati Score -- Neutral Neck Position	Preoperative Observations	
70009	Airway - Mouth Opening	Preoperative Observations	
70012	Airway- Snoring	Preoperative Observations	

70062	Airway-Neck Anatomy	Preoperative Observations	
70083	Airway- Cervical Spine	Preoperative Observations	
70080	General- Previous Anesthetic Problem	Preoperative Observations	
50596	Obstetrics - Labor continued as c-section	Intraoperative Events, Interventions, and Observations	
50113	Airway - Mask Ventilation Difficulty Scaled	Intraoperative Events, Interventions, and Observations	

Other Elements Upon Manual Chart Review

Variable	**Categories**
Anesthesia Provider Experience	Attending, CRNA, Trainee
Preterm Delivery	Yes or No
Multiple Gestation	Yes or No
Presence of Pre-Eclampsia or Eclampsia	Yes or No
Labor to cesarean status	Yes or No
Induction of Labor	Yes or No

Inclusion Criteria:

- Female AND
- Age 15-44AND
- Anesthesia Technique: General AND
- Either of the following procedures: 59510, 59618, 01961, 59515, 59514, 59620, 59622, OR 01968 or any of the search list terms in the appendix AND
- Either of the following concept browser IDs: 50101, 90310, 50119,* 50118,* 50100,* 50134, 90316, 50604, or 50209

(*Has modifying criteria)

Remaining variables are risk factors

Non-Pregnant Control Frequency of Difficult Tracheal Intubation

Data Direct Elements

Name	Category	Criteria
Sex	Demographics	Female
Age	Demographics	15-44
Procedures	Procedures	**58571** (Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)) or **58150** (Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)) or **58260** (Vaginal hysterectomy, for uterus 250 g or less) or **58552** (Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)) or **58661** (Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy) or **59151** (Laparoscopic treatment of ectopic pregnancy; with salpingectomy and/or oophorectomy) or **59150** (Laparoscopic treatment of ectopic pregnancy; without salpingectomy and/or oophorectomy) or **58700** (Salpingectomy, complete or partial, unilateral or bilateral (separate procedure)) or **00851** (Anesthesia for intraperitoneal procedures in lower abdomen including laparoscopy; tubal ligation/transection) or **19301** (Mastectomy, partial (eg, lumpectomy, tylectomy, quadrantectomy, segmentectomy)) or **19303** (Mastectomy, simple, complete) or **19307** (Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle) or **44970** (Laparoscopy, surgical, appendectomy) or **44950** (Appendectomy) or **44960** (Appendectomy; for ruptured appendix with abscess or generalized peritonitis) or **47562** (Laparoscopy, surgical; cholecystectomy) or **47563** (Laparoscopy, surgical; cholecystectomy with cholangiography) or **47605** (Cholecystectomy; with cholangiography) or **47600** (Cholecystectomy) or **49505** (Repair initial inguinal hernia, age 5 years or older; reducible) or **49650** (Laparoscopy, surgical; repair initial inguinal hernia) or

		49560 (Repair initial incisional or ventral hernia; reducible) or **49585** (Repair umbilical hernia, age 5 years or older; reducible) or **44140** (Colectomy, partial; with anastomosis) or **44204** (Laparoscopy, surgical; colectomy, partial, with anastomosis) or **44160** (Colectomy, partial, with removal of terminal ileum with ileocolostomy) or **44205** (Laparoscopy, surgical; colectomy, partial, with removal of terminal ileum with ileocolostomy) or **63030** (Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar) or **22630** (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar) or **22633** (Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar) or **63047** (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar) or **63048** (Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure))
Institution	Demographics	Institution
Emergency Status	Cases	Yes or No

Phenotype Browser Elements

Phenotype Name	**Category**	**Criteria**
Age (Years)	Demographics	15-44
Anesthesia Technique: General	Anesthesia Technique	Yes (1)

