European Surgical Outcomes Study (EuSOS)

A multi-centre, international seven day evaluation of patient care and clinical outcomes for patients undergoing non-cardiac surgery

Study protocol version 1.0

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Introduction

The high-risk non-cardiac surgical population represents a major global healthcare challenge. Recent estimates suggest that 234 million major surgical procedures are performed worldwide each year [1]. Complications following major surgery are a leading cause of morbidity and mortality [2-7]. Sickness absence to undergo surgery is second only to cardiovascular disease in terms of associated long-term mortality [2]. In the overall population, the incidence of post-operative complications and death is low. However, studies from the UK suggest a readily identified high-risk sub-group accounts for over 80% of post-operative deaths but less than 15% of in-patient procedures [5, 6]. In the UK,170,000 patients undergo high-risk non-cardiac surgery each year [5, 6]. Of these patients, 100,000 will develop significant complications resulting in over 25,000 deaths [5-7]. Advanced age, co-morbid disease, major and urgent surgery are the key factors associated with increased risk [5-7]. This pattern of poor outcomes following major surgery can be readily identified worldwide [2-10]. Patients who develop complications but survive will still suffer reductions in functional independence and a substantial decrease in medium and long-term survival [2-4]. A prospective 13 year observational study of the Whitehall II cohort of 6478 British civil servants aged 35-55 examined the link between diagnoses associated with medical absence from work and long term all-cause mortality [2]. Physician-certified sickness absence attributable to undergoing a surgical operation was associated with a two-fold increased risk of mortality. Apart from circulatory disease, surgery was associated with the highest risk of later death compared to psychiatric, infectious, and respiratory disease. Despite strong evidence of the impact of poor surgical outcomes, our understanding of standards of care for patients undergoing major surgery is limited. In particular, little is known about the availability of critical care resources for non-cardiac surgical patients and the impact of critical care admission on clinical outcomes. Importantly, survival amongst patients who develop postoperative complications varies widely between hospitals, confirming both the potential and the need to improve clinical outcomes in this population [11].

Recent developments in peri-operative critical care may significantly improve outcomes for high-risk non-cardiac patients. However, new therapeutic approaches are unlikely to be translated into patient benefit unless suitable critical care facilities are available where they can be administered. In the UK, recent studies have demonstrated that fewer than one third of high-risk non-cardiac surgical patients are admitted to critical care following surgery [5, 6]. In addition, those patients who did receive this level of care were discharged after a median stay of 24 hours and subsequently lingered for many days on standard surgical wards. Premature discharge from critical care was identified as an important risk factor for post-

operative death, suggesting a failure to correctly identify those patients who can be discharged appropriately from critical care [5, 6]. This situation contrasts starkly with peri-operative care for cardiac surgical patients for whom post-operative critical care admission is routine. Cardiac surgical patients also have a high incidence of co-existing disease and undergo major surgery but with an overall mortality rate as low as 2% [12-15]. These observations may relate to poor availability of critical care beds in the UK. However published data do not support this suggestion [16], whilst other data suggest poor surgical outcomes are an international healthcare problem [2-11].

Little is known about standards of care for patients undergoing major non-cardiac surgery across Europe or clinical outcomes following such procedures. It has been suggested by some that poor surgical outcomes may vary between nations but this belief may simply reflect better recognition of the issue. Evidence from sources across the developed world suggests the existence of a large population of patients who can be readily identified as being at high risk of post-operative complications and death [2-10]. There is increasing recognition of the massive potential impact of even small improvements in peri-operative care [17, 18]. However, significant policy change can only be driven by robust and powerful data. Mismatch between critical care resource provision and peri-operative risk may be widespread or confined to a small number of nations. Either way, a rigorous evaluation of standards of peri-operative critical care across Europe would provide important data which could trigger a step-change in the current approach to care of the patient undergoing major non-cardiac surgery.

Research questions

1. What is the in-hospital mortality rate for patients undergoing non-cardiac surgery in Europe?

2. What is the duration of hospital stay for patients undergoing non-cardiac surgery in Europe?

3. What is the current standard of peri-operative critical care provision for patients undergoing non-cardiac surgery in Europe?

4. What is the current standard of haemodynamic (cardiac output) monitoring for patients undergoing non-cardiac surgery in Europe?

5. Is there any evidence of differences in the standard of peri-operative care provision for patients undergoing non-cardiac surgery in different health-care systems within Europe?

6. Is there any evidence of differences in hospital stay and mortality for patients undergoing major non-cardiac surgery in different health-care systems within Europe?

7. What factors determine planned and unplanned admission to critical care after surgery?

8. Are the factors associated with critical care admission similar to those associated with post-operative death?

Methods

Seven day, international cohort study of adult (≥16 years) patients undergoing in-patient non-cardiac surgery.

