An international prospective cohort study evaluating major vascular complications among patients undergoing noncardiac surgery: the VISION Pilot Study

The VISION Pilot Study Investigators

ABSTRACT

Objectives: Among patients undergoing noncardiac surgery, our objectives were to: (1) determine the feasibility of undertaking a large international cohort study; (2) estimate the current incidence of major perioperative vascular events; (3) compare the observed event rates to the expected event rates according to the Revised Cardiac Risk Index (RCRI); and (4) provide an estimate of the proportion of myocardial infarctions without ischemic symptoms that may go undetected without perioperative troponin monitoring.

Design: An international prospective cohort pilot study.

Participants: Patients undergoing noncardiac surgery who were > 45 years of age, receiving a general or regional anesthetic, and requiring hospital admission.

Measurements: Patients had a Roche fourth-generation Elecsys troponin T measurement collected 6 to 12 hours postoperatively and on the first, second, and third days after surgery. Our primary outcome was major vascular events (a composite of vascular death [i.e., death from vascular causes], nonfatal myocardial infarction, nonfatal cardiac arrest, and nonfatal stroke) at 30 days after surgery. Our definition for perioperative myocardial infarction included: (1) an elevated troponin T measurement with at least one of the following defining features: ischemic symptoms, development of pathologic Q waves, ischemic electrocardiogram changes, coronary artery intervention, or cardiac imaging evidence of myocardial infarction; or (2) autopsy findings of acute or healing myocardial infarction.

Results: We recruited 432 patients across 5 hospitals in Canada, China, Italy, Colombia, and Brazil. During the first 30 days after surgery, 6.3% (99% confidence interval 3.9–10.0) of the patients suffered a major vascular event (10 vascular deaths, 16 nonfatal myocardial infarctions, and 1 nonfatal stroke). The observed event rate was increased 6-fold compared with the event rate expected from the RCRI. Of the 18 patients who suffered a myocardial infarction, 12 (66.7%) had no ischemic symptoms to suggest myocardial infarction.

Conclusions: This study suggests that major perioperative vascular events are common, that the RCRI underestimates risk, and that monitoring troponins after surgery can assist physicians to avoid missing myocardial infarction. These results underscore the need for a large international prospective cohort study.

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Competing interests: None declared.

Disclosure: Roche Diagnostics is supplying the Troponin T assays for the full VISION Study in which the VISION Pilot investigators are participating.

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Annually, approximately 200 million adults worldwide undergo major noncardiac surgery.[1,2] Despite its benefits, noncardiac surgery is associated with adverse vascular complications, including vascular death, nonfatal myocardial infarction, nonfatal cardiac arrest, and nonfatal stroke.[2] The increase in the number of elderly patients undergoing surgery, the change in the invasiveness of some surgical interventions, and the limitations of previous research (e.g., dated information, focus on select high-risk groups, single-centre studies), highlight uncertainty about the current incidence of major vascular events among patients undergoing noncardiac surgery.[3] Accurate information about major vascular events associated with noncardiac surgery is necessary to inform clinicians, administrators, and granting agencies about the resources required to confront this problem.

Further, uncertainty exists regarding the optimal clinical risk estimation model for predicting major vascular events in patients undergoing noncardiac surgery.[4] Previous risk modelling studies were underpowered, and most studies were conducted in a single-centre university hospital in North America.[3] It is also important to know whether established risk models provide accurate risk prediction in countries throughout the world, as perioperative practices and outcomes may vary internationally. Accurate risk estimation is essential to facilitate informed patient and physician decision-making regarding the appropriateness of noncardiac surgery and to triage patients to the most appropriate care after surgery.

There is evidence from a large international randomized controlled trial and from several small prospective cohort studies that suggest troponin measurements after surgery can help physicians avoid missing perioperative myocardial infarction.[5,6] If monitoring troponins after noncardiac surgery helps physicians to detect perioperative myocardial infarction that would otherwise go undetected, troponin screening could facilitate appropriate and timely interventions.

We undertook a pilot study with the following objectives: (1) to determine the feasibility of conducting a large international prospective cohort study to address these uncertainties; (2) to estimate the current incidence of major vascular events in patients undergoing noncardiac surgery; (3) to compare the observed event rates with the expected event rates according to the Revised Cardiac Risk Index (RCRI);[3] and (4) to provide an estimate of the proportion of perioperative myocardial infarctions that may go undetected without troponin monitoring after surgery.

