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Determining universal processes related to best outcome in emergency abdominal surgery: a multicentre, international, prospective cohort study

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ABSTRACT

Introduction: Emergency abdominal surgery outcomes represent an internationally important marker of healthcare quality and capacity. In this study, a novel approach to investigating global surgical outcomes is proposed, involving collaborative methodology using 'snapshot' clinical data collection over a 2-week period. The primary aim is to identify internationally relevant, modifiable surgical practices (in terms of modifiable process, equipment and clinical management) associated with best care for emergency abdominal surgery.

Methods and analysis: This is a multicentre, international, prospective cohort study. Any hospital in the world performing acute surgery can participate, and any patient undergoing emergency intraperitoneal surgery is eligible to enter the study. Centres will collect observational data on patients for a 14-day period during a 5-month window and required data points will be limited to ensure practicality for collaborators collecting data. The primary outcome measure is the 24 h perioperative mortality, with 30-day perioperative mortality as a secondary outcome measure. During registration, participants will undertake a survey of available resources and capacity based on the WHO Tool for Situational Analysis.

Ethics and dissemination: The study will not affect clinical care and has therefore been classified as an audit by the South East Scotland Research Ethics Service in Edinburgh, Scotland. Baseline outcome measurement in relation to emergency abdominal surgery has not yet been undertaken at an international level and will provide a useful indicator of surgical capacity and the modifiable factors that influence this. This novel methodological approach will facilitate delivery of a multicentre study at a global level, in addition to building international audit and research capacity.

Trial registration number: The study has been registered with ClinicalTrials.gov (Identifier: NCT02179112).

BACKGROUND

Surgery has an undeservedly low profile in global health priorities.[1] It was not mentioned in the Millennium Development Goals despite an estimated 11–15% of the global burden of disease amenable to surgical treatment.[2] Currently, an estimated 234 million major surgeries are performed worldwide per year, but less than 4% of these reach the populations of the poorest one-third of the world's countries,[3] indicating that there is a considerable unmet surgical need, which has been shown by population-based studies.[4] The situation is aggravated by an acute shortage of patient-level data on surgical outcomes globally[5]—data from high-income countries (HICs) may lack relevance and comparability in low-income and middle-income countries (LMICs)—but previously published work from the UK indicates that postoperative mortality affects up to 15% of patients and morbidity up to 30%.[6 7] There may be a double burden of low access to surgical care and high risk of adverse outcomes in large parts of the world and there is growing recognition of the need to address this issue, as manifested by the recently launched Lancet Commission on Global Surgery,[8] the upcoming third edition of the Disease Control Priorities Project with a full volume on Surgery, and the recent decision by the WHO Executive Board to include a proposed resolution on access to safe surgery and anaesthesia on the agenda of the 2015 World Health Assembly.

Emergency abdominal surgery, including laparotomy, appendectomy and hernia repair is performed in acute hospitals across the world and is likely to be subject to performance variation.[9] Emergency laparotomy is a standard of acute abdominal surgery (including for traumatic injuries, a leading cause of death in young people around the world[10]), and is the most invasive procedure with the highest side effect profile.[7]

Aims

In order to address the lack of surgical outcomes data, we will conduct a global audit of emergency abdominal surgery outcomes, utilising a novel approach to a global surgical outcomes project, that involves collaborative methodology, including institutions in HIC and LMIC settings, and using 'snapshot' clinical data collection.[11 12] This is in keeping with a proposed framework by an international expert group.[13] The primary aim of this study is to identify modifiable surgical practices (in terms of modifiable process, equipment and clinical management) associated with best care. The secondary aims are to describe the epidemiology of indication for emergency abdominal surgery and determine baseline experience and capacity for local audit in surgical settings.

Hypothesis

Detecting variation associated with outcomes of common emergency abdominal surgical operations, and modifiable practices associated with this variation, can act as surrogate markers for best performance of acute surgical units.[9 14]

METHODS

Study design

This is a multicentre, prospective observational study of consecutive patients undergoing emergency intraperitoneal surgery that will be carried out by participants during 14-day, consecutive time periods of the individual participant's choice during a 5-month study period window.

Study setting

All acute care surgical units worldwide are eligible to enter. Centres must ensure that they can include consecutive patients and provide >95% data completeness (centres with >5% missing data will be excluded from analysis). There is no minimum number of patients per centre, as long as the patient(s) included are consecutive and multiple teams covering differing periods from one institution are encouraged.