Inclusion criteria

Consecutive patients admitted to participating centres undergoing elective and non-elective non-cardiac surgery commencing during the seven day study period (00^{00} day 1 to 24^{00} day 7) with a planned overnight stay.

Exclusion criteria

Patients undergoing planned day-case surgery, cardio-thoracic surgery, neurosurgery, radiological or obstetric procedures.

Centres

We aim to recruit as many European centres as possible. We anticipate that a minimum of 150 hundred centres in ten or more nations will be required. We are hopeful that we can meet or exceed this target through the activities of national lead investigators and the support of key organisations such as the European Society of Intensive Care Medicine and the European Society of Anaesthesiology. Centres will receive an individual report allowing comparison of their dataset to that of their national cohort and of the overall dataset. We hope this will act as an incentive to participate.

Ethics approval

Ethics approval may not be required in all participating nations. National lead investigators will be responsible for clarifying the need for ethics approval and applying for this where appropriate. Centres will not be permitted to record data unless ethics approval or an equivalent waiver is in place. This study is in effect a large scale clinical audit. We expect that in most, if not every participating country, there will be no requirement for individual patient consent as all data will be anonymised and is already recorded as part of routine clinical care.

Data collection and collation

Data will be collected in individual centres on paper case record forms (CRFs). Data will then be pseudo-anonymised (coded) and transcribed by local investigators onto an internet based electronic CRF. The paper and electronic CRFs will be translated by the national lead investigators into the relevant languages (English, German, French, Italian, etc) and checked for consistency after back translation into English. CRFs will then be validated in each participating nation by the national lead investigators prior to patient recruitment. Paper CRFs will be stored within a locked office in each centre. This will include identifiable patient data in order to allow follow-up of clinical outcomes. Each centre will be identified by a numeric code and each patient will be assigned a numeric code at the point of electronic data entry. This will allow local investigators to identify individual patients whilst the co-ordinating study team cannot trace data back to an individual patient. Access to the data entry system will be protected by username and password. Username and password will be delivered during the registration process for individual local investigators. All electronic data transfer between participating centres and the co-ordinating centre will be username and password protected. Each centre will maintain a trial file including a protocol, local investigator delegation log, ethics approval documentation etc. A participant (patient) list will be used in each participating centre to match identifier codes in the database to individual patients in order to record clinical outcomes and supply any missing data points. Where individual centres are unable to access the internet based case record form, pseudo-anonymised (coded) facsimile (fax) data transfer will be available to a dedicated fax machine in the co-ordinating office. Pseudo-anonymised (coded) data may also be sent by mail to the coordinating centre if necessary.

Dataset

A realistic data set will be fundamental to the success of the investigation. We have identified the key data points whilst not discouraging centres from participating through an excessive burden of data collection. The reliability of data collection will be analysed formally using K-statistics or intra-class correlation coefficients as appropriate. National co-ordinators may request the addition of a limited number of data points to support the international EuSOS data collection and for subsequent national analyses. All additional data points must be discussed with the chief investigator and if necessary, the steering committee.

Form A: Centre specific data (collect once for each centre)

- Secondary/tertiary centre
- Number of operating rooms
- Number and level of critical care beds.
- Details about the reimbursement status of the hospital
- Public holidays or other local factors affecting patient throughput during study period

Form B: Individual patient data on all patients

Patient factors:

- Age
- Gender
- American Society of Anesthesiologists (ASA) grade
- Date of hospital admission
- Major co-morbid disease including:
    - Heart failure
    - Active cancer
    - Diabetes
    - Asthma / COPD
    - Renal failure

Surgical factors:

- Surgical procedure category
- Grade of surgery (minor, intermediate, major)
- Urgency of surgery (elective or non-elective)
- Duration of surgery (mins)
- Grade of surgeon
- Surgical checklist (Y/N)

Anaesthetic factors:

- Anaesthetic technique (general, regional, sedation)
- Haemodynamic (cardiac output) monitoring
- Airway (endotracheal, laryngeal mask, tracheostomy, etc)
- Grade of anaesthetist

Post-operative care:

- Duration of extended recovery stay (hours)
- Post-operative invasive ventilation within first 24 hours (planned / unplanned)
- Post-operative non-invasive ventilation within first 24 hours (planned / unplanned)
- Post-operative inotrope / vasopressor use within first 24 hours

Follow-up data:

- Date of Hospital discharge
- In-hospital mortality

Form C: Individual patient data for those admitted to critical care

Critical Care admission:

