

CLINICAL TRIAL PROTOCOL

Latin American surgical outcomes study: study protocol for a multicentre international observational cohort study of patient outcomes after surgery in Latin American countries



Ludhmila A. Hajjar^{1,2,*,†}, Vinícius C. Quintão^{1,3,‡}, Alexandra P. Z. Vieira¹, Leticia N. Nakada², Rupert M. Pearse^{4,†}, Martha B. D. Ramirez^{5,†,‡}, Antonio R. la Medina^{6,†,‡}, Adrian Alvarez^{7,†,‡}, Santiago McLoghlin^{7,‡}, Luis Boccalatte^{7,‡}, Greg Padmore^{8,†,‡}, Israël Feraudy^{9,‡}, Monica Martinez^{10,‡}, Nicolas Villablanca^{11,‡}, Carlos Pérez^{12,‡}, José A. Calvache^{13,‡}, Eddy Lincango^{14,‡}, Rodrigo Sosa^{15,‡}, Sebastian Shu^{16,‡}, Juan Riva^{17,‡}, Lisbeth Godínez^{18,‡}, Melba Frias^{19,‡}, Don Major^{20,‡}, Miguel Licea^{21,‡}, Sylvia Batista^{22,‡}, Shane Charles^{23,‡}, Mayra Vaca^{24,‡}, Ismael D. Rosado^{25,‡}, Delia Borunda^{25,‡}, Osama Bahsas Zaky^{26,‡}, Claudia M. C. Cardona^{27,‡}, Maria J. C. Carmona^{3,†,‡} and Luciana C. Stefani^{28,‡}

¹Academic Research Organization, Instituto do Coração InCor, Hospital das Clínicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo, São Paulo, Brazil, ²Department of Cardiopneumology, Instituto do Coração InCor, Hospital das Clínicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo, São Paulo, Brazil, ³Discipline of Anaesthesiology, Faculdade de Medicina, Universidade de São Paulo, São Paulo, Brazil, ⁴Faculty of Medicine & Dentistry, Queen Mary University of London, London, UK, ⁵Department of Clinical Epidemiology and Biostatistics, Anesthesiology Department, Pontificia Universidad Javeriana School of Medicine, Hospital Universitario San Ignacio, Bogota, Colombia, ⁶Research Center for Global Surgery of Veracruz Hospital Español, Veracruz, Mexico, ⁷Department of Anaesthesiology, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina, ⁸Department of Surgery, Queen Elizabeth Hospital, Bridgetown, Barbados, ⁹Caja Nacional de Salud, La Paz, Bolivia, ¹⁰Universidad Finis Terrae, Providencia, Chile, ¹¹Universidad de Chile, Santiago, Chile, ¹²Universidad El Bosque, Bogota, Colombia, ¹³Universidad del Cauca, Popayán, Colombia, ¹⁴Hospital Vozandes, Quito, Ecuador, ¹⁵Hospital de Especialidades Quirúrgicas del Instituto de Prevision Social, Assuncion, Paraguay, ¹⁶University of Texas Southwestern Medical Center, Dallas, TX, USA, ¹⁷Sanatorio Americano, Montevideo, Uruguay, ¹⁸Hospital General de Enfermedades del Instituto Guatemalteco de Seguridad Social, Ciudad da Guatemala, Guatemala, ¹⁹Hospital Nacional en Ciudad de Panama, Ciudad de Panama, Panama, ²⁰University of the West Indies, Nassau, Bahamas, ²¹Hospital Clínico Quirúrgico Hermanos Ameijeiras, La Habana, Cuba, ²²Centro de Diagnostico y Medicina Avanzada Telemedicina, Santo Domingo, Dominican Republic, ²³San Fernando General Hospital, San Fernando, Trinidad and Tobago, ²⁴Asociación de Médicos Anestesiólogos de Costa Rica, San José, Costa Rica, ²⁵Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Ciudad de Mexico, Mexico, ²⁶Hospital Oncológico Padre Machado, Caracas, Venezuela, ²⁷Hospital Escuela Universitario, Tegucigalpa, Honduras and ²⁸Department of Surgery, Faculdade de Medicina, Universidade Federal do Rio Grande do Sul, Porto Alegre, Brazil

*Corresponding author. Av. Dr. Enéas de Carvalho Aguiar, 44, 1 andar, CEP, 05403-000, São Paulo, Brazil. E-mail: ludhmila@usp.br, Twitter:

†Members of the steering committee.

‡Local coordinators.