Patient inclusion and exclusion criteria

The inclusion and exclusion criteria are summarised in box 1. Patients of all ages (adult and paediatric) undergoing emergency intraperitoneal surgery during the chosen period are eligible for inclusion. Emergency procedures are defined as unplanned, non-elective operations and include reoperations after previous procedures. Intraperitoneal surgery includes laparoscopic, laparoscopic converted and open cases. This could include gastrointestinal, vascular, urological and gynaecological surgery.

Elective (planned) or semielective (where the patient is initially admitted as an emergency, then discharged from hospital, and readmitted at later time for surgery) procedures are excluded, along with caesarean sections. The latter represent a separate operative group, whose priorities and treatment pathways differ from those of other abdominal emergency operations, and they have been studied in detail elsewhere.

Outcome measures

The primary outcome measure is the 24 h perioperative mortality rate. This is the number of deaths during operation or within 24 h of conclusion of an operation, divided by the number of operations performed during the same time period.[15] The main secondary outcome measure is the 30-day perioperative mortality rate. This is defined as the total number of deaths within 30 days of a surgical operation divided by the total number of emergency abdominal operations performed during the same time period. Where it is unfeasible to follow patients for 30 days, in-hospital mortality rate (death during hospital stay) will be used as a proxy. The 30-day serious complication rate will be used as a third main outcome measure. These outcomes represent grade III and V of the internationally standardised and validated Clavien-Dindo classification[16] and chiefly occur during the index stay at the hospital, minimising the risk of loss to follow-up. Although not all centres have the critical care facilities necessary to treat grade IV complications, the scale will provide a measure of the reintervention rate. These outcomes are in keeping with those recommended by WHO Safe Surgery Saves Live Measurement and Study Groups.[13] The primary and secondary outcomes measures are summarised in box 2.

Data points

In addition to the main outcome measures, data points related to the patient, surgeon, operation, hospital, operative method and postoperative period will be collected (table 1). In order to maximise completion, the minimum required data set has been designed to be brief and to test only those factors that are likely to be relevant. Descriptions of included data points are

Box 1 Study inclusion and exclusion criteria

Inclusion criteria
- Patients of all ages (adult and paediatric);
- Consecutive patients during the chosen study period;
- Undergoing emergency intraperitoneal surgery;
- Intraperitoneal surgery includes laparoscopic, laparoscopic converted and open cases. This could include gastrointestinal, vascular, urological and gynaecological surgery;
- Emergency procedures are defined as unplanned, non-elective operations and include reoperations after previous procedures.

Exclusion criteria
- Elective (planned) or semielective procedures (where the patient is initially admitted as an emergency, then discharged from hospital, and readmitted at later time for surgery);
- Caesarean sections.

Box 2 Study inclusion and exclusion criteria

Primary outcome measure

- A 24 h perioperative mortality rate. This is defined as the number of deaths during operation or within 24 h of conclusion of an operation, divided by the number of operations performed during the same time period.

Secondary outcomes measures

- A 30-day perioperative mortality rate. This is defined as the total number of deaths within 30 days of a surgical operation divided by the total number of emergency abdominal operations performed during the same time period.
- A 30-day serious complication rate. These outcomes represent grades III and V of the internationally standardised and validated Clavien-Dindo classification.[16]

provided in online supplement 1. Data will be entered by local investigators via a secure online webpage, provided using the Research Electronic Data Capture (REDCap) system[17] hosted at the University of Edinburgh, Scotland. All patient data will be transmitted and held anonymously; the data will not be analysed at identifiable hospital or surgeon level. Identification of individual hospital or surgeon performance will not be reported. To test outcome variation across different contexts, explanatory variables including the 2012 Human Development Index (HDI) and Healthcare Expenditure Per Capita will be retrieved for each of the participating countries and included in statistical analysis.

Investigators

This study will be carried out by investigators from around the world that will disseminate the study protocol, collect data at hospitals, coordinate the study on national levels and finally analyse and write the manuscript. Investigators contributing to data collection will be required to register the details of their unit complete an online survey of previous experience and knowledge of audit principles followed by a training module, and complete a pilot audit prior to starting.

Each included hospital will have a local investigator, required to register centrally for updates, preferably providing an institution email address to maximise the legitimacy of local investigators, or if not possible, a letter of confirmation from their department or colleague.

