Colombian surgical outcomes study insights on perioperative mortality rate, a main indicator of the lancet commission on global surgery – a prospective cohort study

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Summary

Background Surgical care holds significant importance in healthcare, especially in low and middle-income countries, as at least 50% of the 4.2 million deaths within the initial 30 days following surgery take place in these countries. The Lancet Commission on Global Surgery proposed six indicators to enhance surgical care. In Colombia, studies have been made using secondary data. However, strategies to reduce perioperative mortality have not been implemented. This study aims to describe the fourth indicator, perioperative mortality rate (POMR), with primary data in Colombia.

Methods A multicentre prospective cohort study was conducted across 54 centres (hospitals) in Colombia. Each centre selected a 7-day recruitment period between 05/2022 and 01/2023. Inclusion criteria involved patients over 18 years of age undergoing surgical procedures in operating rooms. Data quality was ensured through a verification guideline and statistical analysis using mixed-effects multilevel modelling with a case mix analysis of mortality by procedure-related, patient-related, and hospital-related conditions.

Findings 3807 patients were included with a median age of 48 (IQR 32–64), 80.3% were classified as ASA I or II, and 27% of the procedures had a low-surgical complexity. Leading procedures were Orthopedics (19.2%) and Gynaecology/Obstetrics (17.7%). According to the Clavien–Dindo scale, postoperative complications were distributed in major complications (11.7%, 10.68–12.76) and any complication (31.6%, 30.09–33.07). POMR stood at 1.9% (1.48–2.37), with elective and emergency surgery mortalities at 0.7% (0.40–1.23) and 3% (2.3–3.89) respectively.

Interpretation The POMR was higher than the ratio reported in previous national studies, even when patients had a low–risk profile and low-complexity procedures. The present research represents significant public health progress with valuable insights for national decision-makers to improve the quality of surgical care.

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Keyword: Global health; Public health; Surgery; Health policy; Hospital mortality

Introduction

Surgical interventions account for approximately 30% of the worldwide disease burden. Their significance is pronounced in low- and middle-income countries, where these interventions are not just medical procedures but critical catalysts for improved medical attention and public health.[1] On this note, The Lancet Commission on Global Surgery aims to enhance surgical care globally as a multidisciplinary initiative.[2] Six surgery indicators have been established to evaluate the strengths and weaknesses of healthcare systems and recognize the necessity for improving access to surgical

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Research in context

Evidence before this study

A comprehensive search of multiple databases, including ScienceDirect, PubMed, and Embase, was conducted. The search ranged from 2015 to 2022, aligning with the release of the Lancet Commission on Global Surgery. Search terms included "perioperative mortality," "surgical outcomes," "global surgery," and "postoperative complications." Quality assessment considered study design, sample size, population diversity, methodological rigor, and potential biases. The existing evidence highlights the diverse global landscape of surgical outcomes, emphasizing the perioperative mortality rate (POMR). Pearse et al. (2016) conducted a prospective cohort study in 27 countries involving 44,814 patients across 474 institutions, finding a POMR of 0.5% and a postoperative complication rate of 16.8%. Jawad et al. (2016), in Sweden, with a prospective cohort study of 1314 patients across 8 institutions, reported a POMR of 1.8%. Biccard et al. (2018) studied 11,422 patients across 247 institutions in 25 African countries through a prospective observational cohort study, finding a POMR of 2.1% and postoperative complications at 18.2%. Hewitt-Smith et al. (2018) in Uganda performed a prospective cohort study with 4773 patients across 440 institutions, reporting a POMR of 2.0% and complications of 5.8%–16.8%. Osinaike et al. (2019) in Nigeria conducted a prospective cohort study of 1425 patients across 79 institutions, finding a POMR of 6.0% and complications at 18.5%. Hanna et al. (2020) in Colombia used a retrospective cohort study with national healthcare data, reporting a POMR of 0.73%–0.76%. Finally, Gomez et al. (2022) in Colombia conducted a retrospective cohort study with national healthcare data, reporting a POMR of 0.87%. These studies collectively emphasize the global disparities in surgical outcomes and the need for standardized measures to enhance surgical care quality worldwide.

Added value of this study

The findings of this study contribute to the existing body of knowledge by providing primary data on the POMR in Colombia, an area previously explored primarily through secondary data sources. This research highlights the urgent need for implementing targeted strategies to reduce perioperative mortality in low and middle-income countries (LMICs), where a substantial proportion of surgical deaths occur within the first 30 days post-surgery. By focusing on a multicentre prospective cohort study, our findings offer a granular, real-time perspective on surgical outcomes in Colombia, capturing the details often missed in retrospective analyses. Additionally, the study underscores the disparities in POMR compared to global averages, even among low-risk and low-complexity procedures, suggesting underlying systemic issues that need addressing. The rigorous methodology, including mixed-effects multilevel modeling and comprehensive case mix analysis, ensures robust and reliable data, providing valuable insights for policymakers. This work aligns with the Lancet Commission on Global Surgery's indicators, advancing public health initiatives and guiding national decision-makers in improving the quality of surgical care. Our findings bridge critical gaps in the literature, emphasizing the necessity for standardized measures and consistent data collection to enhance surgical care quality worldwide.

