Morbidity of second stage cesarean sections before and after provider completion of simulation education at Regions Hospital

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1. Summary

Cesarean deliveries performed during the second stage of labor can be very difficult due to impaction of the fetal head deep in the maternal pelvis and is associated with increased risk of both maternal and perinatal complications. On preliminary review, 16% of cesarean deliveries at Regions Hospital since 1/1/2017 were performed during the second stage, making this a common situation encountered by obstetricians. There is little existing data to inform management of deeply impacted fetal heads, therefore these situations can be difficult for surgeons and other healthcare staff when they arise. Our study aims to determine the morbidity of second stage cesarean deliveries before and after implementation of simulation protocols that address delivery of the impacted fetal head for Ob/gyn surgeons, nursing staff, and surgical technicians at Regions Hospital.

2. Study Aims

The primary aim of this study is to assess change in maternal and perinatal morbidity of second stage cesarean section during the time periods before and after simulation education for Ob/gyn surgeons, nursing staff, and surgical technicians at Regions Hospital compared to change in these same metrics during the same time frame at Methodist hospital, where the simulation education is not occurring. The simulation protocol is a Quality Improvement activity that addresses delivery of the impacted fetal head in second stage cesarean section.

- Research question 1.1: Does implementation of a simulation protocol decrease a composite variable of maternal morbidity defined as a) extension of uterine incision, b) operative blood loss > 1000 mL c) requirement of transfusion, d) wound infection within 6 weeks, and d) endometritis within 6 weeks, at Regions Hospital compared to morbidity over the same time period at Methodist Hospital?
- Research question 1.2: Does implementation of a simulation protocol decrease a composite variable of infant morbidity defined as a) 5 minute APGARs <7, b) NICU admission, c) umbilical cord arterial pH <7.1, and d) fetal injury of cesarean delivery during the second stage of labor at Regions Hospital compared to morbidity over the same time period at Methodist Hospital?

The secondary aims of this study are to 1) assess provider confidence with delivery of the impacted fetal head before and after participating in simulation education and 2) assess change in maternal and perinatal morbidity of additional secondary outcomes, 3) assess the association of duration of second stage and maternal and perinatal outcomes.

- Research question 2.1: Does Regions hospital provider and team confidence regarding delivery of impacted fetal head increase after participating in simulation education?
- Research question 2.2: Does implementation of a simulation protocol that addresses delivery of the impacted fetal head decrease morbidity of other individual secondary outcomes (see variables table) of cesarean delivery during the second stage of labor at Regions Hospital compared to morbidity over the same time period at Methodist Hospital?
- Research question 2.3: Is duration of second stage related to maternal and perinatal complications?

3. Background, Rationale, Significance

Cesarean delivery during the second stage of labor has been shown to result a significant increase in maternal and perinatal complications, most often due to difficult delivery of the impacted fetal head [1,2,3,4]. The number of second stage cesarean deliveries is projected to increase for several reasons, particularly due to the overall decrease in operative vaginal deliveries and proposed lengthening of the permissible duration of the second stage of labor [3]. There have been few prospective studies that have compared the two traditional methods of delivery of an impacted fetal head, elevating the fetal head through the vagina (push method) or reverse breech extraction (pull method). These studies have suggested that the pull method is associated with fewer complications [3, 4, 5, 6]; however, there is no definitive, evidence based algorithm to guide management of these difficult deliveries. Because extraction of the fetal head during second stage deliveries can be an obstetric emergency, it necessitates team and provider education to facilitate anticipation, communication and timely management by all team members. Team simulations for obstetric emergencies have been shown to assist with provider comfort, improved clarity of thinking, and quicker action during emergency situations resulting in improved outcomes. Our study aims to show that simulation education for the entire obstetric team can decrease morbidity of difficult fetal head extraction associated with second stage cesarean deliveries and improve provider and nursing staff confidence regarding anticipation and management of this emergency.

QI Project Description:

The simulation education project is not being conducted primarily for the purpose of research, but is a department-wide educational activity and QI project that will be required for all OB staff physicians, residents, nursing staff, and surgical techs at Regions hospital that work in the Birth Center. There are 120 providers or “birth center cesarean section delivery team members” at Regions hospital. Each staff person is require to attend one of the sessions. There will be 6 simulation education events at Regions hospital with approximately 20 individuals attending each two hour session. A pre and post survey will be given at the simulation event. A 3rd survey 6 months after the simulation event will also be distributed to assess team member confidence regarding second stage cesarean sections.