At each centre, local investigators can form a team of up to three people (including themselves) to accurately perform patient identification and data collection. Local investigators will be specifically responsible for gaining local audit or research approval, forming a research team to identify patients and collect data and creating mechanisms to identify and include eligible patients (including daily review of operating theatre lists, team handover sheets, emergency admission lists, ward lists and operating theatre logbooks). Centres should also be proactive in identifying postoperative events (or an absence of them), within the limits of normal follow-up. Local arrangements may include daily review of patient status and notes during admission and before discharge to identify in-hospital complications, reviewing the patient status in outpatient clinic or via telephone at 30 days (if this is normal practice), checking hospital records (electronic or paper) or handover lists for reattendances or readmissions, checking for emergency department reattendances. All investigators will be registered as study coauthors.

Prestudy survey

Before data collection starts, a survey, based on the WHO Tool for Situational Analysis to assess Emergency and Essential Surgical Care, will be performed. In order to pilot data collection locally, all participating centres will be asked to complete patient identification and the initial stages of the data collection form for 1 day during the month leading up to the data collection starting date. This will familiarise local teams with hospital pathways and data systems, and allow any queries to be addressed prior to starting formal data collection.

Statistical analysis and power calculation

At the conclusion of data collection, data will be retrieved from the RedCap database and analysed by members of the study team using the R Foundation Statistical Programme. An estimated rate of seven emergency bowel resections in a 14-day period from 200 centres will provide a minimum data collection for 1400 patients. This will provide adequate power to detect a treatment practice associated with a 2.5% difference in the 24 h perioperative mortality rate (5–7.5%, α 0.05, power 80%). Power calculations were performed using R V.3.0.2 (The R Foundation for Statistical Computing).

Subgroups analyses will be performed based on major (midline laparotomy) versus minor surgical procedures (eg, appendicectomy through non-midline, hernia repair through groin incision), and trauma versus non-trauma indications.

Differences between demographic groups will be tested with the χ^2 test. Multivariable binary logistic regression will be used to test the influence of variables on the outcome measures. Variables entered into these models will be those that may have directly affected the event, were clinically plausible and that occurred before the outcome event. They will be predefined and used to adjust the main explanatory variables irrespective of statistical outcome. Model fit and calibration will be tested.

ETHICS AND DISSEMINATION

Research ethics approval

The proposed study will not affect clinical care and has therefore been classified as an audit of surgical care by the South East Scotland Research Ethics Service in Edinburgh, Scotland (see online supplement 2). However, the mechanisms for gaining permission to perform this study may vary from country to country

Table 1 Required data fields

Data field	Alternatives
Patient ID	Local hospital field
Age	
Gender	Male, female
ASA score (see glossary of terms).	I, II, III, IV, V, not recorded
History of diabetes	No, diet, controlled, tablet controlled, insulin controlled
HIV status	Positive, negative, unknown
Smoking status	Current, previous, never, unknown
Preoperative CT performed?	Yes/no—but CT would be available if needed/no—CT not available for this patient
If CT was unavailable for this patient, what was the main reason?	No CT scanner in this hospital/CT scanner present but electrical supply unavailable/CT scanner present but not working/CT scanner present but no reporting service available/CT scanner present but patient unable to pay for CT/other reason/not applicable
Date of operation	DD/MM/YY
Time of start of operation (knife to skin)	24 h clock
Time from hospital admission to start of operation (h)	<3, 3–5, 6–11, 12–23, 24–47, 48–71, 72+
Was a surgical safety checklist (WHO or equivalent) used?	Yes—fully used, yes—used in part, no
Most senior surgeon present: training	Medically qualified surgical specialist; medically qualified non-specialist; non-doctor surgical specialist; non-doctor and non-specialist
Most senior surgeon present: experience since qualification*	<5 years since finishing medical school*; ≥5 years since finishing medical school*
Most senior anaesthetist present: training	Medically qualified anaesthetic specialist; medically qualified non-specialist; non-doctor anaesthetic specialist; non-doctor and non-specialist; not applicable: no anaesthetist
Most senior anaesthetist present: experience (*or equivalent undergraduate/training course if non-doctor)	<5 years since finishing medical school* ≥5 years since finishing medical school* Not applicable: no anaesthetist
Anaesthetic type	General anaesthetic, spinal anaesthetic, local anaesthetic, sedation only (eg, ketamine)
Supplementary oxygen	Yes—via bottle or mains supply; yes—via oxygen concentrator; no—but oxygen available; no—oxygen not available
Incision	Midline, paramedian, transverse, gridiron, Lanz, groin, rooftop, Kocher's, Laparoscopic (+/− open specimen extraction), laparoscopic converted to open
Primary operation performed	Fixed fields, other (free text)
Was bowel resection performed?	Yes—hand-sewn anastomosis, yes—stapled anastomosis, yes—stoma without anastomosis, no
Stoma formation	Loop ileostomy, loop colostomy, end ileostomy, end colostomy, other, none
Main pathology/indication	Fixed fields, other (free text)
Was a pulse oximeter used throughout surgery?	Yes, no but available, no not available
Were antibiotics given?	Yes, no but available, no not available
Whole blood or blood product(s) used?	Yes—whole blood, yes—blood products (eg, packed red calls, FFP, plasma, platelets), no—but available at this hospital, no blood products available at this hospital
Thromboembolic prophylaxis (drug=heparin, etc, mechanical=stockings/pneumatic boots, etc)	1. Yes—drug and mechanical, 2. yes—drug only, 3. yes—mechanical only, 4. yes—other, 5. none
Intraoperative/24 h mortality	Alive, dead
Was there an intraoperative or postoperative complication that led to an unplanned 30-day critical care admission?	Yes, no—but available if needed, no—critical care not available at this hospital, unknown
30-day re-intervention (tick-box)	Yes—surgical, yes—endoscopic, yes—interventional radiology, no, unknown
30-day mortality (if alive at the point of discharge and no follow-up information available, indicate Alive)	Died-day of surgery, died-inpatient after day of surgery, died-outpatient, alive, unknown Days