Implications of all the available evidence

Since The Lancet Commission of Global Surgery was established, Global Surgery investigation in LMIC regions has gained relevance. Nowadays, accurate and high-quality analysis of surgical system indicators has become the first step in formulating population-adjusted public policies in healthcare. Through the ColSOS study, we aim to contribute to our country with the first research study reporting accurate and prospective data on perioperative mortality in Colombia and Latin America. Moreover, with the coordinated efforts of private health institutions and the Ministry of Health, we expect that the outcomes of this study can guide the construction of a strategy, such as the National Surgery Plan, that can promote effective and equitable perioperative care in Colombia. This strategy has the potential to save many lives and enhance the quality of life in countless others.

care and achieving better perioperative outcomes worldwide.[3] They have become crucial in public health as they improve patient outcomes, increase economic growth, facilitate infrastructure development, and promote gender equality.[4] Moreover, these indicators have also been incorporated into the World Development Indicators dataset.[5]

The fourth indicator of The Lancet Commission on Global Surgery aims to measure perioperative mortality.[3] It is "the number of in-hospital deaths from any cause in patients who have undergone a procedure in an operating theatre, divided by the total number of procedures".[3] Its relevance becomes evident as over four million patients worldwide die within 30 days following surgery annually, with nearly half of these cases being preventable.[6,7] Monitoring this indicator can improve patient safety, guide policymakers, and facilitate research and innovation in surgery.[8] Furthermore, every country should track the perioperative mortality rate and create specific country and region targets to accomplish the goals proposed by The Lancet Commission on Global Surgery target for 2030.

Multiple multicentre collaborative studies on this indicator have emerged.[9,10] However, the evidence must still be provided in low and middle-income countries. Specifically, in Colombia, two studies have aimed to establish perioperative mortality. The first, conducted by Hanna et al., found a 30-day postoperative mortality rate of 0.74%.[9] The second, conducted by Gomez Samper et al., reported a national mortality rate of 0.84%.[10] However, these studies have some limitations, as they rely on secondary data sources and do not strictly adhere to the guidelines set by The Lancet Commission on Global Surgery. This triggers difficulty in interpreting the data accurately and raises questions about their reliability, as represented by a notably lower mortality rate than those reported in Europe and Africa.[11,12] As a result, it highlights the requirement for primary data collection to enhance surgical safety in Colombia.

Colombia is a low- and middle-income country that protects the right to health in its Constitution.[13] In 1993, the Colombian Congress passed Law 100, which aimed to provide a decentralized healthcare system to all its citizens. This law created the General System of Social Security in Health (SGSSS), responsible for healthcare provision under a contracting-out model. Approximately 99% of the national population is enrolled in the SGSSS, with 47% enrolled in the Subsidiary Regime and 48% in the Contributive Regime.[14] However, there is a difference between the coverage of healthcare in the country and the citizens' access, where 80% of municipalities in Colombia present low and very low access.[15] Additionally, the Colombian health system is known for needing complete and feasible data and adequate and unified records, leading to an inability to update the population's health status. Furthermore, economic disparities exist, leading to difficulties in accessing essential healthcare procedures, such as laparotomy, caesarean sections, and fracture management.[3] Identifying these inequalities and understanding their genesis are the first steps toward building a more inclusive and accessible health system.

This study aims to prospectively describe perioperative mortality rate (POMR) and postoperative complications in Colombia, following the Lancet Commission on Global Surgery and STROBE criteria for cohort studies.[16] Moreover, it aims to compare the findings of this study with official national registries from the Colombian Ministry of Health and Social Protection platform and the Health Situation Analysis report.[17] Hopefully, this study can be a basis for governmental bodies and stakeholders to implement evidence-based actions to lower perioperative mortality using intervention strategies to target population-specific risk factors.

Methods

Study design and setting

ColSOS is a multicentre prospective cohort study conducted across Colombia to determine perioperative mortality in surgical patients. The study was conducted in 54 hospitals countrywide. The study data collection started in May of 2022. The primary collection ended in January 2023, and follow-up and data audit were completed in May 2023. For additional details, refer to the extended published protocol.[18] The inclusion criteria involve adult patients (over 18 years of age in Colombia) who underwent any surgical procedures performed in an operation room, excluding radiological/endoscopic procedures. All institutions, irrespective of their public or private nature and complexity, were eligible to participate if they conducted the procedures in an operating room.

Sample size estimation

The study's sample size was determined using the Kelsey proportion formula.[19] A 1353 sample size was estimated using the previous perioperative mortality rates reported in Colombia,[9] setting a desired precision of 0.5%, an alpha value of 0.05, and a design effect of 1.2. However, convenience sampling was utilized to maximize patient inclusion.

Outcomes

The primary outcome was perioperative mortality, defined as death within 30 days of surgery. Furthermore, the secondary outcomes were postoperative complications measured by Clavien–Dindo (CD), being any complication (CD I–V) and major complication (CD III-V). Specific complications were estimated. The variables' definitions and further information are presented in the published protocol.[18] Follow-up was recorded until hospital discharge, death, or 30 inpatient days. The variables of interest in the study are patient-related, procedure-related, and hospital-related conditions such as hospital funding and level of complexity (I–IV) and installed surgical capacity. A case mix analysis was performed to understand mortality trends concerning procedure-related, patient-related, and hospital-related conditions.

Data collection

The country was divided into six regions (geographic and administrative divisions that group together several departments with similar geographic, cultural, economic, or political characteristics), all with different collection start dates so that a logistics team would be fully present for the collection. Each hospital collected surveillance data for one week, and no data was collected simultaneously between regions.

