SRTP - Project Description Form #226

PART I:

Name of Schulich faculty member who will supervise the project	Patrick Teefy
Supervisor's Schulich, Western, Hospital or Lawson Email	patrick.teefy@lhsc.on.ca
Schulich Department	Medicine

PART II - Project Description

Title of Project	Assessing for Femoral Artery Risk Factors for Transcatheter Aortic Valve Risk Factors Using Computed Tomography Scans

Background

TAVI or transcatheter aortic valve implantation has been a major advancement in the treatment of aortic stenosis in the elderly population. Vascular access remains a crucial part of the procedure and when this goes awry, limb ischemia or severe life-threatening hemorrhage can occur. The femoral artery approach is utilized in the vast majority of cases and must be large enough to accommodate 14 – 22 F [4.6 – 7.1 mm] diameter sheaths. The puncture site must be relatively free of calcification on the anterior surface. Preprocedural computed tomography (CT) scan of the peripheral arterial system helps to evaluate the femoral artery and judge its suitability for puncture. During the actual procedure ultrasound is used to determine the site of puncture [above the femoral artery bifurcation and relatively free of calcification on its anterior surface]. Several devices are used for closure of the puncture wound on the anterior surface of the femoral artery. These include ProGlide sutures, Angio-Seal and Manta closure devices. Despite these elegant closure devices approximately 5% of patients have serious vascular complications such as bleeding or arterial compromise.

The Manta device uses a depth finding catheter to judge distance from skin to the puncture site on the anterior surface of the femoral artery. After the procedure, the pledget is deployed based on the depth of the artery from the skin. The majority of cases in which we have used this closure device have achieved successful hemostasis. However, a proportion have resulted in incomplete closure or frankly a failure to engage.

We propose to retrospectively evaluate our documented TAVI cases where Manta was utilized. The depth deployment value was recorded and will be compared in a blinded fashion with the depth estimated from the preprocedural CT scan.

Hypothesis

We expect that increasing puncture depth and femoral artery pathologies will be positively correlated with TAVI complications, especially embolisms of atherosclerotic plaques, bleeding, and perforation of the femoral artery. We expect that other complications unrelated to puncture site differences, arrythmias or poor valve placement, will not have a significant correlation with the study proposed risk factors.

Proposed Methodology

A patient record check will be completed, including analysis of the preoperative variables (demographics, valvular pathologies, comorbidities and type of procedure, valve replacement or redo-replacement), perioperative variables (procedure type, medications, and transfusions) and postoperative complications (bleeding, infection, embolism, and perforations). An analysis of pre/peri/postoperative CT scans will be completed to determine the depth of the puncture

site, presence of femoral vein pathologies, and the presence, extent and location of postoperative bleeding.

Correlations will be studied to determine if preprocedural depth can be accurately predicted by the CT scan. This would provide further confirmation and reassurance on depth of deployment, potentially improving the percentage of correct deployments for hemostasis. The CT scan will also be assessed for calcification in a 60° arc centered on the anterior posterior axis of the vessel to see if this correlates with the device's clinical failure. Lastly, correlations between preoperative risk factors (calcifications and depth) and complications will be completed.

Expected Outcomes
We expected to find a positive correlation for complications and preoperative CT scan findings including depth of catheter puncture site (skin to femoral artery), and pathologies of the femoral artery (peripheral artery disease, calcification). Moreover, we hope to create a preliminary graded rating system to function as an aid for cardiologists to determine the likelihood of complications and plan accordingly.

Research Environment – Description of the number of research personnel, primary location of research, size of lab, etc
There will be one medical student that I plan to include as the primary research assistant. The primary location of the research will be the cardiology department and the in-hospital computers. The data gathering will involve accessing patient records and pre-op CT image analysis.

Names and titles of other individuals who will be involved with the research project?
Medical Student that is planned to join via the STRP: Christian, Neira Agonh. MD(c) MEd BSc

Can this project be done remotely?	No
Duration of Project	One Summer

Expected Objectives/Accomplishments for Student?
The student is expected to complete data collection, statistical analysis and a large portion of the manuscript writing. This includes the patient record checks, and CT scan analysis.

PART III - Certifications

If the project will require any certification approvals from one or more of the following offices, please check the appropriate box below.	- Human Ethics
Human Ethics: If you have the protocol information, please enter it below (or enter the status of the approval).	Approval not submited yet. It will be completed by the medical student in the winter semester.

Note: certification approval should be obtained prior to the start of the summer. Projects without this approval will not be a priority for funding.