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Study Protocol: Correlation Between Intraoperative Tourniquet Use and Limb pH, Functional Measures and Patient Reported Outcomes After Ankle Fracture Surgery

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Abstract

Background

Tourniquets are widely accepted as “safe” for up to two hours of continued intraoperative use, despite risks and scant literature supporting this duration. Clinical outcomes of tourniquet use have been studied, but studies were small and did not use robust physical exam measures or patient reported outcomes.

Purpose

To determine the relationship between intraoperative tourniquet use for ankle fracture surgery and postoperative pain, patient reported outcomes, functional measures and intramuscular pH.

Study Design

Randomized trial with tourniquet and no-tourniquet arms

Inclusion Criteria

Adult patients (18 years to 89 years) undergoing surgical ankle fracture fixation at OHSU will be eligible for this study. Patients with sepsis, other significant long bone or internal injuries will be excluded from the study.

Methods

Patients will be randomized to tourniquet or no tourniquet arms. Preop labs, demographics and fracture type will be recorded. Intraoperatively, only the participants randomized to the "tourniquet" group will have the tourniquet inflated.

For all patients, a pH catheter will be placed in the anterior compartment of the operative leg and continuous intramuscular pH will be measured from immediately after placement of the probe and 2 hours postoperatively.

Postoperative strength, balance and range of motion will be measured by blinded physical therapists and pain score, FAAM and PROMIS PI and PF modules will be collected electronically at multiple postoperative time points.

Data Analysis

Covariates will be compared using chi-squared, fisher's exact, ANOVAs, and t-tests between tourniquet and no tourniquet arms. Regression analysis will be conducted to determine the relationship between the dependent and independent variables.

Implications

Better understanding of patient outcomes and use of intraoperative tourniquet can inform surgeons on best practices for tourniquet use. Characterizing intramuscular pH changes during and after tourniquet use is a novel application of technology that adds to our understanding of muscle physiology.