- Body height and mass
- Critical care admission: Date and time
- Critical care admission: planned/unplanned
- Critical care admission: time since surgery
- Detailed co-morbidities
- Airway at ICU admission (endotracheal, laryngeal mask, tracheostomy, etc)
- Ventilatory support at ICU admission (invasive / non-invasive / none)
- Respiratory arrest prior to critical care admission
- Cardiac arrest prior to critical care admission
- Component data for SAPS III score
- SOFA score (one of four scores in each of six domains)

Physiological data following 24 hours in critical care:

- SOFA score (one of four scores in each of six domains)
- Respiratory support (invasive or non-invasive)
- Renal replacement therapy (planned or unplanned)

Physiological data following 48 and 72 hours in critical care:

- SOFA score (one of four scores in each of six domains)
- Respiratory support (invasive or non-invasive)
- Renal replacement therapy (planned or unplanned)

Follow-up data for patients admitted to critical care:

- Critical care discharge: Date and time
- SOFA score in last 24 hours of ICU stay (for patients staying ≥96 hours)
- Major therapeutic limitation during ICU stay (Y / N, date)
- Critical care discharge: planned or unplanned
- Critical care mortality

Sample size calculation

We anticipate that approximately 20,000 patients will be required to provide a sample of up to 2,000 admissions to critical care after surgery. Assuming an overall mortality rate following surgery of 1%, a sample size of 20,000 patients will yield 200 deaths. This will allow the inclusion of at least fifteen variables in a logistic regression model for mortality. The rate of admission to critical care is likely to vary between nations but an overall rate of 10% (either planned or unplanned) will yield data on 2000 admissions to critical care, whilst an overall rate of 5% will yield 1000 admissions. We expect this to allow a robust logistic regression model for this outcome. 20,000 patients will also provide >99% confidence for the overall mortality rate with 0.37% confidence width. This dataset would also have sufficient generalisability to inform the practice of peri-operative care on an international basis. If 200 deaths are observed in an overall sample of 20,000 patients, the 99% confidence interval for the proportion would be (0.0083 - 0.0120) with a confidence width of 0.37%. This dataset would also have sufficient generalisability to inform the practice of peri-operative care on an international basis.

Statistical analysis

The data to be collected are all collected as part of routine clinical care. Categorical variables will be described as proportions and will be compared using chi-square or Fisher's exact test. Continuous variable will be described as mean and standard deviation if normally distributed or median and inter-quartile range if not normally distributed. Comparisons of continuous variables will be performed using one-way ANOVA or Mann-Whitney test as appropriate. Uni-variate analysis will be performed to test factors associated with planned and unplanned admission to critical care and / or in-hospital death. A multiple logistic regression model will be used to identify independent risk factors. A stepwise approach will be used to enter new terms into the logistic regression model where $p<0.05$ was set as the

limit for inclusion of new terms. A logistic regression model will be performed to assess independent association between prognostic factors and outcomes. Results of logistic regression will be reported as adjusted odds ratios (OR) with 95% confidence intervals. A single final analysis is planned at the end of the study.

Primary outcome measure

- In-hospital mortality

Secondary outcome measures

- Duration of hospital stay
- Planned admission to critical care
- Unplanned admission to critical care
- Duration of critical care stay

Organisation

Subject to funding approval, it is proposed that the EuSOS study will be conducted by the EuSOS study group on behalf of the European Society of Intensive Care Medicine and the European Society of Anaesthesiology. The steering committee will be chaired by RP. The study management team will be appointed by the steering committee and led by RP. The duties of this team will include administration of all project tasks, communication between project partners (including funders, steering committee members, national and local co-ordinators, etc), data collation and management and preparation of reports for individual study sites. The Steering committee is responsible for the scientific conduct and consistency of the project. The Steering committee will ensure communication between the funder(s), study management team and co-ordinators as necessary.

National co-ordinators

National co-ordinators will be appointed by the steering committee to lead the project within individual nations and:

- Identify local co-ordinators in participating hospitals
- Assist with translation of study paperwork as required
- Ensure distribution of research manuals, eCRF and other materials
- Ensure necessary regulatory approvals are in place prior to the start date
- Ensure good communication with the participating sites in his/her nation

Local co-ordinators

Local co-ordinators in individual institutions will have the following responsibilities:

- Provide leadership for the study in their institution
- Ensure all relevant regulatory approvals are in place for their institution
- Ensure adequate training of all relevant staff prior to data collection
- Supervise daily data collection and assist with problem solving
- Act as guarantor for the integrity and quality of data collected
- Ensure timely completion of eCRFs
- Communicate with the relevant national coordinator

Data management and ownership

On behalf of the steering committee, Queen Mary's University of London will act as custodian of the data. The Steering committee will retain the right to use all pooled data for scientific and other purposes. Members of the EuSOS study group will have the right to access the pooled data for research purposes provided the research proposal has been reviewed and deemed satisfactory by the Steering committee. The primary consideration for such decisions will be the quality and validity of any proposed analysis. Only summary data will be presented publicly and all institutions will be anonymised except in the individualised report provided to each institution at the end of the study. Individual patient data provided by participating sites remain the property of the respective institution.