Methods

Study design and eligibility criteria. We conducted a prospective cohort study of patients undergoing noncardiac surgery. The **V**ascular events **I**n noncardiac **S**urgery pat**I**ents c**O**hort evaluatio**N** (VISION) Pilot Study was conducted at 5 centres: the Hamilton Health Sciences McMaster University Medical Centre (Hamilton, Canada), the Prince of Wales Hospital (Hong Kong, China), the Italian National Cancer Institute "Regina Elena" (Rome, Italy), the Hospital Universitario de Santander (Bucaramanga, Colombia), and the Hospital de Clinicas de Porto Alegre (Porto Alegre, Brazil). Three of these centres (China, Colombia, Brazil) were general surgical hospitals, one was a cancer hospital (Italy), and one was a site, within a general hospital, that focused on intra-abdominal and orthopedic surgery (Canada). The Research Ethics Board at each site approved the protocol before patient recruitment.

Patients were eligible if they underwent noncardiac surgery, were > 45 years of age, and received a general or regional anesthetic (plexus block, spinal, or epidural). We included patients who underwent surgery during the day or at night, on a weekday or weekend, or who underwent elective or urgent/emergent surgery. We excluded patients receiving only local or topical anesthesia, those not requiring at least an overnight hospital admission after surgery, patients previously enrolled in the VISION Pilot Study, and patients who did not consent to participate.

Patient recruitment. Most patients gave informed consent for participation in the study prior to surgery. Patients for whom we could not obtain consent preoperatively (e.g., some urgent/emergent and night surgical cases) were included if research personnel obtained consent within the first 24 hours after their surgery. Research personnel screened the daily patient list in the preoperative assessment clinic to identify eligible patients undergoing elective surgery. To identify eligible patients admitted through the emergency department and those who did not attend the preoperative assessment clinic, research personnel screened daily surgical lists, surgical lists from the previous day, patient lists for surgical wards and intensive care units, and patients in the preoperative holding area. Research personnel approached patients who fulfilled the eligibility criteria (or their families) to obtain written informed consent.

Data collection, monitoring, and follow-up. Research personnel interviewed and examined patients and reviewed their charts to obtain information on potential

predictors of major perioperative vascular events, including risk factors from the RCRI.[7] Patients had blood collected to measure a Roche fourth-generation Elecsys troponin T assay 6 to 12 hours postoperatively and on the first, second, and third days after surgery. The coefficient of variation is < 10% at 0.035 μg/L. Based upon guideline recommendations, we considered a troponin T value ≥ 0.04 μg per litre to be elevated. Patients enrolled between 12 and 24 hours after surgery had a troponin T drawn immediately and continued testing as outlined above. An electrocardiogram (ECG) was undertaken immediately after an elevated troponin measurement was detected. If a troponin T measurement was elevated but the patient had no ECG changes or ischemic signs or symptoms to fulfill the diagnostic criteria for myocardial infarction, then we recommended that the patient undergo an echocardiographic study.

Research personnel followed patients throughout their hospital stay, clinically evaluating them and examining their medical records to ensure that caregivers followed study orders and to identify primary and secondary outcomes. We contacted patients by phone at 30 days after surgery; if patients (or their families) indicated that they had experienced an outcome, we contacted their physicians to obtain documentation. Data collection forms and supporting documentation were faxed or entered online from participating centres directly to the iDataFax Management System at the coordinating centre in McMaster University.

Outcomes. Table 1 provides the outcome definitions. For our first objective (to determine the feasibility of conducting a large international cohort study), our primary outcome was achieving > 95% follow-up. For our second and third objectives (to estimate the current incidence of major vascular events and to compare the observed event rates with the expected event rates according to the RCRI), our primary outcome was major vascular events