Bias control

Several strategies were outlined to address potential sources of bias in the study. Information bias was minimized by providing comprehensive training to researchers at participating hospitals and instructing them on the use of data collection tools. Communication systems are established to facilitate collaboration and clarify data collection procedures. Using a convenience sample increases the risk of selection bias and participant bias, but this was acknowledged in the limitations and mitigated by including almost three times the sample size and as many hospitals as possible. Finally, our study rigorously addressed confounding variables through adjusted analyses and conducted sensitivity analyses to assess result robustness. Meticulous data collection procedures were implemented to ensure accuracy. These measures enhance the validity and reliability of our findings, reflecting our commitment to high-quality research. However, we are aware that our adjustments may not fully account for all potential confounders.

A validation protocol was established to ensure the integrity and accuracy of research data. It involved seven critical checks per patient, including appropriate regional classification, extreme values validation of age and Body Mass Index (BMI), matching ASA (American Society of Anaesthesiologists) score with patient comorbidities, surgery code congruence with procedure type and method, surgery duration, and appropriate CD classification with complications and mortality. An independent audit by at least three members from non-participating hospitals ensured the corrections were made. Once validated, the data was cleared for analysis.

Statistical analysis

A descriptive analysis was conducted, utilizing relative and absolute frequencies for qualitative variables. Quantitative variables were subjected to normality tests, either Shapiro–Wilk or Kolmogorov–Smirnov, and measures of central tendency and dispersion were used according to their distribution. Perioperative mortality was presented as a rate and stratified by age and urgency of the procedure. A bivariate analysis for mortality was performed using the chi-square test or Fisher's exact test for categorical variables and the Student's t-test or Mann–Whitney U test, as appropriate, based on the normality of the quantitative variables. The P-value was considered statistically significant if less than 0.05.

The study analysed the association between risk factors and outcomes of interest at individual, department (based on political-administrative subdivisions, each with its own capital and local governance), and regional levels. Mixed-effects multilevel modelling was used due to the hierarchical structure of the data, with repeated measurements at different grouping levels. A selection of predictor variables was made based on exploratory data analysis and previous knowledge of the subject of study. A multilevel mixed linear regression for perioperative mortality was carried out, calculating odds ratios (OR) and 95% confidence intervals (CI) for associated variables. In the mixed-effects multilevel modelling analysis, the effects of risk factors were examined and adjusted at the individual, department, and regional levels, and adjustments were made to control for differences due to confounding factors. The decision to employ mixed-effects multilevel modelling analysis was driven by the hierarchical structure of our dataset, with individuals nested within departments and regions. This approach effectively modelled the correlation between observations within the same department or region. By utilising mixed-effects multilevel modelling analysis, we could derive estimates of fixed effects, such as odds ratios, for the association between predictor variables and perioperative mortality. Additionally, incorporating random effects at the department and regional levels allowed us to explore the effects of risk factors across different levels of aggregation and capture potential clustering effects within departments and regions. Multicollinearity was considered when the variance inflation factor was greater than 5 for any variables. The model fit and discrimination quality were determined using information criteria such as AIC (Akaike information criterion) and R-squared and by inspection of diagnostic plots.

Finally, there was no missing data in primary and secondary outcomes. The number of missing data for variables is presented in Appendix 2. All analyses were carried out in an imputated dataset; the multiple imputation was performed using the AMELIA statistical package of R studio. Sensitivity analyses were performed to evaluate the association between preoperative risk factors and inpatient mortality, addressing potential bias related to missing data by a complete case analysis analysing differences in age groups and hospital characteristics (Appendix 2). All analyses were performed using the R Studio statistical software version 4.2.2.

Ethics statement

This work was registered in Clinical Trials (NCT05147623) and approved by Fundación Cardioinfantil-Instituto de Cardiología Institutional Ethics Committee in 2021 (Ref Number: No. 41–2021. All healthcare hospitals involved had approval from their respective institutional ethics committees. In cases where institutions did not have their own, approval was obtained from the Ethics Committee of the Fundación Cardioinfantil-Instituto de Cardiología. The study was conducted within the guidelines of the ethical principles for medical research on human subjects, and all included patients who provided verbal or written consent in accordance with the requirements of each participating hospital.

Role of the funding source

The study's funders had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Results

The present study analysed 3807 patients from 54 hospitals across 23 departments in Colombia (Fig. 1); the hospital characteristics are in Table 1. The patients had a median age of 48 years (IQR 32–64), and most were female, accounting for 56% of the sample. Only 33.5%

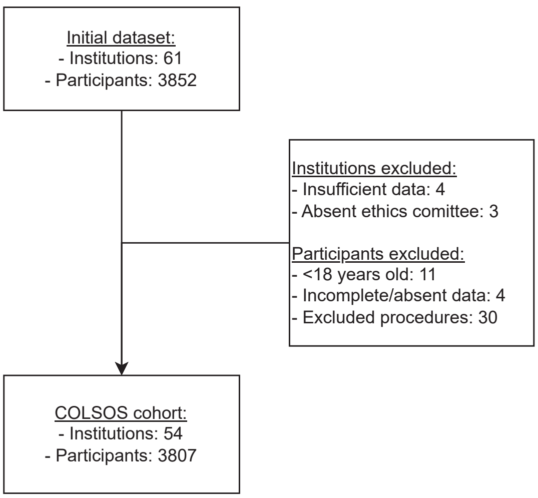

Fig. 1: Flowchart of patient recruitment.

of the patients were classified as ASA I, while more than 60% were ASA II or III. The most prevalent comorbidities observed were arterial hypertension (26.7%), dyslipidaemia (11.7%), diabetes mellitus (10.8%), and thyroid disease (10.4%). Furthermore, almost half of the patients belonged to a low socioeconomic class, and most had contributed (48.3%) or subsidised (37.4%) healthcare affiliation regimens. Most of the patients were mestizo (93.4%), and only 3.5% were violent-displaced persons or migrants. The comprehensive descriptive analysis is presented in Table 2.

