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The effect of obesity in pregnant women undergoing cesarean delivery

Submission date
02/07/2018

Recruitment status
No longer recruiting

Registration date
17/10/2018

Overall study status
Completed

Last Edited
24/10/2018

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Efrain Riveros Perez MD
eriverosperez@augusta.edu

Contact information

Type(s)
Scientific

Contact name
Dr EFRAIN Riveros Perez

ORCID ID
http://orcid.org/0000-0002-3874-5783

Contact details
1120 15th Street BI-2144
Augusta
United States of America
30912
3304074681
efrainriveros@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

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 measure

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

Secondary outcome measures
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

Overall study start date
01/01/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
771

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
1120 15th Street BI-2144
Augusta
United States of America
30912

Sponsor information

Organisation
Augusta university

Sponsor details
1120 15th Street BI-2144
Augusta
United States of America
30912
7067217361
eriverosperez@augusta.edu

Sponsor type
University/education

Website
www.augusta.edu

ROR
https://ror.org/012mef835

Funder(s)

Funder type

Other

Funder Name
Self funded

Results and Publications

Publication and dissemination plan
We intend to publish our results in the journal Annals of Medicine and Surgery

Intention to publish date
01/08/2018

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