Table 1: Outcome definitions

Outcome	Definition
Classification of death	Vascular death is defined as any death with a vascular cause and includes those deaths that occurred after myocardial infarction, cardiac arrest, stroke, cardiac revascularization procedure (i.e., percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery), pulmonary embolus, or hemorrhage; and deaths with an unknown cause. Non-vascular death is defined as any death with a clearly documented non-vascular cause (e.g. , trauma, infection, malignancy).
Myocardial infarction	The diagnosis requires either one of the following: 1. A typical rise of troponin or a typical fall of an elevated troponin detected at its peak post surgery in a patient without a documented alternative explanation for an elevated troponin (e.g., pulmonary embolism). This criterion also required that 1or more of the following defining features existed: a. Ischemic signs or symptoms (i.e., chest, arm, or jaw discomfort; shortness of breath, pulmonary edema) b. Development of pathologic Q waves ≥ 30 milliseconds in any 2 contiguous leads c. ECG changes indicative of ischemia (i.e., ST segment elevation [≥ 2 mm in leads V_1, V_2, or V_3 and ≥ 1 mm in the other leads], ST segment depression [≥ 1 mm], or symmetric inversion of T waves ≥ 1 mm in at least 2 contiguous leads) d. Coronary artery intervention (i.e., PCI or CABG surgery). e. New or presumed new cardiac wall motion abnormality on echocardiography or new or presumed new fixed defect on radionuclide imaging 2. Pathologic findings of an acute or healing myocardial infarction
Non-fatal cardiac arrest	The diagnosis requires a successful resuscitation from either documented or presumed ventricular fibrillation, sustained ventricular tachycardia, asystole, or pulseless electrical alternans.
Congestive heart failure	The diagnosis requires both clinical (i.e., any of the following signs: elevated jugular venous pressure, respiratory rales, crepitations, or presence of S3) and radiographic evidence (e.g., vascular redistribution, interstitial pulmonary edema, or frank alveolar pulmonary edema).
Clinically important atrial fibrillation	Atrial fibrillation that results in angina, congestive heart failure, symptomatic hypotension, or that requires treatment with a rate-controlling drug, anti-arrhythmic drug, or electrical cardioversion.
Hospital readmission for vascular reasons	Hospital readmission for congestive heart failure, ischemic symptoms with ST or T wave changes on an ECG, arrhythmia, or stroke.
Stroke	A new focal neurological deficit thought to be vascular in origin with signs and symptoms lasting more than 24 hours.

(a composite of vascular death, nonfatal myocardial infarction, nonfatal cardiac arrest, and nonfatal stroke) at 30 days after surgery. The original publication of the RCRI used a broad composite outcome of myocardial infarction, pulmonary edema, ventricular fibrillation or primary cardiac arrest, and complete heart block.[7] This initial broad composite outcome did not include death from cardiac causes.[7] A subsequent publication of the RCRI data focused on the composite outcome of death from cardiac causes, nonfatal myocardial infarction, and nonfatal cardiac arrest.[3] We used estimates from this subsequent publication as our expected event rates according to the RCRI, as this more closely matched our composite outcome.[3]

Individual secondary outcomes for our second objective included vascular mortality, myocardial infarction, cardiac arrest, stroke, congestive heart failure, new clinically important atrial fibrillation, and hospital readmission for vascular reasons at 30 days after surgery. For our fourth objective (to provide an estimate of the proportion of perioperative myocardial infarctions that may go undetected without perioperative troponin monitoring), our primary outcome at 30 days after surgery was any myocardial infarction without ischemic symptoms.

Two outcome adjudicators independently assessed all major vascular events without knowledge of the patient's vascular risk factors. All disagreements were resolved through a consensus process that required the adjudicators to discuss the reasoning behind their decisions. If disagreement persisted, a third adjudicator made a final decision.

Analysis. We used a Fisher's exact test to compare the proportion of urgent or emergent patients who underwent surgery on a weekend to the proportion who underwent surgery on a weekday. We determined the proportion of patients suffering a major vascular event and the associated 99% confidence interval. For all patients, we determined the expected number of major vascular events according to the RCRI and calculated the ratio of the observed to the expected number of events and the associated 99% confidence interval.

Ethical considerations. All patients or their families provided written informed consent.

Results

Patients were recruited over a 1- to 2-month period at each participating site. Sites joined the pilot study over a 4-year period. The first site started recruiting patients on 30 March 2005, and the last patient was recruited at the final site on 19 May 2009. We recruited 432 patients who met the eligibility criteria into the VISION Pilot Study, 17 (3.9%) of whom consented during the first 24 hours after surgery. The patient flow chart for recruitment across all sites is shown in Figure 1. A comparison of the study log with operating room surgical records, and, where available, hospital computer systems, demonstrated that study personnel approached 85.0% of all potentially eligible patients. Missed patients were primarily elective patients who were rescheduled on short notice, elective patients with the same booking time as many other elective cases, and some urgent/emergent patients who underwent weekend surgery and were missed by the weekend study personnel. Forty-eight patients refused to participate (10.0% refusal rate).