	Total (N = 54)
Complexity level, *n*(%)	
Second level	13 (24.1%)
Third level	23 (42.6%)
Fourth level	18 (33.3%)
Hospital location, *n*(%)	
Rural	4 (7.4%)
Urban	50 (92.6%)
Number of operation rooms, median [IQR]	6 [4,9]
Number of intensive care unit rooms, median [IQR]	25.5 [14, 44]
Number of surgeons, median [IQR]	10 [5,18]
Number of orthopaedic surgeons, median [IQR]	6 [4,11]
Number of obstetricians and gynaecologists, median [IQR]	6 [3,14]
Number of anaesthesiologists, median [IQR]	15 [8,24]
Hospital funding, *n*(%)	
Private	29 (53.7%)
Public	25 (46.3%)

Table 1: **Hospital surgical capacity and characteristics.**

Concerning surgical procedures, there was a balanced 1:1 ratio of emergent vs. non-emergent procedures, with a median duration of 60 min (IQR 40–97). Orthopaedic (19.2%), gynaecological (17.7%), and gastrointestinal (16.4%) procedures were the most commonly performed. Most surgical procedures were classified as medium (67.1%) or low complexity (27%), with high-complexity procedures accounting for only 5.9%. The open surgical approach was used for 69.9% of patients, followed by the video-assisted approach in 23.6% of cases. During the intraoperative phase, only 0.4% of patients suffered cardiac arrest, and hemoderivative transfusion was required by only 3.2% of patients (Table 2).

The median in-hospital stay was one day (IQR 0–4), and 9.8% of patients required intensive care unit (ICU) with a median stay of 4 days (IQR 2–7). Of all patients, 68.4% did not experience any postoperative complications, while 14.9% had CD I, 5% CD II, 5.5% CD III, and 6.2% presented CD IV-V. The most frequent complications were operative site infection (3%), acute kidney injury (2.8%), and sepsis (2.4%). Complete details of the complications can be found in Table 3.

The perioperative mortality rate occurred in 1.9% of patients (IC 1.48–2.37). The adjusted POMR was 3% in emergency surgery (IC 2.30–3.89), 0.7% in elective surgery (IC 0.40–1.23), 4.7% in patients aged ≥65 (IC 3.42–6.29), and 1% in patients aged <65 (0.67–1.43). POMR adjusted by hospital setting found higher mortality in public and third-level complexity hospitals. The adjusted POMR is graphically represented in Fig. 2, and the geographical distribution of POMR can be found in Fig. 3. The bivariate analysis of perioperative mortality is presented in Table 2.

Multilevel analysis

A multilevel mixed-effects multilevel modelling analysis approach was employed to assess factors influencing perioperative mortality. Healthcare affiliation was a significant factor, showing that patients with a contributive regime had a 55% reduction of mortality risk compared to patients in subsidised regimes. Elective surgery also presented as a protector factor, decreasing mortality risk by 69% compared to emergency surgery. Significant preoperative risk factors included age, increasing mortality probability by 2% by each year growth, low weight compared to normal weight presented a 4.82 odds ratio, 3.98 for COPD, 1.96 for patients with COVID-19 infection, 10.33 times for those with an ASA score of IV compared to ASA I, and 6.57 times for those presenting hemodynamic instability before the procedure. Finally, the only operative significant predictors found were orthopaedic surgery (OR 3.89), gastrointestinal surgery (OR 6.23), urology (OR 6.09), Thoracic surgery (OR 7.21), Neurosurgery (OR 4.99), Otorhinolaryngology (OR 15.69); and the endovascular approach, with an odds ratio of 5.28