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Abstract

Background: Reported data suggest that 4.2 million deaths will occur within 30 days of surgery worldwide each year, half of which are in low- and middle-income countries. Postoperative complications are a leading cause of long-term morbidity and mortality. Patients who survive and leave the hospital after surgical complications regularly experience reductions in long-term survival and functional independence, resulting in increased costs. With a high volume of surgery performed, there is a growing perception of the substantial impact of even minor enhancements in perioperative care. The Latin American Surgical Outcomes Study (LASOS) is an international, multicentre, prospective cohort study of adults submitted to in-patient surgery in Latin America aiming to provide detailed data describing postoperative complications and surgical mortality.

Methods: LASOS is a 7 day cohort study of adults undergoing surgery in Latin America. Details of preoperative risk factors, intraoperative care, and postoperative outcomes will be collected. The primary outcome will be in-hospital postoperative complications of any cause. Secondary outcomes include in-hospital all-cause mortality, duration of hospital stay after surgery, and admission to a critical care unit within 30 days after surgery during the index hospitalisation.

Results: The LASOS results will be published in peer-reviewed journals, reported and presented at international meetings, and widely disseminated to patients and public in participating countries via mainstream and social media.

Conclusions: The LASOS may augment our understanding of postoperative complications and surgical mortality in Latin America.

Clinical trial registration: NCT05169164.

Keywords: hospital mortality; intraoperative complications; Latin America; outcome assessment; postoperative complications

According to the WHO, access to surgical treatment is considered an essential component of healthcare.¹ Surgically treated diseases have increased in recent years, and with increasing incidence of traumatic injuries, cancer, and cardiovascular disease, the impact of surgical interventions on healthcare systems will continue to grow.^{2,3} However, roughly 5 billion individuals worldwide are estimated to not have access to safe surgery, with 94% living in low- or middle-income countries (LMICs).⁴

Worldwide, around 310 million patients are submitted to surgery annually, with an estimated in-hospital mortality between 1% and 4%.^{5–9} Recent reports suggest that 4.2 million deaths occur during the first 30 days after surgery, with LMICs accounting for half of them.¹⁰ Surgical complications and postoperative mortality are essential indicators of healthcare outcomes. According to the WHO, raw mortality after major surgery ranges from 0.5% to 5%.¹ Raw data depend on many factors, such as the patient's health status (patient at high surgical risk or usual risk), type of surgery, the urgency to perform the surgical procedure, number and skills of health professionals, and volume of patients seen by health institutions, in addition to the average follow-up time of patients after surgery.^{5,11–14}

Complications after surgery are an important cause of long-term morbidity and mortality.^{8,15} Patients who survive and leave the hospital after surgical complications regularly suffer reductions in long-term survival and functional independence. Given the high volume of surgery performed, there is increasing recognition of the potential impact of even minor enhancements in perioperative care.¹⁶

The International Surgical Outcomes Study (ISOS) reported a correlation between postoperative complications and death globally but mostly included high-income countries (HICs).⁸ Recently, the African Surgical Outcomes Study (ASOS) reported that patients submitted to surgery in African countries

were twice as likely to die than those in HICs, despite the patients being younger with fewer comorbid diseases.^{17,18}

Surgical care is a cost-effective component of universal health coverage, but it must be safe.^{4,19–21} Rapid demographic and societal changes have led to an escalating burden of non-communicable diseases. Supply of healthcare varies broadly worldwide,^{22,23} including within Latin America, with a mixture of social, private, and government-funded systems. Latin America describes a geographic area, including 25 nations, with countries presenting some of the highest income disparities worldwide.²⁴ A recent report highlighted marked variation in surgical provision within and amongst countries in Latin America.²⁵ Considering the disparity in socio-economic status and care models, this is unsurprising. However, it is unclear how these disparities relate to outcomes for individual patients submitted to surgery.^{26–28} The primary aim of the Latin American Surgical Outcomes Study (LASOS) is to provide detailed data describing postoperative complications and surgical mortality of adults submitted to in-patient surgery in Latin America.

Methods

Design

LASOS is an international, multicentre, prospective, and observational 7 day cohort study designed in accordance with the Declaration of Helsinki. The study is registered at www.ClinicalTrials.gov (trial identification number: NCT05169164).

Patient eligibility

Each national coordinator will select a single 7 day period for participant recruitment. The sites will identify research participants by reviewing the elective operating theatre records, operating theatre logbooks, handover sheets, emergency admissions, and ward records. All adult patients submitted to

surgery during the 7 day period at a participating hospital will be eligible for inclusion, as long as they meet the inclusion criteria. The need for informed consent will be determined by the Institutional Review Board of each centre or nation, complying with local regulations.

