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IRB Proposal – CRC Rotation
9/19/14

Title: Comparison of meso-rex and portosystemic shunts in the management of extrahepatic portal vein obstruction in children

1. Study purpose and rationale

In this study of patients with non-cirrhotic portal hypertension, we seek to demonstrate that these patients have impaired liver function and smaller than normal livers. Retrospective studies indicate that the Rex shunt can produce superior outcomes over conventional shunts due to the fact that normal hepatopedal blood flow is restored. We hypothesize that restoration of portal blood to the liver in patients with non-cirrhotic portal hypertension will improve function as detected by clinical parameters, liver function by lab results, and increased liver size relative to body weight and body surface area comparing post shunt values to baseline and normal controls. We plan to do a retrospective review of all patients at Columbia University Medical Center that have received a surgical shunt to correct portal hypertension resulting from portal vein thrombosis. The purpose of the study will be to document liver atrophy and impaired function at baseline and to provide data demonstrating that the Rex shunt results in improved function and volume. In order to provide this data, we will review medical records and images of liver/spleen volume as taken by magnetic resonance imaging (MRI), and/or Computerized Axial Tomography (CT). Volumetric analysis of both the liver and the spleen will be completed.

2. Study Design and Statistical Procedures

This study will involve data review only. All data will be gathered from one of three sources: (1) Paper chart review, (2) electronic chart review, (3) radiological images (retrospective only). Liver and spleen volume will be analyzed along with previous laboratory results. The outcomes of interest will be changes in: liver and spleen volume, liver function, coagulation markers, platelet reduction, and clinical and functional assessments. Nearly all data to be collected are numeric. Follow up data to be collected at 3, 6, and 12 months when available. Univariate paired comparisons will be made between baseline and post-shunt observations. Based on previously published data, power calculations were done to show an improvement in platelets by 50+/-60 in the meso-Rex group. Based on these calculations, 24 patients will need to be in each group.

3. Study Procedure

This study is a retrospective review of all pediatric patients that have undergone a shunt procedure at New York Presbyterian / Columbia University Medical Center, and have been diagnosed with portal vein thrombosis.

4. Study Drugs or Devices

Not applicable.

5. Study Instruments (e.g., Questionnaires, Interview Outlines, Focus Group Guides)

Not applicable.

6. Study Subjects

We aim to retrospectively review data from approximately 30 patients who have mesorex shunts in our unit over the past decade:

Inclusion criteria:

- a) Diagnosis of portal vein thrombosis
- b) Undergone a mesorex shunt procedure at New York Presbyterian / Columbia University Medical Center
- c) No evidence of cirrhosis

Exclusion criteria:

- a) Patients that did not have pre-shunt three-dimensional (e.g., cross-sectional images CT and MRI) radiologic imaging

Vulnerable populations:

Children are included in this study, but since the data is collected retrospectively, the study poses no more than minimal risk to the patient.

7. Recruitment

This is a retrospective review. Eligible patients will be identified by querying New York Presbyterian / Columbia University Medical Center electronic databases.

8. Informed Consent Process

We request a waiver of consent for this study. Due to the limited follow-up in current standard of care, it is anticipated that consent will not be able to be obtained from the majority of study patients. This study poses no more than minimal risk to the patient and only retrospective chart review will be completed.

9. Confidentiality of Study Data

All patient information will be collected and stored locally in a secure manner. Data will not be transmitted externally. Patient information will be maintained in a paper study charts housed in a locked office with limited access, in the Presbyterian Hospital building. In addition, data will be stored electronically in RedCap, a secure, password protected database. Data will contain direct identifiers as patient names will be needed in order to look up information in patient charts and hospital systems. The data collected in this study will be used for future research and/or made available to other investigators for future research. Only investigators at

Columbia University Medical Center who obtain IRB approval will have access to data collected in this study. The data collected for this study will be stored for a period of 5 years from the end of the study.

10. Privacy Protections

All patient information will be collected and stored in a secure manner. Every effort will be made to safeguard the confidentiality of patient data. Access to study data will only be allowed for the purpose of this study. The HIPAA will be adhered to at all times.

11. Potential Risks

There will be no risks to the patient besides the minimal risk of a confidentiality breach. All patient information will be collected and stored in a secure manner.

12. Data and Safety Monitoring

This study poses minimal risk and will be conducted under IRB approval only.

13. Potential Benefits

There will be no direct benefit to patients involved in this study, however, it is hoped that there will be substantial benefit to future patients with portal vein thrombosis, and to scientific knowledge. If successful, this study will provide compelling evidence to support the use of the Rex shunt versus other conventional shunt procedures. This study aims to show that a rex shunt is a superior choice due to the developmental and neurological benefits as a result of restoring normal hepatopedal flow.

14. Alternatives

The only alternative would be to not perform the study.

15. Research at External Sites

Not applicable.

16. Columbia as Lead Institution

Not applicable.