Publication plan

Data will be presented and disseminated in a timely manner. In discussion with the funder(s), the steering committee will appoint a writing committee to draft the scientific report(s) of this investigation. Specific funding is requested to allow publication of data on an open access basis. On request, centres will be provided with an individual report allowing comparison of their individual centre's summary data to that of their national cohort and the overall dataset. In line with the principles of data preservation and sharing, the steering committee will, after publication of the overall dataset, consider all reasonable requests to make the dataset available in whole or part for secondary analyses and scientific publication. The steering committee will consider the scientific validity and the possible effect on the anonymity of participating centres prior to granting any such requests. Where appropriate, a prior written agreement will set out the terms of such collaborations. The steering committee will consider proposals for secondary analyses on the basis of the scientific quality of the proposal. National groups may wish to perform secondary analyses specifically of their

national dataset. Such proposals are generally encouraged and the Steering committee will make the national datasets available to national co-ordinators on receipt of a national study proposal. However, the steering committee must approve the final version of all manuscripts prior to submission, whether they relate to part or all of the EuSOS dataset.

Deliverables

The main deliverables will be scientific reports of preliminary findings for general and specialty journals, abstracts for presentation to national and international meetings including those of the supporting societies and a final report summarising the overall findings.

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Appendix: Definitions

Anaesthetic technique

General anaesthesia: Pharmacologically induced state of unconsciousness in order to facilitate surgical procedure

Sedation: Pharmacologically induced reduced level of consciousness during which verbal contact is maintained

Regional anaesthesia: injection or infusion of a clinically effective dose of local anaesthetic and / or opioid drugs in order to provide clinically effective anaesthesia

Severity of surgery

Minor: Procedure of less than 30 minutes duration performed in a dedicated operating room which would often involve extremities or body surface or brief diagnostic and therapeutic procedures.
Examples include: *arthroscopy without intervention, removal of small cutaneous tumour, diagnostic proctology procedures, biopsy or excision biopsy of small lesions, etc*

Intermediate: More prolonged or complex procedure performed in a dedicated operating room that may pose the risk of significant complications or tissue injury.
Examples include: *laparoscopic cholecystectomy, arthroscopy with intervention, bilateral varicose vein removal, tonsillectomy, inguinal hernia repair, breast lump resection, haemorrhoidectomy, appendicectomy, partial thyroidectomy, cataract surgery, uvuloplasty, minimally invasive repair of vaginal prolapse, vaginal hysterectomy, tendon repair of hand, fixation of mandibular fracture, etc*

Major: Any surgical procedure that requires anaesthesia, performed in a dedicated operating room and is expected to last more than 90 minutes.
Examples include: *major gut resection, major joint replacement, mastectomy, extensive head and neck tumour resection, abdominal aortic aneurysm repair, major vascular bypass procedure, procedures involving free flap to repair tissue defect, amputation, total thyroidectomy, cystectomy, trans-urethral resection of prostate, resection of liver tumour, carotid endarterectomy, nephrectomy, total abdominal hysterectomy, spinal discectomy, etc*

Urgency of surgery

Elective:	Not immediately life saving; planned within months or weeks
Non-elective:	As soon as possible after resuscitation and ideally within 24 hours

American Society of Anesthesiologists (ASA) score:

I	A normal healthy patient
II	A patient with mild systemic disease which does not limit physical activity
III	A patient with severe systemic disease which limits physical activity
IV	A patient with severe systemic disease that is a constant threat to life
V	A patient who is not expected to survive for 24 hours without the operation

Duration of surgery

Time in minutes from induction of anaesthesia to patient leaving the operating room

Post-anaesthetic recovery unit

A post-anaesthetic recovery unit is dedicated facility for the care of all patients following surgery under anaesthesia. This does not include units which routinely care for invasively ventilated patients overnight. Duration of stay is the time from arrival to departure measured in minutes.

Post-operative Critical Care

For this study, a critical care unit is defined as a facility routinely capable of admitting patients who require invasive ventilation overnight. This differs from a post-anaesthetic recovery unit which has a primary purpose to provide care for all patients after anaesthesia regardless of dependency. Duration of stay is the time from arrival to departure measured in hours (part hours to count as one whole hour).

Duration of hospital stay

Time in days from the day of surgery to the day the patient leaves hospital. This will not be adjusted for delays relating to provision of social care in the community.

Haemodynamic (cardiac output) monitor

Any technology which provides a measurement of cardiac output. This would include oesophageal Doppler, pulmonary artery catheter and arterial waveform analysis but not devices which solely estimate arterial pressure variability.