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Cerebrovascular accident and acute coronary syndrome and perioperative outcomes (CAPO) study protocol: a 10-year database linkage between Hospital Episode Statistics Admitted Patient Care, Myocardial Infarction National Audit Project and Office for National Statistics registries for time-dependent risk analysis of perioperative outcomes in English NHS hospitals

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ABSTRACT

Introduction An increasing number of people who have a history of acute coronary syndrome or cerebrovascular accident (termed cardiovascular events) are being considered for surgery. Up-to-date evidence of the impact of these prior events is needed to inform person-centred decision making. While perioperative risk for major adverse cardiac events immediately after a cardiovascular event is known to be elevated, the duration of time after the event for which the perioperative risk is increased is not clear.

Methods and analysis This is an individual patient-level database linkage study of all patients in England with at least one operation between 2007 and 2017 in the Hospital Episode Statistics Admitted Patient Care database. Data will be linked to mortality data from the Office for National Statistics up to 2018, for 30-day, 90-day and 1-year mortality and to the Myocardial Ischaemia National Audit Project, a UK registry of acute coronary syndromes. The primary outcome will be the association between time from cardiovascular event to index surgery and 30-day all-cause mortality. Additional associations we will report are all unplanned readmissions, prolonged length of stay, 30-day hospital free survival and incidence of new cardiovascular events within one postoperative year. Important subgroups will be surgery specific (invasiveness, urgency and subspecialty), type of acute coronary syndrome (ST or non-ST elevation myocardial infarction) and type of cerebrovascular accident (ischaemic or haemorrhagic stroke).

Ethics and dissemination Ethical approval for this observational study has been obtained from East Midlands—Nottingham 1 Research Ethics Committee; REC reference: 18/EM0403. The results of the study will be made available through peer-reviewed publications and via the Health Services Research Centre of the Royal College of Anaesthetists, London.

Strengths and limitations of this study

- This is the largest database linkage study to date on perioperative outcomes as related to prior cardiovascular events.
- Use of robust data sources (Hospital Episode Statistics, Office for National Statistics and Myocardial Infarction National Audit Project) comprised of national, prospectively collected data reflects overall current clinical practice and is not limited to clinical trial patients therefore making the results more generalisable.
- There is not the clinical equipoise to randomise patients with prior cardiovascular events to surgery or not, especially on the scale of this study looking at all non-cardiac non-neurologic surgery over a period of 10 years.
- This study will produce models for time-dependent perioperative risk in patients with a history of cardiovascular events addressing an identified gap in the evidence.
- The study is limited by including only people with a known previous cardiovascular event in the registries used, with the potential to miss those in whom their cardiovascular risk status is unknown.

INTRODUCTION

Cardiovascular events are recognised risk factors for perioperative morbidity and mortality.[1–3] However, the original data on

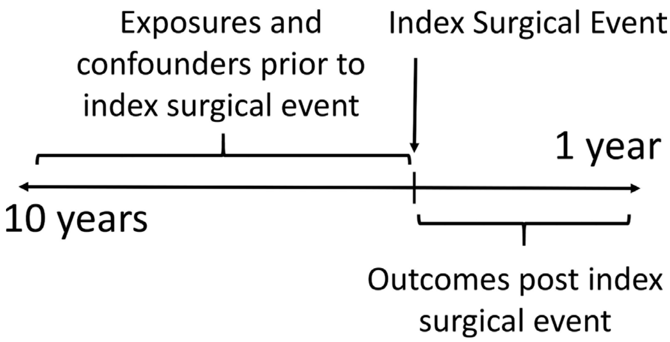

Figure 1 Schematic of study design. Schema to represent the time periods of interest for the overall study from data collection of patient risk factors 10 years prior to their first ‘index’ surgery through to follow-up for outcomes up to 1 year postoperatively.

