Protocol Summary

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Evaluation of anti-Xa levels in surgery patients receiving fixed dose heparin

University of Utah IRB_00095514

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OBJECTIVES:

The aims of this study are to:

- Determine if fixed dose heparin infusions at a rate of 500 units/hour are sufficient to maintain a target anti-Xa of 0.1-0.35 IU/mL for VTE prophylaxis in patients undergoing microsurgical procedures.
- Develop and implement a pilot protocol to titrate heparin drips initiated at 500 units/hour following microsurgical procedures to ensure patients have sufficient VTE prophylaxis.

Hypothesis: Fixed dose heparin drips at 500 units/hour are not sufficient to maintain the target anti-Xa of 0.1-0.35 IU/mL for VTE prophylaxis in all patients undergoing microsurgical procedures.

PARTICIPANT SELECTION CRITERIA:

Inclusion Criteria:

- Patients undergoing microsurgical procedures at the University of Utah Hospital Initiation of a heparin infusion at a rate of 500 units/hour postoperatively

Exclusion Criteria:

- Age <18 years old
- Pregnant
- Incarcerated

DESIGN:

All patients will be enrolled in the observational arm of the study. This portion will examine anti-Xa levels in response to fixed dose unfractionated heparin drips at 500 units per hour.

Patients with out of range (0.1-0.35 IU/mL) anti-Xa levels will cross over to the interventional arm of the study. These patients will receive real time unfractionated heparin dose adjustment and repeat lab draws.

STUDY PROCEDURES:

During the vascular or microvascular procedure, the attending surgeon will determine whether or not the patient will require a fixed dose heparin drip postoperatively. We will enroll a convenience sample of patients placed on fixed dose heparin drip by their surgeons—we will not dictate any portions of the patient's care intraoperatively, but rather will study patients already placed on a study-specific regimen by their attending surgeon. Once the order has been placed, the patient will be approached about joining the study and sign a consent form if agreeing to participate. Patients will be identified through an

alert in TheraDoc. If enrolled, the heparin drip will be managed according to the pilot protocol developed to maintain a target anti-Xa of 0.1-0.35 IU/mL until discontinued by the attending physician.

Standard of Care vs. Research-Related Procedures:
Current practice at the University of Utah Hospital for selected microsurgical procedures is to initiate a heparin drip for patients determined to be high risk for microvascular thrombosis at a fixed rate of 500 units/hour, regardless of patient weight, with no monitoring by PTT or anti-xa.

Patients will be monitored using anti-xa levels and heparin infusion rates will be adjusted to maintain a target anti-xa of 0.1-0.35 units/mL.

STATISTICAL METHODS, DATA ANALYSIS AND INTERPRETATION:

- Sample estimate
    - An estimate of five patients per month is anticipated for the pilot study period (October 1, 2016 to March 1, 2017) for a total of 25 patients.

- Data analysis
    - Continuous data will be analyzed using the student's t-test.
    - Categorical data will be analyzed by the Fisher's exact test.

- Power calculation
    - This is a pilot study whose explicit purpose is to generate preliminary data on pharmacodynamics of intravenous heparin drips at 500 units/hour, as well as the impact of a pharmacist-drive dose adjustment algorithm. By definition, pilot studies do not require power calculations as they are exploratory in nature.