Perioperative mortality in Colombia: perspectives of the fourth indicator in The Lancet Commission on Global Surgery – Colombian Surgical Outcomes Study (CoLSOS) – a protocol for a multicentre prospective cohort study

Carlos J Pérez-Rivera,1 Nicolás Lozano-Suárez,1,2 Alejandro Velandia-Sánchez,1,3 Camilo A Polania-Sandoval,2,3 Juan P García-Méndez,1,2 Sharon V Idarraga-Ayala,1 Julián M Corso-Ramírez,1,2 Danny Conde-Monroy,2 Danna L Cruz-Reyes,2 Carlos F Durán-Torres,2 Juan G Barrera-Carvajal,3,4 Luisa Fernanda Rojas-Serrano,2 Laura Alejandra García-Zambrano,1,2 Silvia Valentina Agudelo-Mendoza,1,2 Leonardo Briceno-Ayala,5,7 Paulo A Cabrera-Rivera,2,4 ColombianSurg Collaborative

ABSTRACT

IntroductionDeath following surgical procedures is a global health problem, accounting for 4.2 million deaths annually within the first 30 postoperative days. The fourth indicator of The Lancet Commission on Global Surgery is essential as it seeks to standardise postoperative mortality. Consequently, it helps identify the strengths and weaknesses of each country’s healthcare system. Accurate information on this indicator is not available in Colombia, limiting the possibility of interventions applied to our population. We aim to describe the in-hospital perioperative mortality of the surgical procedures performed in Colombia. The data obtained will help formulate public policies, improving the quality of the surgical departments.

Methods and analysisAn observational, analytical, multicentre prospective cohort study will be conducted throughout Colombia. Patients over 18 years of age who have undergone a surgical procedure, excluding radiological/endoscopic procedures, will be included. A sample size of 1353 patients has been projected to achieve significance in our primary objective; however, convenience sampling will be used, as we aim to include all possible patients. Data collection will be carried out prospectively for 1 week. Follow-up will continue until hospital discharge, death or a maximum of 30 inpatient days. The primary outcome is perioperative mortality. A descriptive analysis of the data will be performed, along with a case mix analysis of mortality by procedure-related, patient-related and hospital-related conditions.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Colombia lacks accurate national registers of perioperative mortality; therefore, a prospective approach will provide a better quality of data than the available evidence.
⇒ A key strength of the study is the perioperative mortality analysis by assessing the case mix by procedure, patient and hospital related conditions.
⇒ One-week prospective collection could induce bias related to seasonal surgical variation, which will be partially reduced by using different collection weeks for different regions.
⇒ A convenience sample of participating institutions could provoke selection bias and decrease the generalisability of the results to the entire Colombian population.
⇒ Information quality will be improved by training in data collection and methodology for each participating centre and through data validation.

INTRODUCTION

The Lancet Commission on Global Surgery created a movement that is currently the most...
crucial source of data and recommendations regarding surgical services globally, claiming that surgery is a fundamental pillar of public health. The Commission’s main objective was to improve the quality of surgical services worldwide. They established six indicators encompassing comparison between countries and measurement standardisation. The fourth indicator, known as perioperative mortality, is defined as ‘the number of in-hospital deaths from any cause in patients who have undergone a procedure done in an operating theatre, divided by the total number of procedures, presented as a percentage’. This indicator is essential, as it allows each nation to use this percentage to measure improvements in surgical care, and it is ‘a global indicator of access to safe surgery and anaesthesia’. Therefore, multiple multicentre international collaborative studies on this indicator have emerged (table 1).

Approximately 300 million surgical procedures are performed worldwide, with an estimated mortality rate of 1%–4% in the perioperative period. At least 4.2 million deaths occur annually within the first 30 postoperative days, half of which occur in low-income and middle-income countries. These represent 7.7% of the total worldwide, making ‘perioperative death’ the third leading cause of death globally, exceeded only by coronary heart disease and strokes. Without proper care, the early postoperative period will continue to be a significant cause of preventable death and disability based on the absence of solid surgical care.