Ethical approval

The Institutional Review Board of the Instituto do Coração InCor, Hospital das Clínicas HCFMUSP, Faculdade de Medicina, Universidade de São Paulo approved this study under the protocol number 5.235.873.

Inclusion and exclusion criteria

Patients meeting the following criteria will be included: (i) adult patients (aged 18 yr or older), (ii) elective or emergency surgery with a planned overnight stay, and (iii) signed informed consent for those countries or centres that do not waive it. If the country or centre does not waive informed consent, it will include patients undergoing emergency surgery only if it is possible to obtain consent after the surgery. Patients undergoing planned outpatient surgery or radiological procedures will be excluded.

Data collection

Local investigators at each centre will screen all patients scheduled for elective and emergency surgery during a pre-defined period of 1 week. Data describing patient characteristics, intraoperative care, and early postoperative complications will be collected on Day 1 (Table 1). In-hospital postoperative complications and associated mortality will be collected until Day 30 (Table 2). Data collection will be censored for patients who remain in the hospital on Day 30. The starting date for each centre is malleable and will be determined together with the national study coordinators during a predetermined 6 month period.

Patient outcomes

The primary outcome is in-hospital postoperative complication of any cause, censored at 30 days after surgery for patients who remain in hospital.

Secondary outcomes are in-hospital all-cause mortality and duration of hospital stay, both censored at 30 days after surgery for patients who remain in hospital. Admission to critical care within 30 days of surgery during the index hospitalisation will also be measured.

Study organisation

Two co-chief investigators lead the steering committee with representation from countries across Latin America, all of whom contributed equally to the design and review of the original LASOS protocol. Each country has at least one national coordinator responsible for administrative management and communication with the local investigators and guides the participating centres in study management, record keeping, and data management. The process of regulatory approvals varies amongst countries. Local investigators will be responsible for securing research ethics approval, and the national coordinators will ensure it is in place before data collection starts. Local investigators will guarantee the reliability of data

Table 1 Baseline characteristics. AIDS, acquired immune deficiency syndrome; COPD, chronic obstructive pulmonary disease; HIV, human immunodeficiency virus; SD, standard deviation; TB, tuberculosis.

Characteristics of the included patients	
All patients (n=)	
Age (yr)	Mean (range)
Sex	
Male	n/Total (%)
Female	n/Total (%)
Current smoker	n/Total (%)
Ethnicity	
Afro-descendent	n/Total (%)
Indian	n/Total (%)
White	n/Total (%)
Other	n/Total (%)
Unknown	n/Total (%)
Chronic comorbid	
Coronary artery disease	n/Total (%)
Cirrhosis	n/Total (%)
Stroke	n/Total (%)
Chronic renal disease	n/Total (%)
Heart failure	n/Total (%)
Metastatic cancer	n/Total (%)
COPD/asthma	n/Total (%)
Active TB	n/Total (%)
Diabetes mellitus	n/Total (%)
Hypertension	n/Total (%)
HIV/AIDS	n/Total (%)
SARS-CoV-2 infection	n/Total (%)
Most recent blood results (no more than 28 days before surgery)	
Haemoglobin (g dl ⁻¹)	Mean (SD)
Creatinine (mg dl ⁻¹)	Mean (SD)
ASA physical status	
1	n/Total (%)
2	n/Total (%)
3	n/Total (%)
4	n/Total (%)
5	n/Total (%)
Anaesthetic technique	
General	n/Total (%)
Spinal	n/Total (%)
Epidural	n/Total (%)
Sedation	n/Total (%)
Local/regional	n/Total (%)
Surgical procedure category	
Orthopaedic (non-spine)	n/Total (%)
Breast	n/Total (%)
Gynaecology	n/Total (%)
Urology and kidney	n/Total (%)
Upper gastrointestinal	n/Total (%)
Lower gastrointestinal	n/Total (%)
Hepato-biliary	n/Total (%)
Vascular	n/Total (%)
Head and neck	n/Total (%)
Plastic/cutaneous	n/Total (%)
Neurosurgery (non-spine)	n/Total (%)
Thoracic	n/Total (%)
Cardiac	n/Total (%)
Spinal	n/Total (%)
Other	n/Total (%)
Urgency of surgery	
Elective	n/Total (%)
Urgent	n/Total (%)
Emergency	n/Total (%)
WHO surgical checklist before incision?	n/Total (%)
Severity of surgery	
Minor	n/Total (%)

Continued

Table 1 Continued

Characteristics of the included patients	
Intermediate	n/Total (%)
Major	n/Total (%)
Primary indication for surgery	
Infective	n/Total (%)
Trauma	n/Total (%)
Cancer	n/Total (%)
Other	n/Total (%)
Critical care immediately after surgery?	n/Total (%)

Table 2 Clinical outcomes. ARDS, acute respiratory distress syndrome; SD, standard deviation.

