

The effect of obesity in pregnant women undergoing cesarean delivery

Submission date 02/07/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/10/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 24/10/2018	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Obesity is a public health problem in the United States, with the state of Georgia leading the statistics as one of the regions with more cases of this complex problem. It is common knowledge that obesity in general, and morbid obesity in particular, lead to unwanted health consequences. On the other hand, pregnancy is a stressful period for the mother from the physiological standpoint. The combination of pregnancy and morbid obesity is a special situation in which both the mother and the fetus face challenges that may put their lives at risk. The risk is even higher when delivery involves a surgical procedure (cesarean section). Our study aimed to unravel the association between morbid obesity in mothers who underwent cesarean delivery at our institution. We explored the effects of obesity on complications related to surgery and anesthesia.

Who can participate?

Adult pregnant patients over the age of 18 with more than 37 weeks of gestation, with different body mass index values.

What does the study involve?

We conducted chart reviews to explore different aspects related to patient characteristics such as weight and gestational age and outcomes such as obstetric and anesthetic complications. The analysis looked back at the charts of patients who had already delivered at the moment of the study.

What are the possible benefits and risks of participating?

The benefits derived from our study will add to the existing knowledge about the association between obesity and obstetric complications. There are no known risks to participants taking part in this study, as we only reviewed medical records and patient personal information was protected following standards established by our institutional ethics committee.

Where is the study run from?

Department of Anesthesiology and Perioperative Medicine of Augusta University (USA)

When is the study starting and how long is it expected to run for?

January 2015 to March 2018

Who is funding the study?

Department of Anesthesiology and Perioperative Medicine of Augusta University (USA)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

1053583

Study information

Scientific Title

Anesthetic and obstetric outcomes in morbidly obese pregnant patients undergoing cesarean delivery: retrospective analysis of a single-center experience

Study objectives

Obstetric, anesthetic and neonatal complications in morbidly obese pregnant patients undergoing cesarean delivery are associated with the degree of obesity measured by BMI.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board at Augusta University, 05/04/2017, IRB approval #1053583

Study design

Observational retrospective cross-sectional chart review

Primary study design

Observational

Study type(s)

Other

Health condition(s) or problem(s) studied

Cesarean section in morbidly obese pregnant patients

Interventions

Medical records from patients having cesarean section at Augusta University Medical Center during 2015 were retrieved from PowerChart information system and examined for inclusion criteria and study variables. After approval by the Institutional Review Board, we retrospectively studied obstetric patients who underwent cesarean section at Augusta University Medical Center between January 2011 and January 2016. Prenatal and outcome variables will be obtained from the health documentation system of Augusta University. For analysis purposes the patients will be divided into three groups based on body mass index:

1. Non-obese patients: BMI <30 kg/m²
2. Obese patients: BMI 30-39.9 kg/m²
3. Morbidly obese: BMI > 40 kg/m²

Variables that were collected include:

1. Demographic variables (maternal age, ASA status)
2. Morphometric measurements (BMI)
3. Maternal comorbidities
4. Prior cesarean sections
5. Information of pregnancy (gestational age, parity, prior cesarean deliveries, indication for cesarean section, obstetric comorbidities, emergent procedure)

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Bleeding requiring transfusion, measured by quantification of collected blood and common surgical gauze, assessed during the operation
2. Wound infection, measured by visual inspection between surgery and discharge from the hospital
3. Maternal disposition, assessed using medical record notes at the end of surgery
4. Length of stay in hospital, assessed using medical record notes at the point of discharge from the hospital
5. Maternal mortality, assessed using medical record notes at the end of medical record closing

Key secondary outcome(s)

The following are assessed using medical record notes at the end of surgery@

1. Apgar scores
2. Birth weight
3. Anesthetic technique
4. Failed neuraxial block
5. Rate of conversion to general anesthesia

- 6. Phenylephrine dose
- 7. Anesthetic complications

Completion date

10/03/2018

Eligibility

Key inclusion criteria

- 1. Pregnant patients who underwent cesarean section at Augusta University Medical Center
- 2. Aged 18 years or over

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

- 1. Gestational age <37 weeks
- 2. Patients with chronic pain conditions

Date of first enrolment

01/02/2018

Date of final enrolment

28/02/2018

Locations

Countries of recruitment

United States of America

Study participating centre**Augusta University**

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Sponsor information

Organisation

Augusta university

ROR

<https://ror.org/012mef835>

Funder(s)

Funder type

Other

Funder Name

Self funded

Results and Publications

Individual participant data (IPD) sharing plan

The Principal Investigator (Efrain Riveros-Perez, eriverosperez@augusta.edu) was responsible for the conduct of this study, including overseeing participant confidentiality, executing the Data and Safety Monitoring (DSM) plan, and complying with all reporting requirements to local and federal authorities. Since this is a database study uses already existing electronic health record data and does not involve direct patient care, we believe that a DSM Board is not needed. The only patient rights issue is maintaining confidentiality of the data. The data was abstracted from each patient's electronic health record using their name and medical record number (MRN). The patient name and MRN was replaced by a patient study number for use in the analysis file. A separate file was used to maintain linking patient name and MRN with the patient study number. The analysis file might contain limited PHI information, such as dates of hospitalization.

IPD sharing plan summary

Available on request