In low-income and middle-income countries, accurate information continues to be scarce. Likewise, in Colombia, data for this indicator are limited. The study by Hanna et al is the first attempt to apply The Lancet Commission on Global Surgery indicators in Colombia, estimating early postoperative mortality in Colombia at 0.74%. Second stage analysis of the same dataset was recently published, establishing aggregate perioperative mortality at 0.87% and mortality attributable to emergency and elective surgery at 1.5% and 0.73%, respectively. Both studies were based on a retrospective review of data from the National Administrative Department of Statistics and the Individual Service Provision Registries. As stated by Hanna et al, this inclusion methodology poses several problems, including an information bias, as Colombian national databases do not report where and under what circumstances the death occurred, and thus do not correlate with the definition of perioperative mortality in The Lancet Commission on Global Surgery. Furthermore, it is crucial to understand Colombia’s social context and healthcare system for data analysis and the interpretation of the results, as they have multiple factors that may impact the results (online supplemental appendix 1).

We aim to contribute to our country with the first research study reporting accurate and prospective information on perioperative mortality in Colombia and Latin America, by following the instructions created by The Lancet Commission on Global Surgery precisely. The data obtained will be the first step in formulating public policies in the surgical field, adjusted to our population. Moreover, it will help construct a healthcare system with available, affordable and high-quality surgical services by contributing to future interventions that will boost this vital area of healthcare, affecting Colombian patients’ care and quality of life.

### METHODS AND ANALYSIS

#### Objectives of the study:

The primary objective of this study is to describe the Lancet indicator of perioperative mortality in patients who have undergone surgical procedures in participating Colombian institutions.

The secondary objectives are to:

- Characterise the sociodemographic and clinical variables of the patients who underwent surgical procedures in Colombia.
- Determine the secondary postoperative clinical complications associated with surgical procedures in Colombia.
- Describe the installed surgical capacity and infrastructure of the participating health centres.

#### Study design:

A multicentre, observational, analytical, prospective cohort multicenter study will be conducted (figure 1).

#### Study setting

The study will be carried out throughout Colombia. As many institutions as possible that perform surgery will be included. We expect to have at least one institution per region. We currently have 60 confirmed participating institutions and are establishing preliminary contact with others (figure 2). The list of participating centres and researchers will be continuously updated, the final version of the list will be attached to the final report and we will compare their characteristics with official national registries from the Colombian Ministry of Health and Social Protection ‘Datos abiertos’ platform and Health Situation Analysis (ASIS) report.

#### Patient and public involvement statement

Patients were not included in the design of the research. Even so, the aim of the study is to understand the factors related to perioperative mortality with the objective of beginning a discussion around surgery in public health. Study participation will not entail any intervention or change in treatment for the patients; nonetheless, informed consent to participate will be obtained. Once the study has been published, patients all over Colombia will be invited to the discussion and presentation of the results; also, the results will be presented in a non-technical way to deliver the information to everyday citizens.

#### Characteristics of the participants

All patients over 18 years of age who undergo a surgical procedure during the collection period will be included.
### Table 1  Summary of previous studies on national 30-day perioperative mortality

