Accuracy of Fetal MRI in Diagnosing CNS Anomalies

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Study Purpose and Rationale

Prenatal ultrasound is still the standard screening method for detecting fetal CNS anomalies. However, when ultrasound reveals a suspicious finding, pregnant women are increasingly referred to MRI for further evaluation.

Previous studies that have compared fetal MRI to ultrasound have successfully established that MRI is indeed a useful tool in evaluating fetuses with suspected CNS abnormalities on ultrasound. Consequently, parents and physicians turn to MRI when they need a greater degree of certainty in diagnosis to assist them in making decisions about their pregnancy.

Though fetal MRI is becoming more common, there are currently no guidelines on such important issues as: the best gestational age for evaluation, indications for follow-up MRI, which anomalies can be diagnosed with sufficient sensitivity and specificity, and how often MRI correctly predicts anomalies.

Pediatric neurosurgeons are frequently asked to counsel parents about the prognosis of pregnancies with suspected CNS abnormalities on MRI, but have little data from which to draw advice.

Current Literature

Previous studies have established that fetal MRI is a useful adjunct to ultrasound when evaluating a suspected CNS abnormality. MRI can confirm a diagnosis and provide more detailed information relevant to delivery options and postnatal surgical planning. There are very few studies that have compared fetal MRI to postnatal imaging and autopsy reports, and none that have attempted to quantify the accuracy of MRI.

Hypotheses/ Questions

Columbia is one of the top three centers in the nation for utilization of fetal MRI, offering sufficient data for analysis. We have the unique opportunity to investigate the answers to such questions as:

1. What percentage of abnormal ultrasounds lead to referral to MRI?
2. How many MRIs are performed before, and after, 24 weeks of gestation?
3. What types of abnormalities are being diagnosed?
4. How many pregnancies are terminated as a result of the diagnosis?
5. Is there a difference in the accuracy of MRI diagnoses made in pregnancies before 24 weeks vs. later?
6. Is the accuracy of an MRI diagnosis dependent upon the type of anomaly suspected?
7. Do any anomalies improve/ worsen/ resolve over the course of gestation?
8. At what gestational ages is MRI most effective for diagnosing CNS anomalies?
9. What is the sensitivity and specificity of fetal MRI using postnatal imaging as the standard for different diagnoses and at different gestational ages?
10. How often is fetal MRI not useful secondary to excessive fetal movement or technical difficulties?
11. What sequences are most useful and how long do MRI studies take?
12. What slice thickness is best for detecting anomalies?

Study Procedures

This study will consist of two parts:

1. Retrospective chart review

The Center for Prenatal Pediatrics at Columbia has already established a database of pregnant women who have undergone MRI after anatomic anomalies were diagnosed on ultrasound. The data included in the database are: name, referral date, MRN, SSN, address, phone number, date of first visit, age, GP, estimated date of delivery, gestational age (GA) at first visit, race, primary language, residence, zip code, referral source, referral name, type of consult, insurance, gestation type, diagnosis at referral, diagnosis from consultation, outcome, delivery type, child's name, child's MRN, child's sex, child's DOB, GA at birth, Apgar scores, weight, length, head circumference, child's karyotype, pediatric diagnosis, pediatric followup.

We plan to pull from this database pregnancies in which there is a suspected CNS anomaly, create a similar database specifically for these patients that includes: subject ID number, referral date,

MRN, age, GP, estimated date of delivery, race, gestation, diagnosis at referral, referring institution's ultrasound read, CUMC ultrasound read, MRI read, GA at MRI, outcome, delivery, child's MRN, DOB, GA at birth, postnatal imaging read, and neurosurgical operations. We will analyze this database to answer our study questions.

2. Prospective observational

We will follow new patients who are referred for fetal MRI after an abnormal ultrasound, as well as current ongoing pregnancies with diagnosed CNS anomalies, and include them in our database. These patients will be asked to provide informed consent before being added to our study.

Study Design and Statistical Procedures

Radiologists and pediatric neurosurgeons will review the fetal MRIs to determine if there is a significant difference between prenatal and postnatal imaging. Radiologists will determine if there is a radiographic difference, while neurosurgeons will determine if that difference is clinically relevant.

Though Columbia is a major center for fetal MRI, there is still a very limited data set from which to draw conclusions. Preliminary review of the Center for Prenatal Pediatrics' database suggests that there are 30-40 cases relevant to our study. From this limited sample, we plan to calculate accuracy, error rates, positive predictive value and negative predictive value with 95% confidence intervals.

Study Subjects

The study subjects will include all pregnant women (including pregnant teenagers) referred to fetal MRI at Columbia for further evaluation of a suspected CNS anomaly detected on ultrasound. There are no major exclusion criteria. Only patients who are referred to fetal MRI by their physicians will be included in this study. The study researchers will not refer, nor recruit, patients to fetal MRI.

We will obtain informed consent from new fetal MRI patients prior to adding their information to the database. A co-investigator will meet with each patient prior to the patient's MRI appointment to explain the study, answer questions and obtain consent.

Confidentiality

Once we create our database of patients with suspected fetal CNS anomalies, we will de-identify it. Only study researchers will have access to this database. The key linking patient names to their study subject number will be destroyed once all necessary data is obtained. A database containing the names and MRNs of currently pregnant women will be kept until the postnatal imaging and outcomes are available for documentation. Once this information is obtained, we will destroy their identifying information. This database will be kept password-protected and locked in the lab. Only key research staff will have access to it.

Potential Risks

Our study analyzes the results of prenatal imaging and thus poses no additional medical risks to the pregnant women or their fetuses. The database we create will be devoid of names, addresses, MRNs, SSNs, etc., minimizing the potential for subject identification.

Potential Benefits

The best methods for obtaining fetal MRI are currently unknown. By answering our study questions, we can maximize the utility of fetal MRI with suggestions on how and when to obtain MRI, as well as how to interpret the results for parental counseling.

Literature References

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