cerebrovascular accidents (stroke) and acute coronary syndrome (ACS) supporting this assertion are increasingly less relevant to current medical practice: treatment of stroke and ACS along with the resultant prognoses have improved significantly. The Myocardial Infarction National Audit Project (MINAP) has demonstrated the use of primary percutaneous coronary intervention for ST-elevation myocardial infarction in England has risen from 82% to 99.3%, in eligible patients, from 2011 to 2016.[4] UK and European data show crude 30-day mortality has fallen from 12.4% to 9.07% in MINAP (2003 to 2018) and from 15.8% to 9.2% in SWEDEHEART (1995 to 2014).[5–7] From 1999–2008 the crude 56-day mortality from stroke has fallen from 21% to 12%,[8] though it has not fallen significantly since.[9] As a consequence, surgery is being offered to patients with comorbidities previously felt to be significantly high risk or to preclude surgery completely.[10 11]

The duration of time for which risk is increased after a cardiovascular event (ACS or stroke) is based on limited evidence,[12 13] nor is it well known which characteristics of the event or which treatments received at the time may be predictive of an adverse perioperative outcome in the future. This study will ascertain at an individual patient level the strength of any time- dependent association between preoperative cardiovascular events and postoperative mortality, as well as the occurrence of any postoperative major adverse cardiovascular events (MACE). Our aim in the ‘Cerebrovascular accident and Acute coronary syndrome and Perioperative Outcomes’ (CAPO) study is to perform a database linkage between the HES, MINAP and ONS databases for all adult patients who have had non-cardiac, non-neurosurgical operations with NHS funding between 2007 and 2017 in hospitals in England.

It will represent, to the best of our knowledge, the largest study of the time-dependent nature of adverse perioperative outcomes in patients with a known cardiovascular risk factor. We are prospectively publishing our methodology to openly prespecify our study population and statistical analysis plan.

METHODS AND ANALYSIS

Study design

This is a longitudinal observational cohort study of patients undergoing surgery between 2007 and 2017. All data to be analysed have been prospectively collected as part of one of the several national registries. We have data sharing agreements and ethical approval to individually link data for all patients who have had NHS commissioned surgery in any hospital in England between these dates in the Hospital Episode Statistics (HES) Admitted Patient Care (APC) data set to mortality data from the Office for National Statistics (ONS), to those who have had ACS captured in the MINAP from 2003 onwards (the start of MINAP data collection). Patients with a cardiovascular event in the 10 years preceding their index surgery, or within one postoperative year, will be identified in HES APC as well as MINAP. This is described schematically in figure 1.

Data sources

HES APC data set: This is a national registry database containing details of all admissions to NHS hospitals in England. Each HES record contains clinical information about diagnoses and operations, as well as patient, administrative and geographical information. HES data have been available since 1989. NHS Digital is the data controller. We will first identify all patients with a preoperative or postoperative stroke or ACS, in the 10 years preceding index surgery and 1 year postsurgery, from the entire cohort who had surgery between 2007 and 2017. The most recent cardiovascular event preceding the index surgery will be used for calculating the time interval in the primary outcome. This data set will be from HES APC 1997 to 2018.

ONS: The ONS mortality data contain information related to a person’s death taken from the death certificate for all deaths registered in England and Wales. NHS Digital is the data controller. This will be the source of mortality data for primary outcome analysis. This will be ONS data from 2007 to 2018.

MINAP: This is a national cardiac clinical audit that collects information to measure the process and outcomes of care of every patient diagnosed with a myocardial infarction in the UK.[14] MINAP data are available from 2003. The National Institute for Cardiovascular Outcomes Research (NICOR) is the data processor and Healthcare Quality Improvement Partnership is the data controller. This will be the MINAP data set from 2003 to 2018.

MINAP will serve as a secondary method for identifying preoperative and postoperative ACS and as the primary method for obtaining specific treatments of the preoperative ACS events and the pathophysiologic data as detailed in the predictor measurements below.

The MINAP case ascertainment rate is well documented in an accompanying document for annual reports. It highlights the continued trend from their previous reports that non-ST elevation myocardial infarction (NSTEMI) events are underreported whereas there is near complete capture of ST-elevation myocardial infarction (STEMI; which they can reliably cross reference to the NICOR Adult Coronary Intervention Audit. This report also demonstrates some of the data discrepancies between HES and MINAP registries.[15 16]

There is a similar national registry for stroke with data from 2012 onwards that is analogous to MINAP. The programme was approached but declined to provide the requested data for the linkage study during the data-linkage window.