The timeline of the simulation will be as follows: Pre simulation survey- 10 min, ACOG second stage cesarean section slide presentation- 20 min, practice with mannequins (separate for nursing and physician providers based on skill sets required)- 40 mins, combined second stage cesarean section scenario with whole team with debrief- 40 min, Post simulation survey- 10 min. This simulation will be based on a presentation given at the ACOG meeting in 2016. Simulations will be led by Dr. Kamalini Das, Dr. LeeAnn Hubbard, Dr. Larry Goldenberg, and Dr. Katelyn Bojan from mid October 2017 through mid-December 2017 in the simulation center at Regions hospital.

All birth center team members will be notified regarding the simulation events by email and at staff meetings and will be required to attend 1 simulation event from mid-October-December 2017. Three additional simulation events will be offered during the project period for new Birth Center staff.

4. Approach

a. Study design: This study is an observational, time (pre vs. post simulation) by group (Regions vs. Methodist) design using a retrospective programmatic and manual chart review to evaluate the morbidity of second stage cesarean deliveries before and after implementation of

simulation education at Regions Hospital from July 2014 to June 2019. The same morbidity metrics will be gathered from patients at Methodist Hospital during the same pre and post-time periods to serve as a comparison group. Differential pre-post change in morbidity across patients at the two sites will serve as the key comparison. We will also assess staff confidence and change in self-confidence in the management of impacted fetal head using data from pre and post simulation Quality Improvement project surveys.

b. Population

i. Inclusion/Exclusion criteria:

Patient inclusion: The patient study population includes all patients age 18-45 who underwent cesarean section during the second stage of labor (during the time period July 2014-June 2019 at Regions hospital and Methodist hospital). Second stage is defined as the time between complete cervical dilation and delivery of the infant. Exclusion criteria include patients who underwent cesarean section in second stage for malpresentations (i.e., breech and noncephalic presentations), patients who underwent cesarean section prior to 37 weeks gestation, and patients on the exclusion list for research.

Members of the study team have verified the accuracy of this method of identifying cesarean section during the second stage of labor by cross-checking a Clarity pull of EMR data with chart audit for a random sample of 10 patients.

Medical staff inclusion criteria: all 120 staff members (staff physicians, residents, nurses, surgical technicians) at Regions hospital who practice in the Birth center who underwent required simulation education regarding delivery of deeply impacted fetal heads during second stage cesarean section (50 physicians and 65 nurses and 5 techs) and completed the surveys as part of the QI simulation project.

ii. Sample size

Patients: A data pull conducted by an HP Institute RIIS programmer in September 2017 indicated that there are 80 patients per year at Regions hospital having second stage cesarean sections and 80 patients per year at Methodist hospital having second stage cesarean sections. This study will gather data via programming and chart audit on the following counts of patients in these time period:

A. July 1, 2014 – June 30, 2015 (80 Regions patients)
B. July 1, 2015 – June 30, 2016 (80 Regions patients)
C. July 1, 2016 – December 31, 2017 (120 Regions, 120 Methodist) - 18 mo PRE period
D. January 1, 2018 – June 30, 2019 (120 Regions, 120 Methodist) - 18 mo POST period

Different subsets of patients will be used for different research questions. For research questions 1.1, 1.2, 2.2 Group C above will serve as the pre-period patients and Group D for post-period patients. Thus, the total patient sample size for these research question is expected to be n=480. For research question 2.3, in addition to Groups C and D, we will also include utilize the 160 patients from Regions in Groups A and B for a sample size of 400 at Regions and 240 at Methodist (n=640 total).

Medical staff sample size: The simulation center staff will survey 120 staff (50 physicians, 65 nurses, and 5 techs) immediately before and after the required simulation education as part of an existing QI project. This QI project data will be used to address

research question 2.1. The simulation center and medical staff will also contact staff for a survey 6 months following the simulation for the QI project. With an expected response rate to the first and second surveys of 100% (because staff are surveyed at the simulation event), we will have n=120 complete first and second surveys. The response rate for the 6 month survey is expected to be 80%, yielding 96 surveys for this time period.

c. Data collection process

i. Data sources: Data sources for this study are: 1. Data pull from HP electronic medical record; 2. chart review; and 3. medical staff surveys from the simulation QI project.

Patient sample: A Clarity pull of EMR data by the Institute RIIS programmer will gather many of the needed data elements. For data elements not readily available with a programmatic data pull, two University of Minnesota medical students along with Dr. Katelyn Bojan will conduct manual chart reviews of 640 patients to obtain the needed data elements (see outcomes table below).