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Name of the study</th>
<th>Location</th>
<th>Number of countries</th>
<th>Study design</th>
<th>Study description</th>
<th>Study period</th>
<th>POMR</th>
<th>Postoperative complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pérez-Rivera C.J., et al</td>
<td>2016</td>
<td>Global patient outcomes after elective surgery: prospective cohort study in 27 low-, middle- and high-income countries (ISOS).</td>
<td>Global</td>
<td>27</td>
<td>Prospective cohort study</td>
<td>Number of institutions: 474. Number of patients: 44814.</td>
<td></td>
<td>0.5%</td>
<td>16.8%</td>
</tr>
<tr>
<td>Jawad et al</td>
<td>2016</td>
<td>Swedish surgical outcomes study (SweSOS): An observational study on 30-day and 1-year mortality after surgery</td>
<td>Sweden</td>
<td>1</td>
<td>Prospective cohort study</td>
<td>Number of institutions: 8. Number of patients: 1314.</td>
<td></td>
<td>1.8%</td>
<td>N/A</td>
</tr>
<tr>
<td>Bruno et al</td>
<td>2016</td>
<td>An evaluation of preparedness, delivery and impact of surgical and anesthesia care in Madagascar: a framework for a national surgical plan</td>
<td>Madagascar</td>
<td>1</td>
<td>Qualitative semistructured interviews</td>
<td>Data taken from: hospital surveys and standard interviews with health teams. Number of institutions: 22. Number of patients: 394181.</td>
<td></td>
<td>2.5%–3.3%</td>
<td>N/A</td>
</tr>
<tr>
<td>Massenburg et al</td>
<td>2017</td>
<td>Assessing the Brazilian surgical system with six surgical indicators: a descriptive and modelling study</td>
<td>Brazil</td>
<td>1</td>
<td>Retrospective cohort study</td>
<td>Data taken from: the Hospital Information System/Unique Health System (SIH/SUS) and Brazilian Institute of Geography and Statistics (IBGE).</td>
<td></td>
<td>1.71%*</td>
<td>N/A</td>
</tr>
<tr>
<td>Guest et al</td>
<td>2017</td>
<td>Collecting data for global surgical indicators: a collaborative approach in the Pacific Region</td>
<td>Pacific</td>
<td>14</td>
<td>Mixed methods study</td>
<td>Data taken from: a retrospective review of patient records, medical records, databases, hospital death certificates and hospital mortality records.</td>
<td></td>
<td>0.11%–1.0%</td>
<td>N/A</td>
</tr>
<tr>
<td>Biccard et al</td>
<td>2018</td>
<td>Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study (ASOS).</td>
<td>Africa</td>
<td>25</td>
<td>Prospective observational cohort study</td>
<td>Number of institutions: 247. Number of patients: 11422.</td>
<td></td>
<td>2.1%</td>
<td>18.2%</td>
</tr>
<tr>
<td>Hewitt-Smith et al</td>
<td>2018</td>
<td>Surgical outcomes in eastern Uganda: a 1 year cohort study.</td>
<td>Uganda</td>
<td>1</td>
<td>Prospective cohort study</td>
<td>Number of institutions: 440. Number of patients: 4773.</td>
<td></td>
<td>2.0%†</td>
<td>5.8%–16.8%</td>
</tr>
<tr>
<td>Osinaike et al</td>
<td>2019</td>
<td>Nigerian surgical outcomes – Report of a 7-day prospective cohort study and external validation of the African surgical outcomes study surgical risk calculators (NiSOS).</td>
<td>Nigeria</td>
<td>1</td>
<td>Prospective cohort study</td>
<td>Number of institutions: 79. Number of patients: 1425.</td>
<td></td>
<td>6.0%</td>
<td>18.5%</td>
</tr>
<tr>
<td>Gurney et al</td>
<td>2019</td>
<td>Postoperative mortality in New Zealand following general anaesthetic: demographic patterns and temporal trends.</td>
<td>New Zealand</td>
<td>1</td>
<td>Retrospective cohort study</td>
<td>Data taken from: the National Minimum Dataset (NMDS) (hospital events). Number of patients: 1836683. Study period: 2005–2017.</td>
<td></td>
<td>0.5%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Continued
### Table 1  Continued

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Description</th>
<th>Location</th>
<th>Study Type</th>
<th>Data Source</th>
<th>Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hanna et al&lt;sup&gt;9&lt;/sup&gt;</td>
<td>2020</td>
<td>Use of the six core surgical indicators from the Lancet Commission on Global Surgery in Colombia: a situational analysis.</td>
<td>Colombia</td>
<td>Retrospective cohort study</td>
<td>Data Taken from: the Colombian national healthcare information system, Sistema Integral de Información de la Protección Social (SISPRO), and the National Health Survey 2007 (NHS-2007).</td>
<td>0.73%–0.76%‡</td>
</tr>
<tr>
<td>James et al&lt;sup&gt;35&lt;/sup&gt;</td>
<td>2020</td>
<td>Universal access to safe, affordable, timely surgical and anaesthetic care in Papua New Guinea: the six global health indicators.</td>
<td>New Guinea</td>
<td>Mixed methods study</td>
<td>Data taken from: hospital and surgical records. Study period: 2012–2018.</td>
<td>0.3% N/A</td>
</tr>
<tr>
<td>Nunez et al&lt;sup&gt;36&lt;/sup&gt;</td>
<td>2021</td>
<td>Establishing a baseline for surgical care in Mongolia: a situational analysis using the six indicators from the Lancet Commission on Global Surgery</td>
<td>Mongolia</td>
<td>Retrospective cohort study</td>
<td>Data taken from: The Mongolian Health Development Center (HDC) and subsequently confirmed with data from each hospital. Study period: 2006–2016.</td>
<td>0.14% N/A</td>
</tr>
<tr>
<td>Dencker et al&lt;sup&gt;37&lt;/sup&gt;</td>
<td>2021</td>
<td>Postoperative complications: an observational study of trends in the United States from 2012 to 2018.</td>
<td>USA</td>
<td>Retrospective cohort study</td>
<td>Data taken from: the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP). Number of patients: 5,800,829. Study period: 2012–2018.</td>
<td>1.0%‡ 13.2%</td>
</tr>
<tr>
<td>Nepogodiev et al&lt;sup&gt;38&lt;/sup&gt;</td>
<td>2021</td>
<td>Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study.</td>
<td>Global</td>
<td>International cohort study</td>
<td>Number of Institutions: 235. Number of patients: 1,128.</td>
<td>23.8%§ 51.2%</td>
</tr>
<tr>
<td>Gomez et al&lt;sup&gt;39&lt;/sup&gt;</td>
<td>2022</td>
<td>A granular analysis of service delivery for surgical system strengthening: Application of the Lancet indicators for policy development in Colombia.</td>
<td>Colombia</td>
<td>Retrospective cohort study</td>
<td>Data Taken from: the Colombian national healthcare information system, Sistema Integral de Información de la Protección Social (SISPRO), and the National Health Survey 2007 (NHS-2007).</td>
<td>0.87%‡ N/A</td>
</tr>
</tbody>
</table>