Data linkage

NHS Digital will perform rule-based linkage between these data sets using the following record level indicators: NHS numbers (unique identifier assigned at birth or during first contact with NHS care), date of birth, postcode and sex. Once the databases are linked, they perform the pseudoanonymisation process to enable transfer to our institution for analysis.

Data set cleaning

The data in the HES APC undergo a documented cleaning process prior to linkage.[17] After the linkage of NHS Digital's HES APC and ONS to HQIP's MINAP data set, the data will be further cleaned to identify duplicates, lack of agreement and potentially erroneously linked patient episodes.

Participants

Study population selection

All patients aged ≥18 years of age on the day of surgery with an attendance to hospital in the HES APC data set between 2007 and 2017 for an operative procedure are identified using the OPCS-4 codes for surgical procedures, HES APC 'admission date' and HES APC 'age on admission' fields. From this, we will identify patient's first surgical episode within the study window which will act as the index surgical event. The patient's first operation will used in the primary outcome measure.

Patients with a history of ACS or stroke (termed cardiovascular events) in the 10 years preceding this index surgical event will be defined according to their primary diagnosis ICD-10 codes in HES APC and further ACS case identification will occur using with MINAP specific codes (online supplemental appendix 1).

To assess the effect of operative severity, a classification based on OPCS-4 codes taking an inclusive, intermediate and restrictive interpretation of the surgical invasiveness will be used as already described by others.[18] For subgroup analysis of outcomes, we also classify operations by surgical type such as major lower limb joint replacement, vascular, gastrointestinal, gynaecological, urological, ENT, ophthalmological and breast surgery (online supplemental appendix 2). For each of these types of surgery, we will take each patient's first operation within a defined subgroup. Sensitivity analysis will also be performed comparing that analysis by taking the patient's last operation within the same subgroup. There are key operative categories for exclusion: cardiac, neurosurgical, carotid endarterectomy, obstetrics, tracheostomy and percutaneous gastrostomy as identified using their OPCS-4 codes (online supplemental appendix 2). The decision to exclude cardiac surgery was on the basis of a pre-existing subspecialty specific risk prediction tool EuroSCORE II, thus reducing the need to investigate this population. The lack of specificity within ICD-10 codes also means it is not possible to identify type III-V myocardial infarctions, therefore the results may be unreliable in this specific patient population. Neurosurgery and carotid endarterectomy are excluded based on the recognised high stroke risk specific to these surgeries.[19] Both percutaneous gastrostomy insertion and tracheostomy formation were excluded due to a frequent indication for them being poststroke bulbar dysfunction. Obstetric surgical procedures are outside the scope of this study.

Validation studies of codes/algorithms

The use of HES APC data for identifying patients with the preoperative cardiovascular events as risk factors and linking this to ONS data for mortality has already been robustly demonstrated.[20] NHS Digital (HES) and the ONS openly publish how their databases are regularly checked to ensure accuracy of the recorded data, and their methods of data cleaning and quality assurance.[17 21] To the best of our knowledge, this is the first time MINAP will have been combined with surgical fields of HES and there are therefore no pre-existing data on the linkage of MINAP to HES and ONS databases for perioperative outcome measures. The use of OPCS-4 codes for identifying severity of surgical insult has already been well described.[18]

Variables

Exposures

The primary exposure will be the time interval between the most recent preoperative cardiovascular event and index surgery, identified from the 10-year HES data set. MINAP will be the secondary source of identifying ACS events. Table 1 describes how the exposures of interest are identified from the registries. Where this is detailed further, information is provided in the appendices.

Time between preoperative cardiovascular event and surgery will be fitted as a continuous variable for the primary outcome. Additionally, we will provide the time between preoperative event and surgery as categorical data using thresholds at 30 days, 90 days, 6 months and 1 year. The treatment of time as categorical data is to provide clinically meaningful risk intervals in addition to the robust continuous data. These intervals are chosen to allow comparison with the time intervals currently used in clinical practice to delineate time thresholds of increased perioperative risk in those with a preoperative history of a cardiovascular event, and for comparison to existing publications.[3 12] Restricted splines will be used for the time between preoperative cardiovascular event and index surgery in the logistic regression model as necessary.