Continued

Table 1 Continued

Data field	Alternatives
Length of stay following surgery (day of surgery is day 0). Leaving blank indicates unknown. If stay was 30 days or longer, indicate 30 days	
Other complication(s) not resulting in critical care, reintervention or mortality?	Yes/no
Anastomotic leak	Yes/no
Wound infection	Yes/no
Intra-abdominal/pelvic abscess	Yes/no

*Or equivalent undergraduate/training course if non-doctor.

and from hospital to hospital. In many centres, this study may be considered as global audit or global service evaluation, and may not require formal ethical approval. In such cases, the primary audit standard will be that the postoperative mortality rate should not exceed 15%.[6 7 9] Local investigators are expected to gain approval from the appropriate body, such as the local Clinical Audit or Research Department or Institutional Review Boards. If such institutions are unavailable, written permission should be provided from the Chief of Surgery or a supervising consultant/attending physician. Local investigators will be solely responsible for ensuring they have followed correct mechanisms, and will be asked to confirm this when data are submitted.

Data will be entered and stored via a secure online database and will not be analysed at the level of individual surgeon or hospital. All necessary precautions will be taken to ensure that individual surgeons, hospitals or countries will not be identified from the presented data. Patient consent is not deemed necessary and inclusion in the study will incur minimal risk to patients.

Trial registration

The study protocol has been registered with ClinicalTrials.gov public study registry (Identifier: NCT02179112). The registration entry is available to view online: http://clinicaltrials.gov/ct2/show/record/NCT02179112

Dissemination of results

We will endeavour to make the outcomes of this project available to all irrespective of access to academic resources. Depending on the availability of funding or fees waiver, we aim to publish the eventual results open-access. Additionally, data will be modified to ensure that individual patients, hospitals or surgeons cannot be recognised and deposited in an open-access online data repository for others to analyse. The study outcomes will be disseminated to a range of stakeholders and study participants, and made available through the study website: http://globalsurg.org/

DISCUSSION

In this study protocol, we outline a novel approach to collecting data on surgical outcomes worldwide. By using multiple centres over a 2-week period, sufficient patient numbers will be achieved while minimising resource requirements in each centre. This approach allows for the development of a network of surgeons, surgical departments and other interested groups that will have a long-term ability to collaborate on further outcome studies and will empower individual practitioners to participate by facilitating audit and research capacity-building in regions that currently lack local opportunities for development.

Owing to the global setting of this study, some common preoperative laboratory tests and assessment scores have by necessity been omitted as these are not common place in all settings. However, the data set are such that the results will therefore be relevant across all healthcare settings worldwide.

Surgical outcomes data are highly sought after and safety of surgical care is gaining recognition as an important health priority worldwide. Baseline outcome measurement in relation to emergency abdominal surgery has not yet been undertaken at an international level and may provide a useful indicator of surgical capacity and the modifiable process, equipment and clinical management that influences this. This novel methodological approach will facilitate delivery of such a multicentre study at a global level, in addition to building international audit and research capacity in surgery.

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Competing interests None.

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