*Follow-up time was not clear.
†This study only reported complications secondary to caesarean section and laparotomy.
‡In-hospital mortality is not specified in this study.
§This was a study conducted during the SARS-CoV-2 pandemic and therefore evaluates mortality and pulmonary complications in patients who underwent surgery and had a concomitant infection. POMR, perioperative mortality ratio.

<table>
<thead>
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<th>Study</th>
<th>Year</th>
<th>Description</th>
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<th>Study Type</th>
<th>Data Source</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nunez et al&lt;sup&gt;36&lt;/sup&gt;</td>
<td>2021</td>
<td>Establishing a baseline for surgical care in Mongolia: a situational analysis using the six indicators from the Lancet Commission on Global Surgery</td>
<td>Mongolia</td>
<td>Retrospective cohort study</td>
<td>Data taken from: The Mongolian Health Development Center (HDC) and subsequently confirmed with data from each hospital. Study period: 2006–2016.</td>
<td>0.14% N/A</td>
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<td>Data taken from: the American College of Surgeons (ACS) National Surgical Quality Improvement Program (NSQIP). Number of patients: 5,800,829. Study period: 2012–2018.</td>
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*Follow-up time was not clear.
†This study only reported complications secondary to caesarean section and laparotomy.
‡In-hospital mortality is not specified in this study.
§This was a study conducted during the SARS-CoV-2 pandemic and therefore evaluates mortality and pulmonary complications in patients who underwent surgery and had a concomitant infection. POMR, perioperative mortality ratio.
Patients who do not agree to participate in the study through informed consent or who undergo radiological/endoscopic procedures will be excluded.

Only patients older than 18 years old will be considered as it is the national legal age and guarantee the direct process of informed consent with the participants. Also, a surgical procedure will be defined as any procedure conducted in the operating room regardless of the type of anaesthesia used. The excluded procedures are only intervention radiology and endoscopic procedures. Open, video-assisted, endovascular, robotic and mixed procedures that fulfil the eligibility criteria will be included.

Sample size

The minimum number of patients needed to achieve significance in describing the national perioperative mortality ratio was calculated to be 1353. The estimate was made using the 0.74% postoperative mortality rate in Colombia obtained in Hanna et al’s study.9 Bearing in mind this reduced mortality proportion, the sample for prevalence or proportion was calculated seeking an absolute precision of 0.5%, an alpha value of 0.05 and a design effect of 1.2, due to it being a non-randomised sample. The OpenEpi calculator11 was used to estimate the sample size for this proportion, using the following formula:

\[n = \left[ \text{DEFF} \times Np \times (1 - p) \right] / \left[ \left( \frac{Z2}{d} \right)^2 \times (N - 1) + p \times (1 - p) \right]\]

Where DEFF is the design effect (correction factor to adjust the sampling size), n is the sample size, N is the population size, p is the estimated proportion, q is one minus the estimated proportion, \(\alpha\) is the alpha value and d is the desired absolute precision.12

Also, due to the nature of the study, randomisation is not possible. Nevertheless, convenience sampling is considered, as we aim to include all possible patients. Once the sample of patients is achieved, the study will continue until all participating institutions finish their collection week. When the collection is completed, a power analysis will be run to ensure the significance of the sample obtained.
Outcomes