Clinical outcomes	
All patients (n=)	
Primary outcome	
In-hospital postoperative complications (all causes)	n/Total (%)
Infection	n/Total (%)
Superficial surgical site	n/Total (%)
Deep surgical site	n/Total (%)
Body cavity	n/Total (%)
Pneumonia	n/Total (%)
Urinary tract	n/Total (%)
Bloodstream	n/Total (%)
Cardiovascular	n/Total (%)
Myocardial infarction	n/Total (%)
Arrhythmia	n/Total (%)
Pulmonary oedema	n/Total (%)
Pulmonary embolism	n/Total (%)
Stroke	n/Total (%)
Cardiac arrest	n/Total (%)
Other	n/Total (%)
Gastrointestinal bleed	n/Total (%)
Acute kidney injury	n/Total (%)
Postoperative bleed	n/Total (%)
ARDS	n/Total (%)
Anastomotic leak	n/Total (%)
Other	n/Total (%)
Secondary outcomes	
Anaesthetic complications	
Failed intubation	n/Total (%)
Aspiration	n/Total (%)
Cardiac arrest	n/Total (%)
Severe hypoxia	n/Total (%)
Treatment for postoperative complications	
Drug therapy, blood transfusion, or parenteral nutrition	n/Total (%)
Surgical or radiological procedure	n/Total (%)
Critical care admission	n/Total (%)
Hours in PACU after surgery	Mean (SD)
Days in ICU after surgery	Mean (SD)
Days in hospital after surgery	Mean (SD)
Status at 30 days after surgery	
Alive	n/Total (%)
Dead	n/Total (%)

collection and the appropriate completion of the case report forms (CRFs).

Data collection management

For each participating hospital, specific data will be collected, including university or non-university hospital status; number

of hospital beds; number of operating theatres; number and level of critical care beds; details on the reimbursement status of the hospital; the existence of residency programmes in anaesthesia, surgery, internal medicine, or critical care; availability of a rapid response team; if the hospital holds valid accreditation; and the nursing-staff-to-hospital-bed ratio in postoperative care areas. Data will be collected in individual centres on paper CRFs for each participant recruited. CRFs will be kept in a locked office at each hospital. This will include individual patient data to allow follow-up of clinical outcomes. The CRFs will be completed for all research participants, with additional data collection for patients undergoing Caesarean section. Data will be anonymised by creating an individual numeric code (LASOS ID) and transliterated by local investigators onto a web-based CRF. Participants will only be identified on the web-based CRF by their LASOS ID. Thus, the coordinating study team will not be able to track any data back to an individual participant without communicating with the local investigator. Each hospital will use a research participant list to match LASOS ID to individual participants to record clinical outcomes and provide any missing data. The patient list will be destroyed once the follow-up has been completed and data submitted to the database, permanently anonymising the data. Once local investigators confirm data entry is concluded for their centre, they will receive a worksheet of raw data, permitting further assessments for data comprehensiveness and precision.

Caesarean section

A pre-specified data collection will be implemented restricted to patients undergoing Caesarean section. This group has formerly been identified as having inferior results compared with mothers in HIC. Data regarding maternal conditions, parity, gravidity, and gestational age will be collected. Data regarding fetal conditions, such as fetal distress, Apgar scores, birth weight, and neonatal mortality at 30 days, will also be collected.

Research ethics and regulatory approvals

It is expected that requirements in participating countries will vary. Still, the study will be performed according to local regulatory and legal conditions. In prior studies with similar design across more than 80 nations, most countries proceeded without individual participant informed consent. It is the responsibility of the national coordinators and local investigators to clarify the need for ethics clearance or other regulatory approvals and ensure they are in place before data collection. Participating centres will not be allowed to record data without confirming that the required ethics or other regulatory approvals are in place.