Table 1 Exposures to identify patients for inclusion in the models based on their diagnostic criteria and the data sources from which these are derived

Exposure	Source of data	Diagnostic criteria*
Myocardial infarction	HES	I21+22
	MINAP	See online supplemental appendix 1
STEMI	HES and MINAP	See online supplemental appendix 1
NSTEMI		
Unstable angina		
Stroke (CVA)	HES	I61, 63, 64
Ischaemic stroke		I63
Haemorrhagic stroke		I61
Transient ischaemic attack		G45.8, G45.9

*ICD-10 codes only, MINAP specific coding in online supplemental appendix 1.
CVA, cerebrovascular accident; HES, Hospital Episode Statistics Hospital Acute Patient Care; ;MINAP, Myocardial Infarction National Audit Project; NSTEMI, non-ST elevation myocardial infarction; STEMI, ST elevation myocardial infarction.

Table 2 Adverse perioperative outcomes to be measured in patients undergoing surgery 2007–2017

Outcome	Source of data	Note
Death within 30 days	ONS	Primary outcome
Death within 90 days		
Death within 60 days		
Death within 1 year		
Readmission ≤30 days	HES	
Prolonged* length of stay		
Hospital free survival 30 days		
CVA within 1 year of surgery		Excluding TIA
ACS within 1 year of surgery	HES and MINAP	Including UA and NSTEMI
AMI within 1 year of surgery		Including STEMI and NSTEMI

*Prolonged defined as a length of stay above the national upper quartile for the calendar year of index surgery, where>100 cases were performed per annum).
ACS, acute coronary syndrome; AMI, Acute myocardial infarction; CVA, cerebrovascular accident; HES, Hospital Episode Statistics; MINAP, Myocardial Infarction National Audit Project; NSTEMI, non-ST elevation myocardial infarction; STEMI, ST-elevation myocardial infarction; TIA, transient ischaemic attack; UA, unstable angina.

Outcomes

The combined HES-MINAP data set will link to the ONS dates of death to 1 year after surgery. The primary outcome is the association between the time interval from preoperative cardiovascular event to index surgery and 30-day all cause postoperative mortality.

The secondary outcomes are mortality at other time points, length of stay and cardiovascular events after surgery as described in table 2.

For length of stay calculations, we will use the same process already well described elsewhere.[22 23] In brief, HES APC data codes admissions in the form of multiple finished consultant episodes where transfer of care between consultants generates a new episode. The conventional concept of an admission to hospital is termed a 'spell' in HES APC data and represents contiguous Finished Consultant Episodes. A 'super-spell' is the concept of incorporating an admission that spans episodes at multiple hospital trusts which we will use when calculating the total length of stay.

Exploratory analysis on postoperative recovery will comprise of measuring the proportion of days alive and out of hospital up to 30 days postoperatively.[24] These will only be hypothesis generating and reported separately from the above outcomes.

Confounding

The potential confounders in all patients from HES APC that will be included as covariates in the modelling are: age, sex, deprivation index decile ('Index of Multiple Deprivation'), ethnicity, comorbidities (using ICD-10 codes for hypertension, atrial fibrillation, stable angina, peripheral vascular disease, valvular heart disease, congestive heart failure, respiratory failure, diabetes mellitus, renal failure, cancer and liver disease as per table 3), year of surgery and hospital provider (to account for clustering of patients within hospitals). The deprivation index used by HES is 'Index of Multiple Deprivation'.[25] The Charlson Comorbidity Index will be also be calculated as described in online supplemental appendix 3.[26] For people with MINAP data, additional predictors will be included in our models as detailed in table 4.

Selection bias

HES data are recorded by coders specifically trained in recording of healthcare related data based on clinical records. NHS Digital (HES APC) and ONS mortality data involve quality assurance processes and these are published quarterly on their websites.[17 21]

Sample size

The proportion of people undergoing surgery with a previous cardiovascular event has been shown to be 2.7% for ACS and 0.7% for stroke in a UK study of elective joint arthroplasty,[20] and from 1.5% to 5% for stroke in international studies of elective non-cardiac operations.[13 27] The number of intermediate category operations is estimated to be 44 million over 10 years extrapolating from work by Abbott and colleagues.[18] Using a conservative estimate of 30-day mortality of 1.02% (table 5), there would be approximately 450 000 deaths in the study.