ASA Class (cleaned)	Preoperative Exam	
BMI	Demographics	
Race	Demographics	
Sex	Demographics	Female (1), Unknown (-1)

Concept Browser Elements

ID	Concept Name	Concept Type	Criteria
50101	Intubation- Observed to be difficult	Intraoperative Events, Interventions, and Observations	
90310	Difficult Intubation	Outcome Observations	
50119	Intubation Direct Laryngoscopy View	Intraoperative Events, Interventions, and Observations	>/= 3
50118	Intubation Number of Attempts	Intraoperative Events, Interventions, and Observations	>/= 3
50100	Intubation - Videolaryngoscopy View	Intraoperative Events, Interventions, and Observations	>/= 3
50134	Intubation Fiberoptic Existing Airway Device	Intraoperative Events, Interventions, and Observations	
90316	Emergency Surgical Airway	Outcome Observations	
50604	Airway – Cricothyrotomy	Intraoperative Events, Interventions, and Observations	
50209	Airway - Laryngeal Mask Airway placement note	Intraoperative Events, Interventions, and Observations	
70001	Airway - Mallampati Score -- Unspecified Exam Position	Preoperative Observations	
70004	Airway - Hyoid to Mentum	Preoperative Observations	
70005	Airway - Jaw Protrusion	Preoperative Observations	
70006	Airway - Mallampati Score -- Full Neck Extension	Preoperative Observations	

70007	Airway - Mallampati Score -- Neutral Neck Position	Preoperative Observations	
70009	Airway - Mouth Opening	Preoperative Observations	
70012	Airway- Snoring	Preoperative Observations	
70062	Airway-Neck Anatomy	Preoperative Observations	
70083	Airway- Cervical Spine	Preoperative Observations	
70080	General- Previous Anesthetic Problem	Preoperative Observations	
50113	Airway - Mask Ventilation Difficulty Scaled	Intraoperative Events, Interventions, and Observations	

Other Elements Upon Manual Chart Review

Variable	**Categories**
Anesthesia Provider Experience	Attending, CRNA, Trainee

Inclusion Criteria:

- Female AND
- Age 15-44 AND
- Anesthesia technique: General AND
- Either of the following procedures: 58571, 58150, 58260, 58552, 58661, 59151, 59150, 58700, 00851, 19301, 19303, 19307, 44970, 44950, 44960, 47562, 47563, 47605, 47600, 49505, 49650, 49560, 49585, 44140, 44204, 44160, 44205, 63030, 22630, 22633, 63047, 63048, 42826, 42821
  Either of the following concept browser IDs: 50101, 90310, 50119,* 50118,* 50100,* 50134, 90316, 50604 (*Has modifying criteria)

Remaining variables are risk factors

References

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13. Schneeweiss S, Wang PS, Avorn J, Gynn RJ. Improved comorbidity adjustment for predicting mortality in Medicare populations. Heath Serv Res. 2003;38:1103-1120.

Appendix
Search List Terms

c cection
c cesction
c esction
c sec
c- sec
c- section
c setion
c sxn
c. sec
c. section
c/ s
c/d
caaesarian
caecerean
caesaerian
caesearean
caeserian
caessarean
casearean
caserean
cearean
ceasarean
ceasarian
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cesarena
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cesarian section
cesariean
cesasrean
cesasrian
cesceran
cesearan
ceseaream
cesearen
cesearian
ceseraen
ceseran
ceserean
ceserian
cessarian
cs
c-s
csbti
csbtl
csd
csec
c-sec
c-setion
cssab
cssalpin
cssection
csx
csxn
cxsn
esarea
esarean
esarian
lccs
lcts
lscs
ltcs
ltsc
primary section
rcs
rc-s
repeat cs
repeat section
repeat w/ tubal
repeat with tubal
repet cs
s/cection
secondary cs
secondary section
-section
stat cs
teriary cs
tertiary cs
tertiary csx
tertiary section
urgent cs