Vascular events In Surgery patIents cOhort evaluatioN – Cardiac Surgery

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HEALTH THROUGH KNOWLEDGE

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Background

- Globally over 2 million adults undergo cardiac surgery annually
- Change in population having surgery highlights uncertainty regarding current incidence of major complications and optimal clinical risk estimation models
- Promising but inconclusive evidence that troponin measurements after surgery may allow physicians to avoid missing perioperative MIs and predict mortality

Study Design

- Prospective, international, cohort study
- 15,000 adult patients undergoing cardiac surgery in 24 centres
- Representative sample
  - Consecutive patients recruited, including day and night cases, elective and urgent/emergent cases, weekday and weekend cases
- Centre specific recruitment schedules developed to handle large patient volumes

Study Design

- Patient consent collected as determined by local research ethics committee
- Majority of patients consented prior to surgery
- Can consent up to 24 hrs after surgery for emergent cases or other timeline approved by local research ethics committee
- Deferred consent for recruiting critically ill patients (as approved by local research ethics committee)

Study Design

- Troponin measurements using the Abbott high-sensitivity troponin I assay collected at the following time points:

Pre-op	3-12 hrs Post-op	Post-op Day 1	Post-op Day 2	Post-op Day 3

- Centres could run assays on-site or send frozen samples to the Clinical Research Laboratory and Biobank, Hamilton, ON for analysis
- Troponin results blinded to clinicians for minimum 30 days

Patient Population

Inclusion criteria

- Age ≥ 18 years
- Patients who have undergone cardiac surgery (includes coronary artery bypass grafting and all open heart procedures such as valvular repairs/ replacements)

Exclusion criteria

- Previously enrolled in VISION Cardiac Surgery study
- Patients who have undergone an isolated pericardial window, pericardiectomy, permanent pacemaker or defibrillator implantation

Objectives

1. To determine the relationship between postoperative high-sensitivity Troponin I measurements and the 30-day risk of death.

2. To determine the proportion of perioperative myocardial injuries that may go undetected during the first 5 days after surgery without perioperative troponin monitoring.

3. To determine the incidence of major vascular events during the first 30 days and 1 year after surgery.

Outcomes

Objective #1

- *Primary Outcome:* All-cause mortality at 30-days after surgery
- *Secondary Outcome:* Major vascular complications at 30-days after surgery (i.e., a composite of vascular death, nonfatal myocardial infarction, nonfatal stroke, and mechanical assist device)

Objective #2

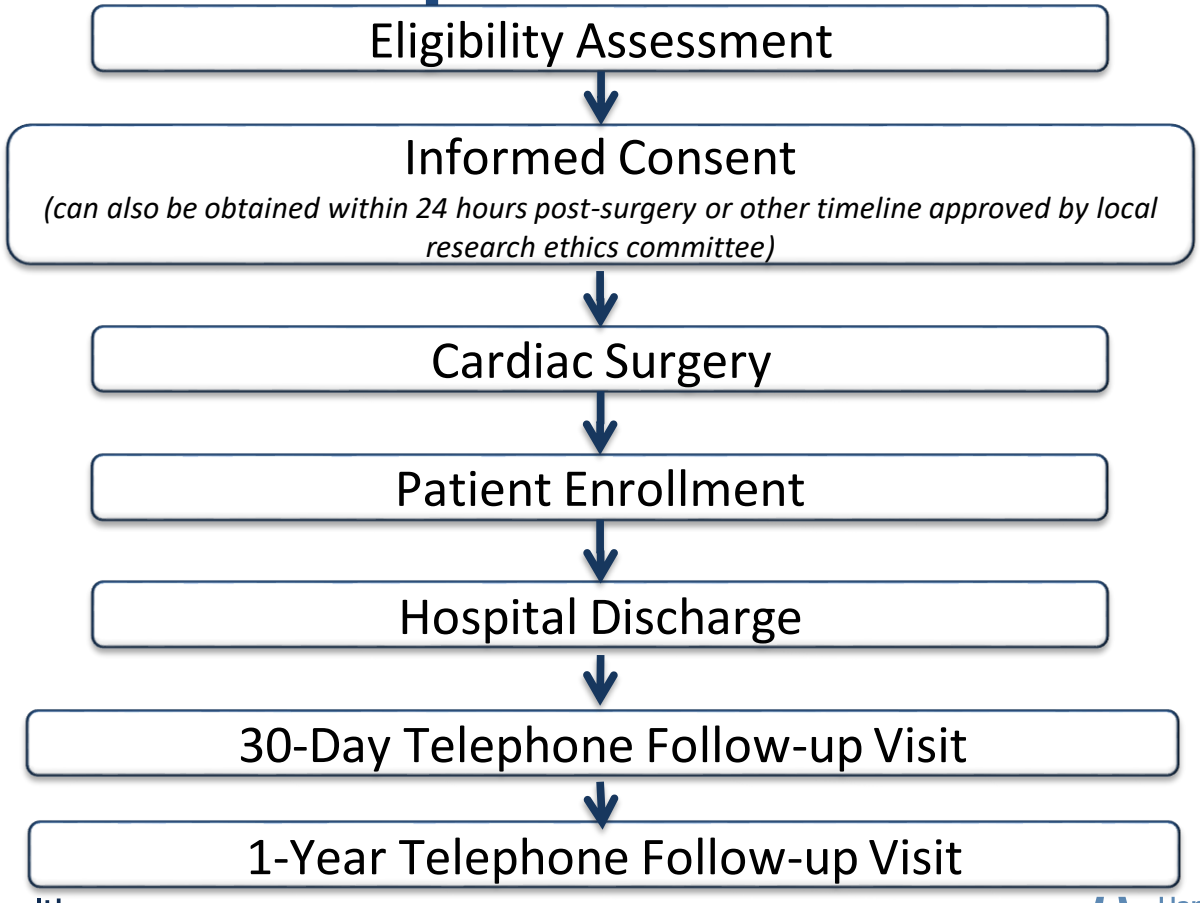
- *Primary Outcome:* Myocardial injuries that were not identified clinically during the first 5 days after surgery

Outcomes

Objective #3

- *Primary Outcome:* Major vascular complications at 30-days and separately at 1-year after surgery
- *Secondary outcome:* Include the following individual outcomes at 30 days and separately at 1 year after surgery: total mortality, vascular mortality, myocardial infarction, nonfatal cardiac arrest, stroke, implantation of mechanical assist device, cardiac transplant, repeat cardiac revascularization procedures, congestive heart failure, new clinically important atrial fibrillation, pulmonary embolus, deep venous thrombosis, major bleeding, new dialysis, sternal infection, pneumonia, sepsis, infection, re-hospitalization for a vascular reason, chronic incisional pain, frailty and functional status.

Follow-Up


Eligibility Assessment
Informed Consent
(can also be obtained within 24 hours post-surgery or other timeline approved by local research ethics committee)
Cardiac Surgery
Patient Enrollment
Hospital Discharge
30-Day Telephone Follow-up Visit
1-Year Telephone Follow-up Visit