The principal outcome of this study is to obtain primary and reliable information on the fourth indicator in The Lancet Commission on Global Surgery in Colombia. The specific definition of perioperative mortality that will be used in this study is ‘all mortality secondary to any cause before leaving the hospital, or within a maximum of 30 days of hospital stay, in a patient who underwent a surgical procedure in an operating room’. This indicator will be represented through the perioperative mortality ratio\(^4\) and will be calculated as follows:

\[
\text{ratio} = \frac{\text{# of procedures with in—hospital mortality}}{\text{total number of procedures}}
\]

It is important to note that the crude national perioperative mortality and adjusted mortality will be calculated, addressing case mix by procedure, patient and hospital related conditions. The variables to be assessed as patient-related conditions will be age, affiliation with the Colombian healthcare system, medical history, illness severity by ASA (American Society of Anesthesiologists) score and preoperative patient status such as haemodynamic instability and preoperative cardiopulmonary arrest. In procedure-related conditions: cardiac risk for non-cardiac procedures, elective versus non-elective procedures and procedure category and type. In hospital-related conditions: hospital funding (public, private or mixed), location (rural vs urban) and level of complexity (I–IV).

The secondary outcomes measured are the installed surgical capacity and the postoperative clinical outcomes associated with surgical procedures in Colombia. The installed surgical capacity is going to be measured by the institutional level of complexity, number of surgical professionals (surgeons, orthopaedists, anaesthesiologists and obstetrician-gynaecologists), number of operating rooms and intensive care unit capacity. Further information on the clinical outcomes and installed surgical capacity is presented in the variables table (online supplemental appendix 2).

Identification and linking of research centres

Four strategies are proposed to attract interested researchers and institutions to participate in this study. Due to the support of the Colombian Surgical Association, a generalised invitation will be sent to all clinics and hospitals with surgical divisions throughout the country, using the ColombianSurg Collaborative organisation’s official mail. This invitation will include general information on the research study to attract interest from these institutions. Additionally, the registration link will be published in the Colombian Surgical Association’s journal and website so students, interns, doctors, residents and specialists interested in participating can register (https://fci-redcap.cardioinfantil.org/surveys/index.php?s=LE3KXAPXDE). Finally, word of mouth and mass dissemination through ColombianSurg Collaborative social networks (Instagram/Twitter/Facebook: @ colombiansurg and the official website) cannot be ruled out.\(^1\)

A hierarchical management organisation was set up to generate specific and personalised attention for each region and institution (figure 3). In addition, researchers will communicate with the ColombianSurg Collaborative team and vice versa through different platforms that will be made available to them, such as instant messaging groups, email and official websites.

Data collection

Data collection has not begun; it is planned to begin in May 2022. Data will be collected and stored online through a Research Electronic Data Capture (REDCap) web application server, allowing the collaborators to enter data and store it in a secure system; this protects patient data as it does not permit third-party access. Each hospital’s designated collaborator will receive the login data in the REDCap system (login) so that the data are sent securely to the server. Only anonymous data will be uploaded to the database. No data will be collected to identify patients. All of this is in adherence to the Strengthening the Reporting of Observational Studies in Epidemiology statement.\(^1\) The Department of General Surgery at the Fundación Cardioinfantil-Instituto de Cardiología will serve as the coordinating centre.

Patient inclusion will be carried out prospectively for 1 week. All patients who meet the criteria between day 1 and day 7 will be included. All patients will be followed until one of the following endpoints is met: (1) the patient dies within the first 30 days of hospital stay, (2) the patient is discharged or (3) the patient completes 30 days of hospitalisation.

Data collection is predetermined to be carried out regionally, 1 week per region and another for the capital
district. The order of collection will be randomly assigned, but there will be flexibility to postpone the collection week based on specific institutional needs.

As stated, all institutions and surgical specialties that wish to participate will be incorporated. Consequently, a collection team will be required for each institution. These teams consist of a leader and three to five collaborators. In cases where teams have more than 30 patients per collaborator, they may include more team members, maintaining the same rule of 30 patients per person, not including the team leader. There is no minimum number of patients to be collected or participants in a research team.