Table 2 presents the patient characteristics. Seventy-one patients (16.4%) underwent surgery within 72 hours of an acute event (i.e., urgent/emergent surgery). Of the 19 patients who underwent surgery on a weekend, 12 (63.2%) met our definition for urgent/emergent surgery, whereas 59 (14.3%) of the 413 patients who underwent surgery on a weekday were in this category ($p < 0.001$). Sixty-one (14.1%) patients had a history of coronary artery disease, and 184 (42.6%) had a history of hypertension.

The anesthesia received by patients included the following types: general, 369 patients (85.4%); spinal, 55 patients (12.7%); thoracic epidural, 35 patients (8.1%); lumbar epidural, 12 patients(2.8%); and nerve block, 12 patients (2.8%). Some patients received more than 1 type of anaesthesia. Patients underwent surgery for a median of 105 minutes (interquartile range [IQR] 70–165).

Three patients withdrew from the study, and we completed our 30-day follow-up on the remaining 429 (i.e.,

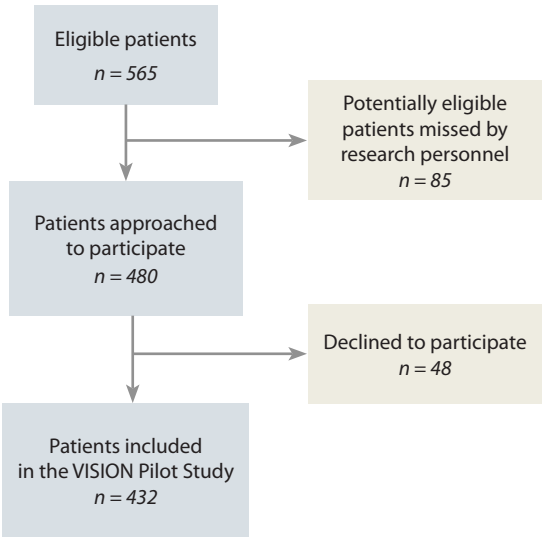

Figure 1: Patient flow chart

99.3% of patients completed follow-up). The median length of hospital stay was 5.5 days (IQR 3.0–10.0). During the first 30 days after surgery, 6.3% (99% CI 3.9–10.0) of the patients suffered a major vascular event (10 vascular deaths, 16 nonfatal myocardial infarctions, and 1 nonfatal stroke). Secondary outcomes included 10 (2.3%) patients who died of vascular causes, 18 (4.2%) patients who developed a myocardial infarction (16 nonfatal, 2 fatal), 2 (0.5%) patients who had a stroke (1 nonfatal and 1 fatal), 4 (0.9%) patients who developed congestive heart failure, 7 (1.6%) patients who developed new clinically important atrial fibrillation, and 1 (0.2%) patient who was readmitted to hospital for vascular reasons within 30 days after surgery. Among urgent/emergent surgery patients, 8 (11.3%, 99% CI 3.7–24.3) suffered a major vascular event, and 5 (7.0%, 99% CI 1.6—18.7) suffered a myocardial infarction within 30 days after surgery. Among elective surgery patients 19 (5.3%, 99% CI 2.7–9.1) suffered a major vascular event, and 13 (3.6%, 99% CI 1.6–7.0) suffered a myocardial infarction within 30 days after surgery.

Among the 18 patients who suffered a perioperative myocardial infarction, all had an elevated troponin T measurement and 1 or more of the following defining features: 6 (33.3%) had ischemic signs or symptoms, 3 (16.6%) developed ST segment elevation, 5 (27.8%) developed ST segment depression, 9 (50.0%) developed T wave inversions, 1 (5.6%) underwent a coronary artery intervention, and 5 (27.8%) had a new or presumed new cardiac wall motion abnormality on echocardiography. All of the patients who suffered a myocardial infarction and had a new or presumed new wall motion abnormality on echocardiography also had ischemic ECG changes.