	Survival (N = 3735)	Perioperative Mortality (N = 72)	Total (N = 3807)	P-value
Age (Years), *Median [Q1, Q3]*	48.0 [32.0, 63.0]	68.0 [53.0, 79.3]	48.0 [32.0, 64.0]	<0.0001[b]
Sex, *n(%)*				
Feminine	2102 (56.3%)	29 (40.3%)	2131 (56.0%)	0.11
Masculine	1630 (43.6%)	43 (59.7%)	1673 (43.9%)	
Other	3 (0.1%)	0 (0%)	3 (0.1%)	
Smoke history, *n(%)*				
No	3285 (88.0%)	53 (73.6%)	3338 (87.7%)	0.001[a]
Yes	450 (12.0%)	19 (26.4%)	469 (12.3%)	
Actual smoking, *n(%)*				
No	2039 (54.6%)	34 (47.2%)	2073 (54.5%)	0.19
Yes	1696 (45.4%)	38 (52.8%)	1734 (45.5%)	
BMI (kg/m^2), *Median [Q1, Q3]*	25.3 [23.0, 28.5]	23.1 [20.1, 25.8]	25.2 [23.0, 28.5]	<0.0001[b]
Hypertension, *n(%)*				
No	2754 (73.7%)	35 (48.6%)	2789 (73.3%)	<0.0001[b]
Yes	981 (26.3%)	37 (51.4%)	1018 (26.7%)	
Cardiac arrhythmia, *n(%)*				
No	3608 (96.6%)	63 (87.5%)	3671 (96.4%)	0.0002[b]
Yes	127 (3.4%)	9 (12.5%)	136 (3.6%)	
Cardiac failure, *n(%)*				
No	3559 (95.3%)	61 (84.7%)	3620 (95.1%)	0.0002[b]
Yes	176 (4.7%)	11 (15.3%)	187 (4.9%)	
Dyslipidaemia, *n(%)*				
No	3301 (88.4%)	60 (83.3%)	3361 (88.3%)	0.41
Yes	434 (11.6%)	12 (16.7%)	446 (11.7%)	
Diabetes mellitus, *n(%)*				
No	3337 (89.3%)	57 (79.2%)	3394 (89.2%)	0.022[a]
Yes	398 (10.7%)	15 (20.8%)	413 (10.8%)	
COPD, *n(%)*				
No	3624 (97.0%)	56 (77.8%)	3680 (96.7%)	<0.0001[b]
Yes	111 (3.0%)	16 (22.2%)	127 (3.3%)	
CKD, *n(%)*				
No	3592 (96.2%)	60 (83.3%)	3652 (95.9%)	<0.0001[b]
Yes	143 (3.8%)	12 (16.7%)	155 (4.1%)	
Thyroid disease, *n(%)*				
No	3347 (89.6%)	63 (87.5%)	3410 (89.6%)	0.84
Yes	388 (10.4%)	9 (12.5%)	397 (10.4%)	
Covid 19 antecedent, *n(%)*				
No	3310 (88.6%)	61 (84.7%)	3371 (88.5%)	0.57
Yes	425 (11.4%)	11 (15.3%)	436 (11.5%)	
Covid 19 infection, *n(%)*				
No	2892 (77.4%)	38 (52.8%)	2930 (77.0%)	0.82
Yes	843 (22.6%)	34 (47.2%)	877 (23.0%)	
Socioeconomic status, *n(%)*				
Lower	831 (22.2%)	15 (20.8%)	846 (22.2%)	0.86
Upper lower	1219 (32.6%)	29 (40.3%)	1248 (32.8%)	
Lower middle	1068 (28.6%)	22 (30.6%)	1090 (28.6%)	
Upper middle	406 (10.9%)	2 (2.8%)	408 (10.7%)	
Lowe high	149 (4.0%)	2 (2.8%)	151 (4.0%)	
Higher	62 (1.7%)	2 (2.8%)	64 (1.7%)	
Healthcare affiliation, *n(%)*				
Contributive	1813 (48.5%)	25 (34.7%)	1838 (48.3%)	0.25
Subsidized	1387 (37.1%)	37 (51.4%)	1424 (37.4%)	
Special regimen	183 (4.9%)	5 (6.9%)	188 (4.9%)	

(Table 2 continues on next page)

	Survival	Perioperative Mortality	Total	P-value
	(N = 3735)	(N = 72)	(N = 3807)	
(Continued from previous page)				
Prepaid	233 (6.2%)	2 (2.8%)	235 (6.2%)	
Cash	43 (1.2%)	0 (0%)	43 (1.1%)	
International insurance	5 (0.1%)	1 (1.4%)	6 (0.2%)	
None	25 (0.7%)	1 (1.4%)	26 (0.7%)	
SOAT	46 (1.2%)	1 (1.4%)	47 (1.2%)	
Race/Ethnicity, *n*(%)				
Mestizo	3486 (93.3%)	70 (97.2%)	3556 (93.4%)	0.21
Caucasian	88 (2.4%)	1 (1.4%)	89 (2.3%)	
Afrodescendant	114 (3.1%)	0 (0%)	114 (3.0%)	
Indigenous	47 (1.3%)	1 (1.4%)	48 (1.3%)	
Migration, *n*(%)				
No	3601 (96.4%)	71 (98.6%)	3672 (96.5%)	0.99
Inmigrant (other country)	77 (2.1%)	1 (1.4%)	78 (2.0%)	
Forced migration (inside country)	57 (1.5%)	0 (0%)	57 (1.5%)	
ASA score, *n*(%)				
I	1271 (34.0%)	5 (6.9%)	1276 (33.5%)	<0.0001[b]
II	1766 (47.3%)	16 (22.2%)	1782 (46.8%)	
III	573 (15.3%)	30 (41.7%)	603 (15.8%)	
IV	115 (3.1%)	21 (29.2%)	136 (3.6%)	
V	10 (0.3%)	0 (0%)	10 (0.3%)	
Surgical complexity, *n*(%)				
Low	1018 (27.3%)	8 (11.1%)	1026 (27.0%)	0.010[a]
Medium	2501 (67.0%)	55 (76.4%)	2556 (67.1%)	
High	216 (5.8%)	9 (12.5%)	225 (5.9%)	
Surgery urgency, *n*(%)				
Emergency	1858 (49.7%)	58 (80.6%)	1916 (50.3%)	<0.0001[b]
Elective	1877 (50.3%)	14 (19.4%)	1891 (49.7%)	
Preoperative hemodinamical inestability, *n*(%)				
No	3646 (97.6%)	52 (72.2%)	3698 (97.1%)	<0.0001[b]
Yes	89 (2.4%)	20 (27.8%)	109 (2.9%)	
Preoperative cardiac arrest, *n*(%)				
No	3722 (99.7%)	71 (98.6%)	3793 (99.6%)	0.31
Yes	13 (0.3%)	1 (1.4%)	14 (0.4%)	
Surgical categories, *n*(%)				
Orthopaedic	717 (19.2%)	14 (19.4%)	731 (19.2%)	0.99
Gynaecology and obstetrics	672 (18.0%)	0 (0%)	672 (17.7%)	0.0003[b]
Breast surgery	78 (2.1%)	0 (0%)	78 (2.0%)	0.46
Gastrointestinal	603 (16.1%)	23 (31.9%)	626 (16.4%)	0.001[b]
Coloproctology	79 (2.1%)	2 (2.8%)	81 (2.1%)	0.92
Hepatobiliary	203 (5.4%)	2 (2.8%)	205 (5.4%)	0.61
Urology	277 (7.4%)	5 (6.9%)	282 (7.4%)	0.98
Vascular	161 (4.3%)	8 (11.1%)	169 (4.4%)	0.021[a]
Cardiovascular	84 (2.2%)	5 (6.9%)	89 (2.3%)	0.033[a]
Thoracic	94 (2.5%)	7 (9.7%)	101 (2.7%)	0.0008[b]
Head and neck	125 (3.3%)	2 (2.8%)	127 (3.3%)	0.96
Plastic	239 (6.4%)	3 (4.2%)	242 (6.4%)	0.74
Transplant	24 (0.6%)	0 (0%)	24 (0.6%)	0.79
Neurosurgery	102 (2.7%)	4 (5.6%)	106 (2.8%)	0.35
Otorhinolaryngology	48 (1.3%)	1 (1.4%)	49 (1.3%)	0.99
Ophthalmology	35 (0.9%)	0 (0%)	35 (0.9%)	0.71
Abdominal wall	102 (2.7%)	1 (1.4%)	103 (2.7%)	0.78