Data management

Data will be recorded on paper CRFs and transferred to the LASOS electronic database, where only anonymised data are collected. Each participating centre will maintain an investigation site file, including the study protocol, local investigator delegation log, paper CRFs, documentation of the regulatory approvals, screening log, and research participating list. The specific study documents will be available to download on the LASOS website. LASOS paper CRFs will be stored securely in a locked cabinet and processed only by

clinical staff familiar with handling personal data. Considering that only routine clinical data will be collected, study CRFs will be completed based on the hospital medical records, which are considered source data for this study. All identifiable data collected, processed, and stored for the project will remain confidential and comply with the Data Protection Act, the General Data Protection Regulation (GDPR), NHS Caldicott Principles, and the UK Policy Framework for Health and Social Care Research. Data will be collected by the patients' direct care team and anonymised before transfer to the LASOS group. Access to the database entry system will be protected by username and password, delivered during the registration process for individual local investigators. All electronic data transfers between participating hospitals and the coordinating centre will be encrypted using the SSL 3.0 protocol (HTTPS). Desktop and laptop security will be maintained through usernames and passwords. The data centre facilities are accredited to robust international standards for transferring healthcare data: ISO 27001, ISO 9001, ISO 14001, and PCI DSS. When registering on the LASOS database entry portal, all users will review an information governance document and electronically sign it. Data sharing agreements will be requested from each individual local investigator.

Record retention and archiving

According to local hospital policies, all data and trial documentation will be stored for at least 2 yr after the main study findings are publicly reported and then archived or destroyed by participating hospitals. Electronic data sets will be stored indefinitely.

Statistical analysis

Categorical variables will be described as proportions. Continuous variables will be described as mean and standard deviation, if normally distributed, or median and interquartile range, if not normally distributed.

Univariate analysis will be performed to test factors associated with in-hospital postoperative complications, admission to critical care, and in-hospital death. Single-level and hierarchical multilevel logistic regression models will be constructed to identify factors independently associated with these outcomes and to adjust for differences in confounding factors. Factors will be entered into the models based on biological plausibility and low rate of missing data. Results of logistic regression will be reported as adjusted odds ratios with 95% confidence intervals.

Sample size

As many centres as possible will be recruited in participating countries. A specific sample size was not calculated, and statistical models will be adjusted to the event rate presented by the final sample recruited and included. All eligible participants during the recruitment period will be included.

Dissemination plans

Following the principles of data preservation and sharing, the LASOS steering committee will consider all reasonable requests to conduct secondary analyses after the publication

of the overall and final results. The primary consideration for decisions to conduct secondary analyses will be the quality and validity of the proposal. Synopsis of data will be reported publicly; all national, institutional, and individual patient data will be accurately anonymised. Individual participant data will remain the property of the respective participating hospital. Once each local investigator has validated that the data from their centre are complete and correct, they will receive a worksheet of the raw data for their institution. The entire LASOS data set, anonymised for research participants, centres, and countries, will be made publicly available 2 yr after the publication of the main scientific report. Before this, the steering committee will not release any data to the study collaborators or a third party if they believe this is related to the broader aims of the LASOS project.

A writing committee to draft the scientific reports will be appointed by the steering committee, which will be disseminated on time. LASOS investigators will prioritise leading secondary analyses; authorship and participation opportunities will be established on the contribution to the main study. The LASOS steering committee will consider the scientific rationality and the anonymity of the participating hospitals before conceding any such requests. A prior written agreement will set out the terms of collaborations for secondary analyses when necessary.

The LASOS steering committee will approve the final version of all scientific reports before submission. If a disagreement occurs between the steering committee members, the co-chief investigators will reach a final decision. Every analysis using LASOS data from two or more centres will be counted as secondary analysis and is subject to these policies.

LASOS is the first study to evaluate the incidence of surgical complications and associated mortality in patients from Latin America. We intend to recruit at least 20 000 patients from all countries, considering the large population of Latin America and the previous studies that used the same methods.^{5,17} Also, considering the high incidence of Caesareans in those countries, this study will assess the related incidence of surgical complications and mortality in that population, including maternal and neonatal outcomes. As a pragmatic study, data will be collected until 30 days after surgery. Therefore, long-term outcomes will not be recorded, which could be a limitation of the study considering that the length of hospitalisation could influence in-hospital mortality.

In conclusion, the results of LASOS may augment our understanding of postoperative complications and surgical mortality. Considering the high volumes of surgery performed, recognising and understanding postoperative complications and mortality could improve perioperative care.

Authors' contributions

Study conception/design: LAH, LCS, RMP.
Administrative support: VCQ, LNN, APZV.
Drafting of article: VCQ, LNN, APZV.
Revising of article: all authors.

Declarations of interests

The authors declare that they have no conflicts of interest.

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