Table 2: Patient characteristics

Characteristics	Canada (n = 99)	Colombia (n = 50)	Italy (n = 101)	Hong Kong (n = 111)	Brazil (n = 71)	Total (n = 432)
Mean age, years (SD)	64 (11)	65 (13)	64 (100	64 (13)	61 (8)	63 (11)
Female sex, n (%)	60 (60.6)	26 (52.0)	50 (49.5)	54 (48.6)	39 (54.9)	229 (53.0)
Type of surgery						
Orthopedics	9 (9.1)	14 (28.0)	0 (0.0)	9 (8.1)	4 (5.6)	36 (8.3)
Intra-abdominal	43 (43.4)	9 (18.0)	6 (5.9)	24 (21.6)	21 (29.6)	103 (23.8)
Neurosurgery	0 (0.0)	1 (2.0)	0 (0.0)	13 (11.7)	2 (2.8)	16 (3.7)
Urology/Gynecology	0 (0.0)	9 (18.0)	54 (53.5)	14 (12.6)	15 (21.1)	92 (21.3)
Head & Neck surgery	1 (1.0)	1 (2.0)	10 (9.9)	4 (3.6)	2 (2.8)	18 (4.2)
Thoracic	0 (0.0)	2 (4.0)	20 (19.8)	2 (1.8)	3 (4.2)	27 (6.3)
Vascular	0 (0.0)	1 (2.0)	0 (0.0)	1 (0.9)	7 (9.9)	9 (2.1)
Low-risk surgeries	46 (46.5)	14 (28.0)	11 (10.9)	52 (46.8)	18 (25.4)	141 (32.6)
Timing of surgery, n (%)						
< 24 hours after acute event	3 (3.0)	4 (8.0)	0 (0.0)	12 (10.8)	2 (2.8)	21 (4.9)
24–72 hours after acute event	14 (14.1)	11 (22.0)	0 (0.0)	21 (18.9)	4 (5.6)	50 (11.6)
Other	82 (82.8)	35 (70.0)	101 (100)	78 (70.3)	65 (91.6)	361 (83.5)
History of coronary artery disease, n (%)	20 (20.2)	5 (10.0)	12 (11.9)	15 (13.5)	9 (12.7)	61 (14.1)
History of peripheral vascular disease, n (%)	2 (2.0)	5 (10.0)	8 (7.9)	1 (0.9)	7 (9.9)	23 (5.3)
History of cerebrovascular event, n (%)	6 (6.1)	3 (6.0)	2 (2.0)	10 (9.0)	4 (5.6)	25 (5.8)
History of congestive heart failure, n (%)	4 (4.0)	0 (0.0)	0 (0.0)	1 (0.9)	2 (2.8)	7 (1.6)
Use of insulin or an oral hypoglycemic, n (%)	13 (13.1)	2 (4.0)	7 (6.9)	12 (10.8)	14 (19.7)	48 (11.1)
Hypertension, n (%)	36 (36.4)	15 (30.0)	44 (43.6)	46 (41.4)	43 (60.6)	184 (42.6)
Smoking status, n (%)						
Never	68 (68.7)	23 (46.0)	39 (38.6)	77 (69.4)	31 (43.7)	238 (55.2)
Current	15 (15.1)	4 (8.0)	30 (29.7)	15 (13.5)	15 (21.1)	78 (18.2)
Former	16 (16.2)	23 (46.0)	32 (31.7)	19 (17.1)	25 (35.2)	115 (26.6)
Serum creatinine >1175 μmol/L, n (%)	0 (0.0)	2 (4.0)	1 (1.0)	4 (3.6)	5 (7.0)	12 (2.8)

*Low-risk surgeries include: parathyroid, thyroid, breast, hernia, local anorectal procedure, oopherectomy, salpingectomy, endometrial ablation, peripheral nerve surgery, ophthalmology, ears/nose/throat surgery, vertebral disc surgery, spinal fusion, hand surgery, cosmetic surgery, arterio-venous access surgery for dialysis, other surgeries.

Table 3 reports the observed major vascular event rates and the expected major vascular event rates according to the RCRI. Observed event rates were 6 fold higher (99% CI 3.5–9.7) than the expected event rates according to the RCRI.[3]

The median number of protocol troponin assays measured (maximum of 4 per patient) was 4.0 (IQR 3.0–4.0) per patient. Of the 18 patients who suffered a myocardial infarction, 12 (66.7%) had no ischemic symptoms to suggest myocardial infarction, but all had another defining feature of myocardial infarction (e.g., ischemic ECG changes). Therefore, probably 12 (66.7%) of these myocardial infarctions would have gone undetected without perioperative troponin monitoring.

