

Summer Student Research Program
Project Description

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PROJECT TITLE (200 Characters max):

An Observational Prospective Study of Transfusion Requirements During Spinal Surgery for Severe Scoliosis

HYPOTHESIS:

What are the transfusion requirements for children undergoing spinal surgeries for severe scoliosis?

PROJECT DESCRIPTION (Include design, methodology, data collection, techniques, data analysis to be employed and evaluation and interpretation methodology)

This is a retrospective, observational study.

Our research is divided into two phases. Retrospectively, Dr Sabharwal's patients' data that have undergone spinal surgery for severe scoliosis (**IRB 0120080347**) was analyzed. Data collected included patient's preoperative hemoglobin, INR and MCV levels, gender, age and weight. Intraoperatively we collected core body temperatures, hemoglobin and hematocrit concentrations, estimated blood loss as well as transfusion products administered (both crystalloid and colloid), length of surgical duration, number of curves instrumented, type of instrumentation, drain placement and drainage. For the 48 hours post operative interval, we collected data regarding hemoglobin and hematocrit concentrations as well as further transfusion requirements. Having analyzed data from this study and having spoken with co-investigator, Dr. Sabharwal, who voiced his concerns over the accuracy of the retrospective data, as he changed his surgical technique, we now propose a prospective study.

Prospective Study

We plan to include 50 patients. There will be no exclusion criteria. Data collected prior to surgery will include patient's hemoglobin, INR, MCV, gender, age and weight. Immediately prior to surgery patients will have a complete blood count drawn to assess preoperative hemoglobin/hematocrit concentrations. During surgery patient's core temperature, hemoglobin and hematocrit levels, estimated blood loss, Central Venous Pressure, blood pressure, heart rate, cell saver, the amount irrigation fluid, colloid, crystalloid, blood and blood products will be recorded hourly throughout surgery. Patients will be transfused allogenic blood if hemoglobin levels fall below 8.0 g/dL or patients present with clinical signs/symptoms of anemia or hypoxemia (hypotension, tachypnea, tachycardia, or low SaO₂ levels). Data collection concerning allogenic blood transfusion will include intraoperative transfusion rate, volume of transfused units per patient and transfusion index. Surgical intraoperative data will be collected to ascertain the number of curves, the curve magnitude, the number of levels fused and the type of instrumentation required. The type of wound drain and their respective outputs will be noted. Post-operatively patients will be followed to determine hemoglobin, hematocrit levels at 24, 48 hours, and just prior to discharge. Further transfusion requirement will be recorded as well as length of Intensive Care Unit stay and length of hospital stay. Regarding surgical procedure all

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patients will be operated on by the same surgical team, under standardized anesthesia, antibiotic and antithrombotic prophylaxis, and postoperative analgesia. Data will be expressed as percentages or as a mean +/- SD. T-test analysis will be used for comparison for quantitative variables and a p value < 0.05 will be considered statistically significant. This observational, prospective study is considered a pilot study as there is no existing information regarding the correlations which the investigators intend to study. Therefore, there is no power analysis or sample size estimation which could be applied appropriately. In fact, the results of this study will aid in determining power analysis and sample size estimation for a future study. A multiple regression model will be used to analysis the correlation between the primary outcome variable and multiple secondary outcome variables

SPONSOR'S MOST RECENT PUBLICATIONS RELEVANT TO THIS RESEARCH:

Dr. Patel has no publications relevant to this research but has publications related to anesthetic management of children.

IS THIS PROJECT SUPPORTED BY EXTRAMURAL FUNDS?

Yes or No

THIS PROJECT IS: Clinical Laboratory Behavioral Other

THIS PROJECT IS CANCER-RELATED N/A

Please explain Cancer relevance

THIS PROJECT IS HEART, LUNG & BLOOD- RELATED

Please explain Heart, Lung, Blood relevance

This study has relevance as it seeks to address minimizing the need for blood transfusion in a specific patient population where the majority of patients require blood transfusion both intraoperatively and postoperatively.

THIS PROJECT INVOLVES THE USE OF HUMAN SUBJECTS

PENDING APPROVED IRB PROTOCOL # M0120090203

THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS ENTERING FRESHMAN
SOPHOMORES ALL STUDENTS

THIS PROJECT IS WORK-STUDY: Yes or No

**THIS PROJECT WILL BE POSTED DURING ACADEMIC YEAR
FOR INTERESTED VOLUNTEERS?:** Yes or No

WHAT WILL THE STUDENT LEARN FROM THIS EXPERIENCE?

The student will benefit from their participation in a structured research study. They will be exposed to Good Clinical Practice (GCP) which ensures the rights and safety of clinical trial subjects and the integrity of clinical data obtained during the conduct of a clinical trial. The student will have the opportunity to have a comprehensive review of the protocol, participate in subject-investigator interactions, ongoing and risk appropriate safety monitoring throughout the conduct of the study and assist in data collection, analysis and reporting.

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The student will have an opportunity to interact with the minor subject and parent/legal guardian to assess the eligibility for inclusion to the study. They will learn the normal laboratory parameters for a Complete Blood Count and indications for administering blood and blood products intraoperatively. They will benefit from the experience of spending time in the Operating Room and having the opportunity to witness surgical procedures as well as anesthetic technique.