**Information quality control**

All data will be collected from the patients' electronic medical records. The database will comply with confidentiality rules, and the information analysis will not identify results by institution or researcher. Given the importance of data quality, validation will be done in three stages:

Stage 1: the collection tool will be designed to restrict answers clearly and concisely, using the correct symbology, without giving space for discussion. Also, it will contain a logical sequence in terms of information coherence, deploying a specific questionnaire depending on the information recorded previously.

Stage 2: the researchers at the participating centres will be trained in the use of REDCap and will be instructed on how to fill in the database. Likewise, a communication system will be enabled between the researchers at the participating centres and the leading researchers to answer questions, ensuring an adequate collection of data.

Stage 3: extreme results (outliers) will be validated through diagrams and corroborated with the collection centres, including patients, as needed. A member of the participating centre other than the leader or collaborators will be assigned to audit the data. A statistical sampling approach will be used to explicitly determine the percentage of data taken to validate the results.

**Data analysis plan**

A descriptive analysis of the data will be performed to address the primary and secondary objectives. The distribution of the variables will be assessed by graphical analysis and normality tests (Shapiro-Wilk or Kolmogorov-Smirnov). If the variables have a normal distribution, they will be expressed as means (a measure of central tendency) and SD (a measure of dispersion). Conversely, if the variables have a non-normal distribution, they will be expressed as medians (a measure of central tendency) and IQR (a measure of dispersion).

Continuous data with a normal distribution will be studied using parametric tests according to the number of comparators: Student’s t-test or analysis of variance will be used if more than two groups of the variable are being compared. For continuous data with a non-normal distribution, non-parametric tests will be used: if two groups are compared, the Mann-Whitney test will be used, and if three groups are compared, the Kruskal-Wallis test will be used. The p value shall be considered statistically significant at <0.05. Categorical variables shall be presented with absolute frequencies and proportions. Categorical data will be compared between two groups using the \( \chi^2 \) test or Fisher’s exact test.

Perioperative mortality will be represented as a ratio or proportion of mortality in all patients who have undergone a surgical procedure within the collection period. To fully understand these phenomena, we will adjust mortality for procedure, patient and hospital related conditions, as previously described. Also, a mixed effect mode for geographical clustering and a multivariate logistic regression for perioperative mortality will be used to adjust for differences in confounding factors and assess possible associations. Possible risk factor variables will be assessed with lasso regression and a variance inflation factor to avoid collinearity. All analyses will be multi-level, carried out by city or municipality, department and country.

A multiple imputation method using the AMELIA algorithm in R Studio will be employed before any analysis. Model yields will be evaluated using model calibration and discrimination. A calibration analysis is proposed using the known data and finding the observed relationship between dependent and independent variables. Sensitivity analyses of the association between preoperative risk factors and inpatient mortality in those with complete data versus cases with multiple imputations of missing data will be performed to test the potential bias associated with missing variables.

Statistical analyses will be performed using the R statistical software and the Statistical Package for the Social Sciences.

**ETHICS AND DISSEMINATION**

The Fundación Cardioinfantil-Instituto de Cardiología Institutional Ethics Committee approved this study in 2021 (Ref Number: No. 41–2021), and a copy of the official letter is attached.

The study will be conducted within the guidelines of the ethical principles for medical research on human subjects according to the Declaration of Helsinki – 59th General Assembly, Seoul, Korea, October 2008. The CIOMS Guidelines, Good Clinical Practice Guidelines of the International Conference on Harmonization and national ethical disclosures will also be taken into account. The investigators will be responsible for maintaining absolute confidentiality of the information contained in medical records and personal information, complying with the current regulations regarding the handling of this information. Absolute confidentiality will be maintained, and the proper professional, institutional name will be preserved. The confidentiality of the data will be guaranteed by masking with a code created by the researchers.
According to the Colombian Ministry of Health and Public Protection’s Resolution 8430/1993, this is a no-risk study since no additional intervention or treatment modification is carried out on the participants, as all the information will be collected from the patients and will undergo anonymisation. However, as it is a multicentre study, institutions whose institutional ethics committees believe consent is necessary for participation (as is the case of the Fundación Cardioinfantil-Instituto de Cardiología) will be allowed to collect it. The participant consent form that will be used can be found in online supplemental appendix 3.

Dissemination is planned to occur in three different scenarios: via submission of an article to a high-impact scientific journal, at the Colombian Surgical Forum and at the Congress of the American College of Surgeons.