(Table 2 continues on next page)

	Survival (N = 3735)	Perioperative Mortality (N = 72)	Total (N = 3807)	P-value
(Continued from previous page)				
Soft tissues	58 (1.6%)	0 (0%)	58 (1.5%)	0.56
Surgical approach, *n(%)*				
Open	2608 (69.8%)	54 (75.0%)	2662 (69.9%)	0.027[a]
Video-assisted	884 (23.7%)	13 (18.1%)	897 (23.6%)	
Endovascular	33 (0.9%)	5 (6.9%)	38 (1.0%)	
Open/video-assisted	61 (1.6%)	0 (0%)	61 (1.6%)	
Open/endovascular	17 (0.5%)	0 (0%)	17 (0.4%)	
Robot assisted	2 (0.1%)	0 (0%)	2 (0.1%)	
Percutaneous	38 (1.0%)	0 (0%)	38 (1.0%)	
Vaginal	69 (1.8%)	0 (0%)	69 (1.8%)	
Other	22 (0.6%)	0 (0%)	22 (0.6%)	
Intraoperative transfusion, *n(%)*				
No	3628 (97.1%)	57 (79.2%)	3685 (96.8%)	<0.0001[b]
Yes	107 (2.9%)	15 (20.8%)	122 (3.2%)	
Intraoperative cardiac arrest, *n(%)*				
No	3722 (99.7%)	68 (94.4%)	3790 (99.6%)	<0.0001[b]
Yes	13 (0.3%)	4 (5.6%)	17 (0.4%)	
Surgical duration, *Median [Q1, Q3]*	60.0 [39.0, 96.0]	82.5 [60.0, 118]	60.0 [40.0, 97.5]	0.007[a]

Descriptive analysis of the variables collected. ASA, American Society of Anesthesiologists; COPD, chronic obstructive pulmonary disease; CKD, Chronic kidney disease. [a]Statistically significant P value < 0.05. [b]Statistically very significant P value < 0.005.

Table 2: **Description of cohort.**

compared to open surgery. ORs, CI, and model characteristics are summarised in Table 4.

Upon model evaluation, the residual variance of 3.29 and null regional variability are not accounted for by the proposed model. The intraclass correlation coefficient revealed that 29% of the total variability was attributed to variations among the five evaluated regions. Additionally, the model exhibited a good fit with an AIC of 549 and an R2 exceeding 0.96, indicating that the model explains over 96% of mortality changes. Confounding and multicollinearity analyses were conducted, yielding no significant findings.

Sensitivity analysis

Age was a significant risk factor for perioperative mortality; therefore, we conducted a bivariate analysis to understand the differences between patients over and under 65 years old. Revealing that the older group had a higher prevalence of comorbidities and more severe systemic disease determined by ASA score categories. They also had lower body mass index, underwent surgeries of greater complexity and more elective procedures, required more in-hospital days and ICU care, and experienced higher rates of severe surgical complications as per the CD classification.

Third-level hospitals see the highest surgical volume at 1727 patients, explaining the increased adverse events and mortalities compared to 545 at s level and 1532 at fourth-level hospitals. Despite fourth-level hospitals performing more complex procedures, their lower mortality rates are not attributed to the age, sex, or comorbidities of the patients but rather to the better socioeconomic conditions of their patients. Only 44.1% of fourth-level patients are from lower socioeconomic backgrounds, compared to 54.6% at third-level hospitals. Additionally, fewer patients at fourth-level hospitals are on subsidised health plans (19.1%) compared to third-level hospitals (43.1%) and had less public funding (17.4% vs. 40.7%). While operating under more challenging socioeconomic conditions, second-level hospitals have simpler procedures and less surgical volume, resulting in fewer complications and lower mortality rates.