Table 3 Characteristics general to all surgical patients with a history of cardiovascular for inclusion in the models as confounders of perioperative outcome

Confounder	Source of data	Diagnostic criteria
Age	HES	HES demographic data
Year of birth		
Sex		
Deprivation index decile		
Year of surgery		
Charlson Comorbidity Index		See online supplemental appendix 3
Hypertension		ICD-10 codes (see online supplemental appendix 4)
Atrial fibrillation		
Stable angina		
Peripheral vascular disease		
Valvular heart disease		
Congestive heart failure		
Respiratory failure		
Diabetes mellitus		
Renal failure		
Cancer		
Liver disease		
Hospital provider		

HES, Hospital Episode Statistics.

For the a priori subgroup of total hip and knee arthroplasty, where annual numbers are around 100 000 and mortality is 0.2% at 30 days, approximately 2000 deaths would be observed. Taking the heuristic for logistic regression of 10 events per predictor, this would allow analysis of greater than 100 predictors.

While this could be considered an overpowering for the study to detect mortality differences in elective arthroplasty patients, it is necessary to power the study to detect differences in less frequently performed operations wherein the patient population is much smaller but the importance of cardiovascular burden of disease is still highly relevant, and for operations in which mortality is much rarer.

Statistical methods

Primary outcome

Primary analysis will be undertaken using logistic regression modelling for the association between the time interval from the most recent preoperative cardiovascular event to index surgery, and the postoperative 30-day mortality.

Control for confounding

The procedure for logistic regression will follow established guidelines and the covariates are summarised above in tables 3 and 4.[28] Models will account for the clustering of patients within hospitals using random hospital-level effects as necessary.[29] Model performance will be summarised using receiver operating characteristic curve concordance statistic, calibration plots and Brier scores.

Table 4 Characteristics specific to patients with a preoperative ACS event for inclusion in the models as predictors for perioperative outcome

Predictor	Source of data	Diagnostic criteria
Type of myocardial event	HES and MINAP	See online supplemental appendix 1
Primary percutaneous coronary intervention		
Territory of infarction		
Reperfusion treatment*	MINAP	
Thrombolysis		
Left ventricle ejection fraction		
QRS width		
Killip class		
Cardiac arrest		
Peak troponin		
Reinfarction		
High-risk NSTEMI		

*Reperfusion treatments as a predictor will have the following levels: primary percutaneous coronary intervention, thrombolysis, urgent coronary artery bypass graft and none.
ACS, acute coronary syndrome; MINAP, Myocardial Infarction National Audit Project; NSTEMI, non-ST elevation myocardial infarction.

Subgroup analysis

Secondary analyses will use logistic regression analysis to address the following subgroups a priori. The invasiveness of surgery and the surgical specialty will be used to form subgroups as well as surgical urgency (elective and emergency). The categorisation of surgery is described in detail in online supplemental appendix 2. For those with prior ACS, analysis will be between STEMI and NSTEMI; unstable angina will be excluded. In patients with preoperative history of stroke, the subgroups will be ischaemic or haemorrhagic stroke; transient ischaemic attacks will be excluded. Additionally, subgroups will analyse those

Table 5 Perioperative UK mortality data 2009–2014 stratified by invasiveness of surgery derived by Abbott and colleagues[18]

	Inclusive	Intermediate	Restrictive
Approximate annual numbers in England	6.8 million	4.4 million	1.3 million
Mortality			
30 days	1.10%	1.02%	1.50%
60 days	1.77%	1.57%	2.24%
90 days	2.31%	2.02%	2.83%

with more than one preoperative cardiovascular event: multiple ACS events as compared with one ACS event, multiple strokes as compared with one stroke, and those with both ACS and stroke as compared with only one of ACS or stroke.

Variables in the regression models will include all comorbidities on surgical admission, patient demographics of age, deprivation index and ethnicity. Survival analysis will be used where continuous time-to-death data are available, plotting Kaplan-Meier survival curves for mortality after surgery in those with and without a preoperative cardiovascular event. Cox proportional-hazards model will be used to provide an estimate of the median endpoint ratio as well as HR.