Table 3: Observed and expected event rates (according to the Revised Cardiac Risk Index) by number of risk factors

	Number of risk factors†	Number of patients	Observed events‡	Observed event rate	Expected event rate§	Expected events	Ratio of observed to expected events (99% CI*)
Canada	0	41	0	0%	0.4%	0.18	0 (0–28.8)
	1	39	3	7.7%	1.0%	0.37	8.0 (0.9–29.4)
	2	12	2	16.7%	2.4%	0.28	7.1 (0.4–32.8)
	≥ 3	7	3	42.9%	5.3%	0.37	8.0 (0.9–29.3)
	All	**99**	**8**	**8.1%**	**1.2%**	**1.21**	**6.6 (2.1–15.3)**
Colombia	0	30	1	3.3%	0.4%	0.13	7.4 (0.04–55.2)
	1	18	3	16.7%	1.0%	0.17	17.4 (2.0–63.8)
	2	1	0	0%	2.4%	0.02	0 (0–224.9)
	≥ 3	1	0	0%	5.3%	0.05	0 (0–99.1)
	All	**50**	**4**	**8.0%**	**0.8%**	**0.38**	**10.4 (1.8–32.8)**
Italy	0	64	2	3.1%	0.4%	0.29	7.0 (0.4–32.3)
	1	28	1	3.6%	1.0%	0.27	3.7 (0.02–27.7)
	2	7	0	0%	2.4%	0.16	0 (0–32.1)
	≥ 3	2	0	0%	5.3%	0.11	0(0–49.6)
	All	**101**	**3**	**3.0%**	**0.8%**	**0.83**	**3.6 (0.4–13.3)**
Hong Kong	0	62	2	3.2%	0.4%	0.28	7.2 (0.4–33.3)
	1	36	4	11.1%	1.0%	0.34	11.6 (2.0–36.6)
	2	6	0	0%	2.4%	0.14	0 (0–37.5)
	≥ 3	7	3	42.9%	5.3%	0.37	8.0 (0.9–29.3)
	All	**111**	**9**	**8.1%**	**1.0%**	**1.14**	**7.9 (2.8–17.6)**
Brazil	0	29	0	0%	0.4%	0.13	0 (0–40.7)
	1	25	1	4.0%	1.0%	0.24	4.2 (0.02–31.1)
	2	12	0	0%	2.4%	0.28	0 (0–18.7)
	≥ 3	5	2	40.0%	5.3%	0.27	7.5 (0.4–34.7)
	All	**71**	**3**	**4.2%**	**1.3%**	**0.92**	**3.3 (0.4–11.9)**
Total	***0***	226	5	2.2%	0.4%	1.01	4.9 (1.1–13.9)
	1	146	12	8.2%	1.0%	1.40	8.6 (3.5–17.3)
	2	38	2	5.3%	2.4%	0.90	2.2 (0.1–10.4)
	≥ 3	22	8	36.4%	5.3%	1.18	6.8 (2.2–15.8)
	All	**432**	**27**	**6.3%**	**1.0%**	**4.48**	**6.0 (3.5–9.7)**

† Risk factors = ischemic heart disease, cerebrovascular event, congestive heart failure, diabetes, creatinine > 175 μmol/L, and high risk surgery (i.e., vascular, intraperitoneal, or intrathoracic)

‡ Events = cardiovascular death, nonfatal myocardial infarction, nonfatal cardiac arrest, or nonfatal stroke

§ Expected event rates = rates based on the Revised Cardiac Risk Index[3]

* CI = confidence interval

Discussion

Principal findings. Among patients >45 years of age undergoing noncardiac surgery requiring hospital admission, we demonstrated a 6.3% (99% CI 3.9–10.0) event rate for major vascular events during the first 30 days after surgery. In our study, the RCRI substantially underestimated the risk of major perioperative vascular events. Physicians probably would have missed a majority (i.e., 66.7%) of perioperative myocardial infarctions if we had not monitored troponin measurements during the first few days after surgery.

Strengths and weaknesses of the study. Strengths of our study include its reflection of current practice across multiple international hospital sites (with representation from North America, South America, Europe, and Asia). Research personnel used a wide variety of approaches to identify eligible patients (e.g., screening patient lists in the preoperative assessment clinic, surgical wards, intensive care units, and preoperative holding area). We included patients who underwent urgent/emergent surgery, and patients who underwent surgery on weekends. Two independent outcome adjudicators, blinded to patients' vascular risk factors, evaluated all major vascular events, and we used a consensus process to resolve disagreements. We achieved 99.3% follow-up at 30 days after surgery.