Discussion

The study aimed to characterise POMR in Colombia, encompassing over 50 hospitals nationwide. A national POMR of 1.9% was identified, with approximately one in three surgically intervened individuals experiencing a deviation from the normal postoperative course. This is the first study to identify POMR in Colombia as defined by the Lancet Commission on Global Surgery. Previous research[9,10] typically reported 30-day postoperative mortality, encompassing extra hospital settings. Despite this, these results reported a POMR of 1.9%, notably higher than previous findings. Hanna et al.'s study[9] reported a national mortality rate of 0.74% (IQR 0.48–0.84), while

	Total (N = 3807)
In hospital stay (days), *Median [Q1, Q3]*	1.00 [0, 4.00]
UCI requirement, n (%)	373 (9.8%)
UCI stay (days), *Median [Q1, Q3]*	4.00 [2.00, 7.00]
Clavien Dindo, *n(%)*	
I	568 (14.9%)
II	189 (5.0%)
III	208 (5.5%)
IV	165 (4.3%)
V	72 (1.9%)
No complications	2605 (68.4%)
Surgical reintervention, *n(%)*	263 (6.9%)
Surgical site infection, *n(%)*	
Superficial	35 (0.9%)
Deep	45 (1.2%)
Organ/Space	35 (0.9%)
Urinary tract infection, *n(%)*	61 (1.6%)
Pneumonia, *n(%)*	50 (1.3%)
Sepsis, *n(%)*	93 (2.4%)
Cerebrovascular accident, *n(%)*	12 (0.3%)
Kidney acute injury, *n(%)*	
KDIGO I	39 (1.0%)
KDIGO II	42 (1.1%)
KDIGO III	27 (0.7%)
Acute myocardial infarction, n (%)	24 (0.6%)
Cardiac arrhythmia, *n(%)*	58 (1.5%)
Postoperative cardiac arrest, *n(%)*	48 (1.3%)
Acute respiratory distress syndrome, *n(%)*	45 (1.2%)
Pulmonary embolism, *n(%)*	21 (0.6%)
Surgical haemorrhage, *n(%)*	70 (1.8%)
Postoperative ileum, *n(%)*	59 (1.5%)
Anastomosis dehiscence, *n(%)*	18 (0.5%)
Fistula, *n(%)*	10 (0.3%)

ICU: intensive care unit, 30-day major complication (Clavien–Dindo grade ≥ III), 30-day any complication (Clavien–Dindo grade I-II).

Table 3: **Descriptive analysis of the main perioperative complications.**

Samper et al.'s granular analysis[10] reported 0.87%. Discrepancies may stem from diverse data collection methods, sources, and surgical procedure definitions.

Comparisons with low- and middle-income countries revealed lower mortality rates than African cohorts, such as ASOS (African Surgical Outcomes Study) at 2.1%, 6% in Nigeria, 2.0% in Uganda, and 2.5–3.3% in Madagascar.[11,19–22] Conversely, compared with Latin American countries, our POMR was higher than Brazil's reported rate of 1.71%.[23] However, this indicator has not yet been described in the region following the definition proposed by the Lancet Commission on Global Surgery. Comparisons with ISOS (International Surgical Outcomes) at 0.5% and EuSOS (European Surgical Outcomes Study) at 4% also showed similarity, suggesting our findings align with economically similar regions.[11,24] Significant differences exist between cohorts, such as a higher proportion of elective procedures and lower complexity in our study compared to African cohorts. In contrast, comparisons with European studies showed younger patients, fewer comorbidities, and a lower proportion of high-complexity procedures.

It is crucial to note that various national-level factors can influence POMR, even in high-quality healthcare systems.[25] Therefore, our study adjusted POMR by age and intervention timing, revealing that urgent procedures had a fourfold higher mortality risk than elective ones, and patients over 65 years had almost five times higher mortality than younger individuals. These findings align with evidence from other continents, such as the African ASOS study[12] and national studies like Samper's,[2] which reported 0.73% mortality for elective procedures and 1.3% for urgent ones, with mortality 5.6 times higher in elderly patients.

To understand perioperative mortality, not only was adjusted, but a mixed-effects multilevel modelling analysis was used, within which we evidenced one of the most surprising findings of the research. The results suggested that patients in the contributive regime had a 54% reduction in risk of perioperative mortality compared to the subsidised regime. This finding aligns with existing studies highlighting substantial healthcare access and quality disparities between Colombian contributory and subsidised regimens.[26] While it's undeniable that subsidised regimen encapsulates social determinants of health such as income, education, employment, housing, and gender,[27] our investigation led us to hypothesise a significant issue: affiliation to the subsidiary regimen itself is a risk factor for perioperative mortality. Our finding corroborates the results of Hilarión-Gaitán,[27] who describes serious health inequalities according to the affiliation regime. Among his results, he describes that of 61 events notified to Sivigila (Public Health Surveillance System), 37 had higher rates of incidence or mortality in the subsidised regime, with 31.74 times higher mortality from malnutrition in children under five, but also higher rates of maternal mortality, infectious diseases, diarrhoea, and malnutrition. Similarly, the Health Situation Analysis (ASIS) of 2022 describes that the highest proportion of deaths were affiliated with the subsidised regime.[17] Other studies relate the subsidised regime to longer waiting times for care and less access to and use of health services.[27–30]