Staff sample: Staff-provided information from the simulation QI project. Pre and post electronic surveys of medical staff at the time of the simulation event as well as email surveys 6 months after the simulation event. Surveys will be administered using REDCap. These data collection activities are being done for a QI project, but this QI project data will be used to address research question 2.1

ii. Process steps for identification of patients or records:
Patient data: The study programmer (HP Institute RIIS programmer) will use the inclusion criteria specified earlier and used for the preliminary data counts to gather patient data on the expected 640 patients who are expected to be study-eligible at Regions and Methodist Hospitals in the pre and post-simulation periods. The data pull for patient identification will occur at multiple times to accommodate data needs for specific research questions. A chart review (described below) will be conducted to gather additional morbidity data.

iii. Process steps for data acquisition
Patient data: The Institute programmer will work with clinical study staff to operationally define all study data elements and will use a programmatic data pull to obtain all data elements from Clarity that can be obtained using this method. A Redcap database will be constructed by the study programmer containing the expected 640 patients, and will be used by chart auditors to manually chart audit data elements that cannot be obtained programmatically.

Staff data: The study team will receive a data file of staff survey responses collected as part of the QI project. Surveys will be administered using REDCap or on paper at the time of the simulation. Simulation center staff will send survey data to the Institute study team via secure file transfer.

d) Outcomes/endpoint and other variable definitions, and instruments used:
A data source of “EMR” means that the data elements can be gathered by an Institute programmer using a programmatic data pull of Clarity (EMR) data. “Chart” means that the data

element will be manually abstracted from the EMR. The detailed listing of variables below will serve as the start of a data dictionary. The study programmer will add detailed codes to this document as the project progresses to document codes used to define each data element. The chart audit tool will be built in Redcap and does not yet exist. However, the listing of variables below with a data source of “chart” indicates which variables will be collected through the chart audit.

Variable name	**Data Source**	**Purpose**	**Measurement scale**
Patient data			
Hospital at which second stage cesarean section occurred (Regions, Methodist)	EMR	Key grouping variable	Binary
Time period of cesarean section (pre or post Regions simulation)	EMR	Key grouping variable	Binary
Fetal station at time of delivery	Chart	Covariate	Continuous
Push vs pull method	Chart	Description	Binary
Use of instrumentation (vacuum or forceps)	EMR	Covariate	Binary
Person doing the head extraction (staff or resident)	EMR	Covariate	Binary
Maternal BMI	EMR	Description	Continuous
Fetal weight	EMR	Description	Continuous
Cesarean indication (maternal or fetal)	EMR	Description	Binary
Gestational age at the time of c/s	EMR	Description	Continuous
Parity	Chart	Description	Continuous
Length of second stage	EMR	Covariate	Continuous
Use of tocolytics at the time of c/s	Chart	Relationship to morbidity outcomes	Binary
Operative time	Chart	Secondary Study endpoint	Continuous

Length of stay	EMR	Secondary Study endpoint	Continuous
Time from skin incision to delivery or uterine incision to delivery	Chart	Secondary Study endpoint	Continuous
Head pushed up from below prior to c/s	Chart	Relationship to morbidity outcomes	Binary
Previous c/s	Chart	Description	Binary
Extension of uterine incision	Chart	Component of Primary maternal study endpoint	Binary
Operative blood loss (codes as < 1000 mL vs. > 1000 mL for primary endpoint)	Chart	Component of Primary maternal study endpoint	Continuous, binary
Number of blood transfusions (coded as 0 vs. any for primary endpoint)	Chart	Component of Primary maternal study endpoint	Continuous, binary
Endometritis within 6 weeks postpartum	EMR	Component of Primary maternal study endpoint	Binary
Wound infection within 6 weeks postpartum	EMR	Component of Primary maternal study endpoint	Binary
UTI during maternal admission	EMR	Secondary study endpoint	Binary
Bladder/ureteral/urethral injury	Chart	Secondary study endpoint	Binary
Type of uterine incision made	Chart	Description	Continuous
Maternal discharge Hemoglobin	EMR	Secondary study endpoint	Continuous
APGAR score at 5 minutes (coded as <7 vs. >=7 for primary endpoint)	EMR	Component of Primary infant study endpoint	Continuous, binary
APGAR score at 1 minute	EMR	Secondary study endpoint	Continuous