Our study has several limitations. We enrolled only 432 patients and observed only 27 major vascular events; therefore, the findings of this pilot study warrant cautious interpretation. We evaluated the accuracy of the RCRI but were unable to conduct similar analyses according to other risk indices (e.g., Veterans Affairs Model, Modified Cardiac Risk Index)[8,9] because the original publications did not report the precision of their estimates. Using the data from the original RCRI Study, we previously reported the expected incidence of major perioperative cardiac events (i.e., cardiac death, nonfatal myocardial infarction, and nonfatal cardiac arrest) according to the RCRI Score.[3] In the VISION Pilot Study our primary outcome also included fatal and nonfatal stroke. This increased our observed event rate; however, this accounts only for a small portion (i.e., 2 events) of the difference between our observed event rate (i.e., 27 events) and our expected event rate (i.e., 4.5 events), Table 3.

Our study in relation to other studies. Considering prior research, the study by Lee and colleagues[7] provides the best estimate of the incidence of major vascular events in unselected adults undergoing noncardiac surgery requiring hospital admission.[3] This study suggests that major perioperative vascular events occur in 1.4% (95% CI 1.0–1.8%) of adults.[3]

Several potential explanations exist for the higher event rate (i.e., 6.3%) in the VISION Pilot Study. First, the patient population may have changed in the time (i.e., >a decade) between the study by Lee et al. and our study. Since then patients with coronary artery disease are living longer and developing conditions that require noncardiac surgery, and a higher proportion of elderly patients are now undergoing noncardiac surgery, raising questions regarding the applicability of Lee and colleagues results from the late 1980s and early 1990s. Second, we used troponin T whereas Lee and colleagues used CK-MB in the diagnostic criteria for myocardial infarction. CK-MB is prone to false-positive and false-negative values for perioperative myocardial infarction.[5] Third, we included emergent surgical cases (8 events occurred in emergent patients), and we considered stroke a major adverse outcome whereas the study by Lee and colleagues excluded emergent surgical cases, and stroke was not considered as a major vascular event.[7] Our study included data from 5 hospitals in 5 countries, whereas the study by Lee and colleagues included patients from a single hospital. Finally, our results may represent a chance finding as a consequence of the small sample size.

We are unaware of any prior studies that have compared observed event rates to the expected event rates according to the RCRI. Several prior studies have demonstrated similar results to our current finding that most patients suffering a perioperative myocardial infarction do not experience ischemic symptoms. Three small prospective cohort studies[10–12] of patients undergoing various noncardiac surgeries who had at least 1 postoperative measurement of a cardiac enzyme or biomarker suggested that approximately half (45%, 95% CI 29–62%) of the patients who suffered a perioperative myocardial infarction had no ischemic symptoms to suggest myocardial infarction.[5] One large international study that evaluated 415 perioperative myocardial infarctions demonstrated that 65.3% of these patients did not experience ischemic symptoms, and patients suffering an asymptomatic perioperative myocardial infarction had equally poor prognoses as patients suffering a perioperative myocardial infarction with ischemic symptoms.[6] The findings from these studies and the VISION Pilot Study provide consistent and strong evidence that monitoring troponin measurements after surgery will allow physicians to avoid missing the majority of patients suffering a perioperative myocardial infarction.

On the basis of the results of the VISION Pilot Study we have initiated the full-scale large international VISION Study. This study is designed to ensure adequate power (i.e., we aim to have at least 720 major vascular events) to allow us to determine the optimal clinical risk estimation model for predicting major perioperative vascular events and myocardial infarction. A model establishing risk groups for perioperative myocardial infarction will allow us to determine the cost to avoid missing a myocardial infarction across risk groups, and this will allow physicians and funders to decide what patient groups they want to target for monitoring troponin measurements after surgery. An accurate risk estimation model for major perioperative vascular complications is essential to facilitate informed patient and physician decision-making regarding the appropriateness of noncardiac surgery. Further, such a model has the potential to improve patient outcomes through the identification of high-risk patients who may benefit from prophylactic measures (e.g., a statin) and enhanced monitoring after surgery (e.g., telemetry unit).[2]

Conclusions

Our results suggest that major perioperative vascular events are more common than previously reported, that the RCRI underestimates risk, and that monitoring troponins after surgery will allow physicians to avoid missing myocardial infarction. Results from the ongoing VISION Study will further inform these issues.

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