**Study Title:** Obstetric Trauma: A Review of the Incidence, Risk Factors, and Maternal-fetal Outcomes

1. **Study aim, background, and design**

Trauma occurs in approximately 6-8.3% of pregnancies and is associated with high rates of maternal and fetal morbidity.1–3 In fact, trauma in pregnancy is the leading cause of non-obstetrical maternal death and accounts for 20-46% of maternal deaths during pregnancy.4,5 Pregnant women are at an increased risk of mortality and violent trauma compared to non-pregnant patients.6 Blunt trauma, including motor vehicle accidents and falls, are the most common traumatic injuries occurring during pregnancy and account for 54.7% and 13.1% of traumas, respectively.1,7 Violent injury including gunshots, stab wounds, sexual assault, and strangulation account for up 10% of cases.1,7 Trauma in pregnancy is also associated with high rates of fetal complications, including spontaneous abortion, preterm prelabor rupture of membranes, preterm birth, uterine rupture, cesarean delivery, placental abruption, and stillbirth.8,9 Following admission for any trauma, vaginal or cesarean delivery is required in approximately 5.1% of patients.1 Given the relatively low incidence of trauma during pregnancy and the even lower likelihood of a pregnant trauma patient requiring delivery, data regarding maternal and fetal outcomes following traumatic injury is limited.

Few studies have investigated maternal and fetal outcomes of pregnant trauma patients in New Orleans, LA. New Orleans has a uniquely undeserved population and many pregnant women have risk factors for trauma in pregnancy. Independent risk factors include younger age, African American or Hispanic ethnicity, Medicaid or non-insured status, lower socioeconomic status, drug or alcohol use, and minimal or no prenatal care.1

This is a retrospective observational cohort study and data review of the University Medical Center (UMC) trauma registry. We will perform a retrospective review to examine pregnant females who sustained a blunt or penetrating trauma injury during their pregnancy and sought evaluation at University Medical Center (UMC) between 2008 and 2021. This study aims to determine the incidence, risk factors, and maternal and fetal outcomes following trauma in pregnancy at a urban Level 1 Trauma center. We hypothesize that pregnant trauma patients and associated maternofetal outcomes will have identifiable risk factors that should be targeted during future educational or interventional programs.

1. **Subject Population**

We will perform a retrospective review to examine pregnant females who sustained a blunt or penetrating trauma injury during their pregnancy and sought evaluation at University Medical Center (UMC) between 2008 and 2021. Pregnant females will be compared to their non-pregnant female counterparts of reproductive age (12-51 years). Any data collection obtained on fetal outcomes will be obtained only through the maternal electronic health record. There will be no direct data collection using the fetus/neonate’s electronic health record. We estimate we will review 1000 patient charts.

1. **Procedure**

This is a retrospective observational cohort study and data review of the University Medical Center (UMC) trauma registry. It will include review of pre-existing data at UMC and will be obtained from electronic medical records at UMC (items 1-41). Dr. McGrew has access to patient data at UMC. We will obtain data on pregnant females that experienced a traumatic injury during their pregnancy and required evaluation as a formal trauma activation at UMC. Pregnant females will be compared to their non-pregnant female counterparts of reproductive age (12-51 years). There will be no direct data collect using the fetus/neonate’s electronic health record.

The patients' medical record numbers will be recorded and retained in order to have a way to access the medical chart to extract any additional data that will be necessary to obtain in order to complete the study. However, to protect the patient’s privacy, they will be de-identified during this process by assigning each subject a code number. We will keep the list of code numbers assigned to each subject separate from the database. Both this list and the database containing our collected data and subjects’ code numbers will be kept as an electronic file in a password-protected folder on the PI’s office computer; only the PI and other members of the research team with have access to the database, and only the PI will have access to the list of code numbers associated with each subject. The database with all identifiers removed will be archived on the PI’s office computer again as a password-protected file for a period of 3 years. The data will not be disclosed to anyone else other than the members of the study team will have access to the data.

Data collected for each patient will include:

1. Age
2. Gender
3. Race
4. Ethnicity
5. Pregnancy history (gravida, para, abortion)
6. Gestational age
7. Comorbid conditions
8. Insurance type
9. Marital status
10. Mechanism of injury
11. Prehospital CPR
12. GCS
13. ISS
14. AIS Head
15. AIS Thorax
16. AIS Abdomen
17. AIS Lower Extremity
18. AIS Spine
19. TBI
20. SCI
21. Urine drug screen
22. Serum ethanol
23. EMS HR
24. EMS SBP
25. EMS Shock index
26. ED HR
27. ED SBP
28. ED Shock index
29. Pelvic exam
30. Fetal heart tones
31. Abdominal ultrasound
32. Transvaginal ultrasound
33. CT Chest
34. CT Abdomen/Pelvis
35. Injuries
36. Operative intervention
    1. Thoracotomy
    2. Laparotomy
    3. Cesarean section
37. ED Procedures
38. Delivery
    1. Cesarean section
    2. Vaginal delivery
    3. Age at delivery
    4. APGARS
    5. Required intubation
    6. NICU admission
39. Disposition
    1. Admission to trauma center
    2. Transfer to obstetric hospital
40. Length of stay (LOS)
    1. Hospital
    2. ICU
41. Mortality
    1. Maternal
    2. Fetal
42. **Risks**

This is a retrospective chart review without patient contact. There are minimal risks to the patient population. The main risk to patients is loss of privacy due to the data collection. The minimum amount of information necessary to complete the study will be obtained with no additional information that could increase any potential risks to the subjects. We will minimize this risk by assigning each subject a code number and then keep the list of code numbers assigned to each subject separate from the database. Both this list and the database containing our collected data and subjects’ code numbers will be kept as an electronic file in a password-protected folder on the PI’s office computer; only the PI and other members of the research team with have access to the database, and only the PI will have access to the list of code numbers associated with each subject. The database with all identifiers removed will be archived on the PI’s office computer as a password-protected file for a period of 3 years.

1. **Benefits**

There will be no direct benefits to subjects for participating in this research, but the knowledge gained from the study may benefit society in general.”

1. **Remuneration**

There will be no payment for participation in this research study.

1. **Academic or Extra Credit**

N/A

1. **Costs**

This is a retrospective research study. There will be no direct costs to the subject for participating in this research study.

1. **Alternatives**

N/A

1. **Consent process and documentation**

This is a retrospective chart review. The study subjects will not be contacted at any point during this study. Therefore, there will be no deviation of the standard of care or the management protocols for the subjects included in this study.

1. **Qualifications of the investigators**

Dr. Patrick McGrew, MD, Assistant Professor, is the director of the Surgical ICU at Tulane University Medical center, and a trauma surgeon. He will serve as the principal investigator on this study. Dr. McGrew has conducted numerous studies in the past.

Dr. Tyler Simpson, MD, MS, is a General Surgery resident and will be the research coordinator. Tyler has participated in numerous IRB approved studies in the past.

Dr. Christofer Anderson, MD, MS, is a General Surgery resident and will be a research co-investigator. Christofer has participated in numerous IRB approved studies in the past.

Dr. Vidda Simpson, MD, MS, is a Obstetrics & Gynecology resident and will be a research co-investigator. Vidda has participated in numerous IRB approved studies in the past.

Student physician Allegra Ploeg, BS, is a third year medical student at Tulane University School of Medicine. She will serve as a co-investigator ins the study and has conducted IRB approved studies in the past.

1. **References**

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