The principle of collaborative authorship will be used throughout this study. Collaborators from each institution will be acknowledged in the resulting publications as PubMed-citable coauthors. The criteria for authorship are the following:

► Principal investigators: train collection teams, coordinate the study, analyse obtained data and write the manuscripts.
► Departmental leaders: support recruitment and coordination of institutions in specific regional areas.
► Hospital/research centre leaders: coordinate teams to complete data collection in the established period and attend meetings with the principal investigators.
► The team from each hospital: collect data from all patients at each institution who meet the study criteria.

Discussion

This study focuses on ascertaining postoperative in-hospital mortality in Colombia and its determinants, as a first step in developing the surgical field through public health. We consider that a prospective and multicentre approach can generate updated and more representative data than the currently available evidence. The few attempts to measure perioperative mortality have often involved different definitions than those proposed by The Lancet Commission on Global Surgery and study samples that are not representative of the Colombian national population or have reported data associated with a specific type of procedure.9 10 16 This indicator is convenient and of significant impact, as the possibility of a standardised measurement of perioperative mortality between countries, regardless of their income level, has been demonstrated in the literature.17

The specific methodology for the prospective data collection was chosen to decrease bias. Patients will be included if they are discharged prior to 30 days after surgery; alternatively, they will be followed until they complete 30 days of hospitalisation. The rationale for this is that patients who die during this lapse of time reach the primary outcome; patients who are discharged or who die after 30 days in the hospital may be influenced by external causes that are not always secondary to the surgical procedure; therefore, a censorship of the discharged patients will be conducted.

Previously, the 30 days after surgery have been considered to be part of the perioperative mortality interval, as the Thoracic Society of Surgeons defines operative mortality as ‘death, that occurs before hospital discharge regardless of whether it occurred after 30 days, and all deaths that occur after hospital discharge in the first 30 days after surgery’.18 However, this is considered to limit the effectiveness and use of this measure and makes it impossible to make valid comparisons between jurisdictions or countries.4 10

The Lancet Commission for Global Surgery recommends that mortality be presented as the number of postoperative in-hospital deaths, overall, in patients undergoing surgical procedures.1 This is supported by a study that compared the different perioperative mortality rates in different care facilities in New Zealand, South Africa and Papua New Guinea. The authors determined that there are considerable differences between representatives of the high-income, medium-income and low-income countries, with one of the main differences being the lack of 30-day follow-up in the middle-income and low-income countries. Therefore, they recommended not considering deaths following hospital discharge.19

Additionally, multicentre studies using the proposed methodology in this study have shown tremendous impact, and country and region-specific data are necessary to make them truly useful, with several interventions that can be carried out to improve the surgical quality of each area.

Previous studies on postoperative mortality were conducted measuring mortality through the civil registry and vital statistics; by 2015, the specific postoperative mortality rate registered in low-income countries was only 1%.4 17 20 Nevertheless, the EuSOS study reported an in-hospital mortality rate of 4%, higher than expected, and described substantial differences between mortality in different countries, even after adjustment for all confounding variables.21 Meanwhile, ISOS (International Surgical Outcomes Study) main objective was not to describe postoperative mortality but in-hospital complications. However, they also reported in-hospital mortality at a rate of 0.5%, being significantly lower than that observed in the EuSOS study.16

The differences in perioperative mortality in similar populations was observed in EuSOS and in several other studies.5 16 21 This supports perioperative mortality ratio variability, which could be influenced by various factors even in safe and high-quality health systems.22 In fact, major changes can be triggered by risk stratification according to procedure and patient, age, preoperative clinical status and institutional factors such as location and funding (public vs private sector).6 22 23 Therefore, in order to succeed, a complete understanding of perioperative mortality is necessary to adjust mortality by the previous factors. In the Colombian population, it may also be important to adjust for type of affiliation to the
healthcare system, because this defines access to timely, efficient and priority healthcare. Furthermore, other sociodemographic variables could play determinant roles, such as socioeconomic status, ethnicity and being migrants or communities displaced by violence.

Overcoming its limitations, the understanding of perioperative mortality identifies realistic figures and essential differences that impact the determinants and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

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ORCID iDs
Alejandro Velandia-Sánchez http://orcid.org/0000-0001-6681-1883
Silvia Valentina Agudelo-Mendoza http://orcid.org/0000-0002-7965-3724
Leonardo Briceno-Ayala http://orcid.org/0000-0003-4452-3818

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