NICU admission	EMR	Component of Primary infant study endpoint	Binary
Umbilical artery pH <7.1	Chart	Component of Primary infant study endpoint	Binary
Fetal injury (fractures, head injury, brachial plexus injury)	EMR	Component of Primary infant study endpoint	Binary
Fetal death	EMR	Secondary study endpoint	Binary
Fetal hyperbilirubinemia	EMR	Secondary study endpoint	Binary
Uterine incision to delivery time (also categorized as <1 minute >=1 minute)	Chart	Secondary study endpoint	Continuous
Maternal discharge hemoglobin	Chart	Secondary study endpoint	Continuous
Medical staff confidence in handling second stage cesarean sections	QI Project Staff Survey	Secondary study endpoint	Continuous
Medical staff perceptions of second stage cesarean sections	QI Project Staff Survey	Secondary study endpoint	Continuous
Medical staff knowledge of interventions & medications for second stage cesarean sections	QI Project Staff Survey	Secondary study endpoint	Continuous
Medical staff teamwork when handling second stage cesarean sections	QI Project Staff Survey	Secondary study endpoint	Continuous

Staff survey: The pre and post staff surveys are used for the QI project to assess staff perceptions of the required simulation training, and are included as the end of the narrative as appendices. These surveys use items developed for this project rather than existing tools. Surveys include a label to identify whether they are gathered before or after the simulation, and contain items such as confidence in handling second stage cesarean sections.

f) Statistical analysis plan

Descriptives (mean, standard deviation, proportion) and frequency distributions of all variables will computed and examined for distribution shape, outliers, missing data, and implausible data. Tables of descriptive statistics summarizing patients in both care systems (Regions, Methodist)

will be created. Because there are only 2 primary outcomes (both of which are composite variables), there will be no control for multiple testing. Inferential analysis of secondary endpoints will be considered exploratory with the known limitation that multiple testing could yield type 1 errors. Covariates in regression analysis will be specified a-priori on the basis of theory and when such covariates are unbalanced in comparison groups.

Research question 1.1: Does the simulation protocol decrease a composite variable of maternal morbidity defined as a) extension of uterine incision, b) operative blood loss > 1000 mL, c) requirement of transfusion, d) wound infection within 6 weeks, and d) endometritis within 6 weeks, at Regions Hospital compared to morbidity over the same time period at Methodist Hospital?

Analytic sample: 480 maternal patients (120 Regions before/120 after simulation; 120 Methodist before/120 after simulation). Each sample of 120 is viewed as an independent sample.

Analytic approach: Logistic regression will be used to predict the composite maternal morbidity endpoint (0/1) from hospital (Regions, Methodist), time (pre or post simulation), and their interaction. Covariates will be included if needed as described earlier. Model-based proportions, standard errors, and 95% CIs for each hospital for each time point, change over time, and differential change over time by hospital will be computed. A significant hospital * time interaction and pattern of effects showing more improvement over time in Regions than Methodist will support the underlying hypothesis of differential improvement over time favoring Regions and potentially due to the effects of the simulation.

Research question 1.2: Does the simulation protocol decrease a composite variable of infant morbidity defined as a) 5 minute APGARs <7, b) NICU admission, c) umbilical cord arterial pH <7.1, and d) fetal injury, at Regions Hospital compared to morbidity over the same time period at Methodist Hospital?

Analytic sample: 480 infant patients (120 Regions before/120 after simulation; 120 Methodist before/120 after simulation). Each sample of 120 is viewed as an independent sample.

Analytic approach: Same as 1.1, but uses the endpoint of composite infant morbidity

Research question 2.1: Does Regions hospital provider and team confidence regarding delivery of impacted fetal head increase after participating in simulation education?

Analytic sample: The 120 staff completing the pre and post simulation surveys, and sample of 80 completing the pre and 6 month surveys. This data is obtained from surveys from the QI project utilizing the required simulation training events.

Analytic approach: Descriptive statistics (mean, proportion) and 95% CIs will be used to summarize staff survey items at each time point, and change from pre-simulation to immediately post-simulation, and pre-simulation to 6 month post-simulation. Plots over time of key survey items will illustrate staff reactions and perceptions over time. Simple paired-data analyses (e.g., paired t-tests, McNemar's test) may be used to test change over time in key items or composites specified a-priori. Where possible, composites of multiple items will be summarized rather than individual items to reduce the number of comparisons and tests made.

Research question 2.2: Does implementation of the simulation protocol decrease morbidity of other individual secondary outcomes (see variables table) during the second stage of labor at Regions Hospital compared to morbidity over the same time period at Methodist Hospital?

Analytic sample: 480 infant/maternal patients (120 Regions before/120 after simulation; 120 Methodist before/120 after simulation). Each sample of 120 is viewed as an independent sample.

