Preoperative Vitamin K to Minimize Scoliosis Operative Blood Loss

Lay Summary of Protocol

Purpose: The purpose of this study is to determine if Vitamin K given preoperatively will decrease the amount of blood loss compared to a control group.

Rationale: Patients that undergo adult spinal scoliosis surgery typically can lose up to 1000 cc of blood during the surgery. After a few hundred cc's of blood loss, the patient becomes coagulopathic due to the loss of clotting factors, and subsequently blood loss accelerates. Vitamin K has been widely used in certain coagulopathic pathology due to its ability to carboxylate certain glumate residues that in turn are involved in the blood coagulation cascade. It is anticipated that correctly time preoperative oral Vitamin K, the patients will have an up regulated clotting cascade that may lead to less intraoperative blood loss.

Study Design: This study will be a prospective observational study. Adults 18 years of age and older will be included in the study. All patients with the diagnosis of scoliosis with plans to undergo spinal scoliosis surgery will be involved in the study. These patients will receive the standard oral dose of 2.5 mg of Vitamin K in the AM the day before the planned surgery. The intraoperative blood loss as documented by intraoperative Cell-Saver will be recorded, as well as the number of spinal levels fused and the number of osteotomies performed, all of which can affect the amount of

anticipated blood loss. These calculations will be compared to a current data base of similar patients.

Study Sample: A sample size of 30 patients that fulfill the above criteria and are willing to participate in the study will be evaluated. The goal is to obtain at least 20 patients undergoing posterior spinal scoliosis surgery and fusion.

Measurements: First, demographic information on the patients (age and gender) will be collected. The patients' medical history, current spinal diagnosis, and procedure performed will be determined. Numeric values of blood loss and need for transfusion will be recorded during the patients entire hospital stay.

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Full Protocol:

Objective:

The purpose of this study is to determine if preoperative oral Vitamin K given will decrease the amount of blood loss compared to a control group.

Hypothesis:

We hypothesize that:

- Vitamin K, if given preoperatively, will decrease intraoperative blood loss as documented by cell saver.
- There will be a decreased need for transfusion in the patients that receive the preoperative Vitamin K.

Background: Scoliosis is a spinal deformity in either the coronal or the sagittal plane. Patients may experience cosmetic changes, pain, or even lung and respiratory compromise 6. Often they undergo physical therapy and a pain management regimen prior to surgical intervention. Surgery is indicated for unrelenting pain, cosmetic disapproval by the patient, prevention of curvature progression, and for failure of conservative management. Patients may undergo anterior correction, posterior fusion, or a combination of anterior and posterior surgery depending on the indications and goals of surgery 7.

During surgical intervention, a segmental surgical fusion is customarily performed. Although there are reports of different fusionless scoliosis surgery, these are usually reserved for the growing spine 8,9. During the segmental fusion process, blood loss begins from the skin incision and continues during the stripping of the paraspinal muscles, to the placement of the hardware to the decortications process; blood loss continues postoperatively as is appreciated by drain outputs. Additionally, bonegraft harvesting only increases to the blood loss in these patients; in fact, including postoperative drainage, it may lead to blood loss of up to 260 cc's 10. With loss of coagulation products, a dilutional coagulapathy ensues 11,12. This cascade of events leads to increased blood loss leading to difficulties with visualization in the operative field, increased additional blood loss, and further complications with spinal cord perfusion, as well as, with heart and lung perfusion.

There have been many techniques to help minimize the loss of blood during scoliosis surgery such as hemodilution 5, the use of antifibrolytic products such aminocaproic acid and tranexamic acid 2,4 and cell saver 3, however, even with these techniques, the blood loss is significant. Even with these blood conservation methods these patients can lose upwards of 1 liter or more of blood 1,2,3.

Vitamin K has been safely used in other surgical interventions for controlling different forms of anticoagulation 16,17,18,19. We feel that vitamin K used preoperatively can help reduce the coagulapathy that occurs with scoliosis surgery and subsequently decrease the operative blood loss.

Experimental Design and procedures to be used:

Design: Adults 18 years of age and older will be included in the study. All patients with the diagnosis of scoliosis with plans to undergo spinal scoliosis surgery will be involved in the study. These patients will receive the standard oral dose of 2.5 mg of Vitamin K in the AM the day before the planned surgery 13. The intraoperative blood loss as documented by intraoperative Cell-Saver will be recorded, as well as the number of spinal levels fused and the number of osteotomies performed, all of which can change the amount of anticipated blood loss. These calculations will be compared to a current data base of similar patients who were unexposed to Vitamin K prior to surgery.

Selection Procedure: Patients 18 years and older will be included. All patients with the diagnosis of scoliosis will be included in the study. Patients with tumor, infections, or traumatic induced scoliosis will be excluded from the study. Additionally, patients with prior surgery will also be excluded. Patients with a diagnosis of a coagulopathic disorder such as Lupus anticoagulation disorder or Factor V Leiden disease will also be excluded. Patients on preoperative Coumadin will be excluded as well. A sample size of 30 patients that fulfill the above criteria and are willing to participate in the study will be evaluated. The goal is to obtain at least 20 patients undergoing posterior spinal scoliosis surgery and fusion.

The unexposed population will be randomly selected from the Spine Institute Outcomes Registry database which contains the records 6300 current and former Spine Institute

surgery patients. The data of 60 scoliosis patients with spinal scoliosis surgery who meet the same criteria as the Vitamin K group (see above) will be used in the analysis.

Population studied: The exact composition of the study population is not known. Patients will not be excluded from the study based on gender or ethnicity.

Instrumentation and collection of data: First, demographic information on the patients (age and gender) will be collected. The patients' medical history, current spinal diagnosis, and procedure performed will be determined. Numeric values of blood loss and need for transfusion will be recorded during patients entire hospital stay.

The data will be first collected on a data extraction sheet (Appendix 1) and then entered in a spreadsheet to be analyzed. Each subject will be assigned an ID number. The personal identifiers that we will collect on the data extraction form will be the ID number, name, date of birth, medical record number, the amount of levels fused, the amount of operative blood loss, and the date of surgery (Appendix 1). All the data extraction forms will be kept in locked rooms. The identity of the patient will remain confidential. The spreadsheet will be stored on a secure drive at Beth Israel Medical Center and will be protected by a password. Only persons involved in the analysis will have access to the spreadsheet.

Analysis: Continuous variables will be summarized by mean ± SD or median. Categorical variables will be summarized by frequencies with 95% confidence intervals (CIs). The paired T-test will be used to test our main hypothesis. The student t-test will

be used to see if there is a difference in the amount of blood loss between the two groups. We will also use simple linear regression and multivariate linear regression, including statistically significant or clinically important variables.

Patient risk and confidentiality: We will get informed consent and the research authorization from each subject. This study poses a minimal risk to patients receiving the oral vitamin K. In the 8 studies reviewed, only one thrombotic event was described among the 344 patients who received oral, subcutaneous or intravenous vitamin K therapy 13,14,15.

Tentative Timeline:

- develop and finalize protocol September 2009
- obtain IRB approval for study October 2009
- data collection, entry, and analysis November 2009-March 2010
- Project report, presentation at conference, development of manuscript April-June 2010
- submission of manuscript, IRB: closing of study June-July 2010

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