Missing data

Missing data will be dealt with in two ways. The extent is expected to be generally modest with HES. We anticipate needing to exclude <0.1% of records with an unknown or invalid age, sex and length of stay following the linkage process. Records with unknown deprivation index will be assigned to a placeholder deprivation decile and retained for analysis. With MINAP, missing data for continuous variables will be handled using standard multiple imputation. For categorical variables, we will create an artificial category as for missing deprivation in HES.

Limitations

During the study period, four successive iterations of the universal definition of myocardial infarction have been adopted, with the potential to effect change in which patients are captured in HES data. Within the use of ICD-10 codes for HES APC, the changes in definition are minor, and many of the changes in the universal definitions concern those surrounding myocardial injury and ischaemia around the time of a cardiac intervention, thus not meaningfully affecting the study populations' incidence of all cause myocardial infarction. We recognise that not all patients who have had a cardiovascular event will have presented to an English hospital or received inpatient care.

The data granularity of HES precludes absolute differentiation of whether the postoperative myocardial infarctions were type 1 (coronary artery disease related) or type 2 (related to a supply/demand imbalance).

Clinical management of ACSs and strokes has evolved over this time: particularly, wider access to primary percutaneous coronary intervention for STEMI and endovascular clot retrieval in strokes. At the same time, perioperative management of patients with a previous vascular event has also progressed over this time as the evidence on the perioperative management of anticoagulants and antiplatelets changed.

Generalisability

These are patient-level national data incorporating all available non-cardiac, non-neurosurgical operations in NHS hospitals in England and NHS-commissioned services performed in private hospitals in England over a 10-year period. As such, these represent real-world data incorporating how evidence is applied to clinical practice, not only how patients within the constraints of a clinical trial may be managed. It will also represent analysis of the largest data set of perioperative MACE outcomes in patients with a history of ACS or CVA.

While the data sets cover England, prior work has demonstrated concordance between Danish registries and HES based studies, which would suggest the results are generalisable to at least northern European healthcare settings.[19]

ETHICS AND DISSEMINATION

Formal applications for data sharing have been made to relevant bodies including: research ethics committee approvals for the linkage of these data sets for secondary analysis of the data (REC reference: 18/EM0403, East Midlands—Nottingham 1 REC on 19/12/2018); HRA Confidentiality Advisory Group (CAG) with respect to Section 251 (4) of the NHS Act 2006 (CAG ref: 19/CAG/0013) in order that we could retrieve and receive anonymised patient data from NHS digital and MINAP without consent from patients. CAG's statutory role is to consider the feasibility of obtaining consent for research for what in this study will be approximately 44 million admissions. To comply with relevant UK/EU data protection, legislation privacy notices will be displayed through the organisations that hold the data and a mechanism for opting out will be made available for patients to dissent to the use of their pseudoanonymised data prior to linkage.

The expected output from linking these databases is the most robust estimate to date of any time-dependent association between a preoperative cardiovascular event and postoperative MACE. Secondary analyses will stratify patients' risk by the degree of surgical invasiveness and surgical specialty; the type of the stroke or ACS and patients with multiple preoperative cardiovascular events. For those with ACS, we will also investigate how the treatment received and pathophysiology at the time of their preoperative event may be predictive of subsequent adverse perioperative outcomes.

Reporting of the results will be through publication within peer-reviewed journals, posters and presentations at scientific and educational meetings, and to the public through online media so as to obtain maximal reach and inform patient choice as well as expanding scientific knowledge.

PATIENT INVOLVEMENT

The research topic itself has been identified as a research priority by the recent James Lind Alliance priority setting partnership, which was a coproduction between patients, researchers and clinicians. MINAP and NHS Digital have robust patient and public involvement in their approvals process, which is independent of the authors.

Comments were also sought from the Royal College of Anaesthetists' 'Patient, Carer and Public Involvement and Engagement in research' working group, a body of clinicians and members of the public; they were also supportive of the study.

As this study is non-intrusive, working with completely anonymised data and where the outcomes were already fixed by the nature of the databases, there was no need identified for further patient and public involvement.

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Contributors IKM and TMM were responsible for the developing the original idea for the study. All authors (MSL, WL, TMM and IKM) were involved in the writing of the study protocol, MSL drafted the first version of this manuscript, and all authors approved the final version prior to submitting it for publication.

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