Analytic approach: Same as 1.1, but dependent variables for these analyses will include the individual component items of the primary endpoints, and variables listed as "secondary endpoints" in the variable table. Due to the large number of tests conducted, these analyses will be viewed as more exploratory.

Research question 2.4: Is duration of second stage related to maternal and perinatal complications?

Analytic sample: 640 infant/maternal patients at Regions and Methodist seen June 2015-June 2019.

Analytic approach: Within each hospital (Regions, Methodist), duration of second stage will be stratified (<1 hour, 1-2 hrs, 2-3 hrs, 3-4 hrs, >4 hours). Individual maternal and infant endpoints in the variable table above will be summarized in terms of mean and proportion and 95% CIs within the strata. This analysis is considered descriptive and exploratory.

g) Power analysis: Based on recent literature (Laughton, 2014; Vousden 2014, Kawakita 2017), the estimate of the composite maternal endpoint for research question 1.1 ranges from 20% (if all elements of the composite are completely overlapping) to 40% (if all elements of the composite are independent and additive). Making the simplifying assumptions that Regions and Methodist have the same morbidity in the pre-period, and that Methodist morbidity will not change from the pre to post-period, this study is powered at 80% (alphas=.05, 2-sided) to detect a difference in the Methodist and Regions maternal morbidity composite of 20% (Methodist) vs. 8% (Regions); 30% vs. 15%, or 40% vs. 23%, using a logistic regression model. Similar assumptions could be applied to the infant composite endpoints. For the staff survey, the study is powered to detect a change in a continuous survey item (e.g., staff confidence in handling the procedure) from one time point to a later time point of 0.26 standard deviation units for the sample of n=120 (pre to post simulation) and 0.32 standard deviation units for the sample of n=96 (pre to 6 months, or post to 6 months).

h) Strengths and limitations

Strengths: Large N, broad availability of data elements, comparison group (Methodist Hospital) for more carefully assessing the effect of the QI project simulation training, enthusiastic buy-in by OB/GYN area in Regions, required QI project simulation training so all staff are exposed to simulation.

Limitations: Lack of randomization, elements in chart might not be complete, two hospital systems might not be completely comparable, unknown baseline level of primary endpoints.

5. Setting/Environment/Organizational feasibility

The Regions Hospital birth center team delivers about 2400 babies a year. The staff and providers involved in cesarean sections are a relatively stable population. We do not have

providers from other groups performing cesarean sections. Residents are consistent over a period of 4 years. The Regions Hospital birth center has protocols for cesarean sections that are standard for all patients undergoing this procedure. The study outcomes should be easily compared without variations in cesarean section protocol. At Regions Hospital, team simulation events are organized with the simulation center staff throughout the year for other obstetrical emergencies such as shoulder dystocia, postpartum hemorrhage and hypertensive emergencies. We have the support of the birth center administration for this study

6. Risks and Benefits

There should not be risks to mothers, babies, and providers with this study. There is minimal risk to conducting this study; it is a retrospective, data-only study.
Benefits may include:
Knowledge of whether simulation training improved maternal and perinatal outcomes in patients with deeply impacted fetal head at cesarean section, staff and provider teamwork, and staff and provider morale.

7. Data Confidentiality and Privacy

Data will be stored on secure servers with limited access. Servers are in a physically secure location on campus and backed up nightly. Data will also be protected by username and password requirements.

Data will be kept separately from patient identifiers. Identifiers will be destroyed at the earliest opportunity and data shared with the statistician will be completely de-identified.

Patient identifiers will not be printed at any time during the study.

8. Timeline

Mid October-mid December 2017: QI project. Hold 6 simulation events for the impacted heat at cesarean section scenario. Each scenario will be 2 hours in length and mandatory for all Regions Hospital birth center providers, residents, nursing staff and techs. Will administer pre and posttest questionnaire before and after simulation event.
December 2017- June 30th 2019: Study data extraction via Epic and chart review, from charts of patients undergoing second stage cesarean sections from pre and post simulation time periods.
June 2018: QI project. Administer staff questionnaire 6 months after simulation event.
June 2019: Data and statistical analysis and presentations and manuscript write up.

9. Dissemination/Sharing Results/Integration and Impact

Submit manuscript to peer reviewed journal
Research poster at the GME event in May 2018 and 2019
Resident research presentation May 2019
Submission for presentation at ACOG in May of 2018 and 2019
Birth center presentation at Regions Hospital
Sharing results, simulation with Park Nicollet, Mercy Abbott and Stillwater Birth centers

10. References

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