

Summer Student Research Program

Project Description

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PROJECT TITLE (200 Characters max):

A Retrospective Analysis of transfusion Requirements During Spinal Surgery for Scoliosis.
A Prospective Study to Determine the Effects of Ferrous Sulfate on Transfusion Requirements for Patients Undergoing Spinal Surgery for Scoliosis

HYPOTHESIS:

Does the administration of preoperative ferrous sulfate therapy reduce autologous blood transfusion requirements in spinal surgery for severe scoliosis?

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

Introduction: Many of the patients suffering from severe scoliosis (female to male ratio 8:1) are borderline anemic adolescent females who are post menarche. Allogenic blood transfusions are often necessary during and after spinal surgeries for severe scoliosis. The rate of postoperative infection is higher in those patients receiving allogenic blood transfusion most probably due to a transfusion related immuno-suppression. In addition, there are allogenic blood transfusion risks such a transfusion reactions through storage induced mechanisms, errors in administration and viral or bacterial contamination, which leads us to development of different strategies to reduce or avoid the need for allogenic blood transfusions. Our goal via preoperative iron therapy is to achieve a reduction and perhaps eliminate the need for transfusion related products given to these patient undergoing major spinal surgery for scoliosis.

References:

1. Reamy, BV, et al: Adolescent Idiopathic Scoliosis: Review and Current Concepts. **AAFP**.2001 Jul,: 1-9
- 2.Andrews CM, Lane DW, Bradley JG. “ Iron pre-load for major joint replacement.” **Transfus Med**.1997 Dec;7 (4):281-6
3. Cuenca J, Garcia-Erce JA et al. “Preoperative haematinics and transfusion protocol reduce the need for transfusion after total knee replacement”. **Int J Surg**. 2007 Apr 5(2):89-94 Epub 2006 Apr27
4. Kuklo TR, Owens BD et al. Perioperative blood and blood products management for spinal deformity surgery. **Spine J**.2003 Sep-Oct;3(5):388-93
5. Joseph SA Jr, Berekashvili K, et al Blood conservation techniques in spinal deformity surgery: a retrospective review of patients refusing blood transfusion. **Spine** 2008 Oct 1;33 (21):2310-15
6. MacEwn GD, Bennett, E, Guille JT. Autologous blood transfusions in children and young adults with low body weight undergoing spinal surgery. **J Pediatr Orthop**. 1990 Nov-Dec;10(6):750-3
7. Vitale MG, Privitera DM et al. Efficacy or preoperative erythropoietin administration in pediatric neuromuscular scoliosis patients. **Spine**.2007 Nov 15;32(24):2662-7

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Retrospective Study

Our research is divided into two phases. First we would like to retrospectively analyze data of Dr Sabharwal's patients over the last three years who have undergone spinal surgery for severe scoliosis. Data collected will include subjects': preoperative hemoglobin levels, gender, age and weight. Intraoperative data collection will include core body temperatures, hemoglobin and hematocrit concentrations, estimated blood loss as well as fluids administered (both crystalloid and colloid) and blood products. Finally in the 48 hour post operative interval we will collect data regarding hemoglobin and hematocrit concentrations as well as further transfusion requirements. Regarding transfusions, we will specifically be interested in transfusion rate (percentage of transfused patients), volume of transfused units per patient and transfusion index (blood units per transfused patient). Patients with data collected for retrospective analysis will be considered the control group.

Prospective Study

As part of **the prospective study** we will approach Dr. Sabharwal's patients scheduled for spinal surgery for idiopathic scoliosis. We plan to include 50 patients in this prospective clinical study. Dr. Sabharwal will counsel the patients and their parent/legal guardian as to possible surgical intervention approximately 8 weeks prior to scheduled surgery. The study will also be introduced and explained by one of the members of the study team. After the study

consent/assent is signed a small fingerstick blood sample, using a device called the Hemocue®, will be obtained to evaluate patient's hemoglobin levels. Data collected prior to surgery will include patient's hemoglobin concentration, gender, age and weight. Patients will be stratified according to hemoglobin levels in regards to ferrous sulfate dosing regimens. Patient with hemoglobin levels greater than 13.0 gm/dL will receive the US Recommended Daily Allowance of elemental iron (maintenance dose) 15.0 mg per day for an interval of 6 to 8 weeks. The remaining patients with hemoglobin levels less than 13.0 gm/dL will receive therapeutic doses of elemental iron (30 mg/kg/day in divided doses BID or TID) for an interval of 6 to 8 weeks. All patients will be advised to take ferrous sulfate as a source of elemental iron (ferrous sulfate contains 20% elemental iron) on an empty stomach with fruit juices to facilitate absorption. In order to avoid constipation, the subjects will be asked to take Colace 150-300 mg in divided doses BID or TID. The subject and their parent/legal guardian will be instructed in the use of a diary. They will be asked to document the daily doses of ferrous sulfate taken and what doses if any were missed. They will be asked to bring the diary with them on the day of surgery. Transfusions will be administered intraoperatively if the Hgb is 7 gm/dL or below and if the vital signs are unstable (systolic blood pressure is less than 40% of baseline and heart rate is 40% above baseline for more than 15 minutes, with accompanying blood loss).

Patients **excluded** from the study will include:

- those with those with iron overload syndrome
- hemolytic anemia (a lack of red blood cells),
- porphyria (an enzyme disorder that causes blue discoloration of the skin),
- thalassemia and sickle cell anemia(a genetic disorder of red blood cell),
- patients receiving regular blood transfusions.
- patients who have had previous surgery on their gastro-intestinal tract or have a history colitis.

Immediately prior to surgery, but after induction of anesthesia, patients will have another complete blood count drawn to assess preoperative hemoglobin/hematocrit concentrations. This is customarily done to establish a baseline. During surgery patient's core temperature, and

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hematocrit level, and estimated blood loss will be monitored. These blood samples will be taken via an arterial line which will be inserted after the induction of anesthesia and is a customary practice for children undergoing scoliosis surgery. Patients will be transfused allogenic blood if hemoglobin levels fall below 7.0 mg/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. Post-operatively patients will be followed for a 24 hour interval where hemoglobin and hematocrit levels and further transfusion requirement will be recorded. Regarding surgical procedure all patients will be operated on by the same surgical team, under standardized anesthesia, total intravenous anesthesia (TIVA), and postoperative analgesia.

SPONSOR'S MOST RECENT PUBLICATIONS RELEVANT TO THIS RESEARCH:

None

IS THIS PROJECT SUPPORTED BY EXTRAMURAL FUNDS?

Yes or No

THIS PROJECT IS: Clinical Laboratory Behavioral Other

THIS PROJECT IS HEART, LUNG & BLOOD- RELATED

Please explain Heart, Lung, Blood relevance

This study has relevance as it seeks to minimize 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 # M

THIS PROJECT IS SUITABLE FOR:

UNDERGRADUATE STUDENTS ENTERING FRESHMAN
SOPHOMORES ALL STUDENTS

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.

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 become familiar with a device called the Hemacue® which measures hemoglobin levels. They will learn the normal laboratory parameters for a Complete Blood Count. 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.