The third level of hospital care shows a considerable increase in surgical volume, with 1727 patients, compared to the second (545) and fourth (1532) levels, which could explain the increase in adverse events and mortalities. However, even though more complex procedures are performed at the fourth level, the mortality rate is lower than the third. Based on the results, it has been ruled out that age, sex, and comorbidities may be related to this trend. Instead, a possible relationship has

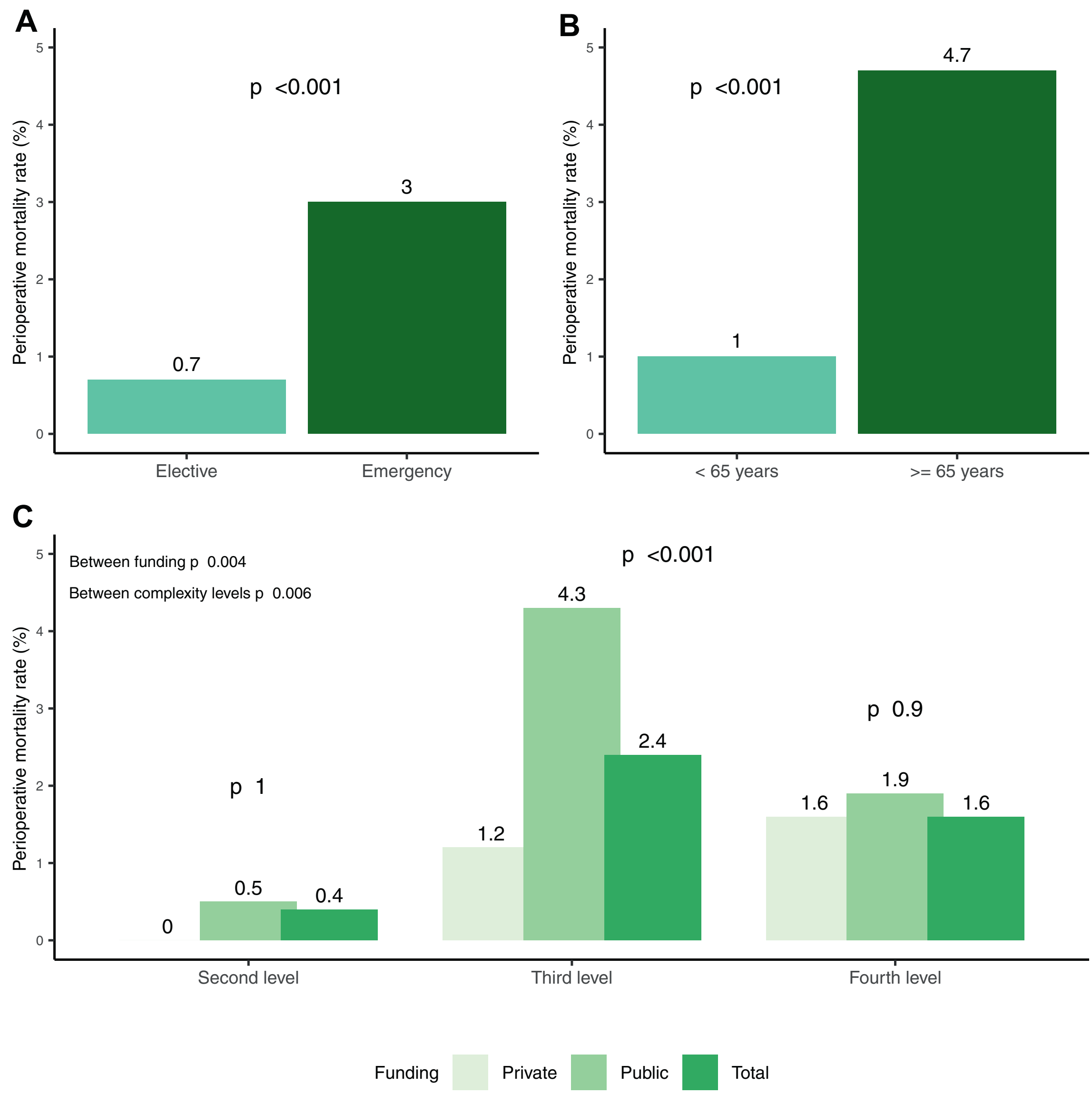

Fig. 2: Adjusted POMR by (A) surgical emergency, (B) patient age, (C) hospital funding and complexity level.

been identified with the socioeconomic conditions of the patients attended at this level. It stands out that a considerably higher percentage of patients attending the third level belong to low socioeconomic strata (54.6%) compared to those at the fourth level (44.1%). In addition, a significant difference is observed in the percentage of patients belonging to the subsidized regime, higher in the third level (43.1%) than in the fourth level (19.1%). On the other hand, a correlation has been observed with the hospitals' public funding level, being higher in the third level (40.7%) compared to the fourth level (17.4%). Nevertheless, although the second level has more precarious socioeconomic conditions and a lower surgical capacity than the third level, its lower complexity of procedures translates into a lower rate of complications and mortality.

In our cohort, a high body mass index compared to a decreased one behaved as a protective factor, reducing the risk of perioperative mortality. Still, moreover, low weight was a significant risk, increasing almost five times the perioperative mortality risk compared to normal weight. In the Swedish EuSOS cohort, there was no statistical significance between body mass index and 30-day perioperative mortality. Still, when extending the follow-up to 1 year, it presented an adjusted OR of 0.93 (CI 0.88–0.98, p 0.0012).[31] Other authors reported that overweight and obesity in patients undergoing major surgery was a protective factor for mortality but a risk

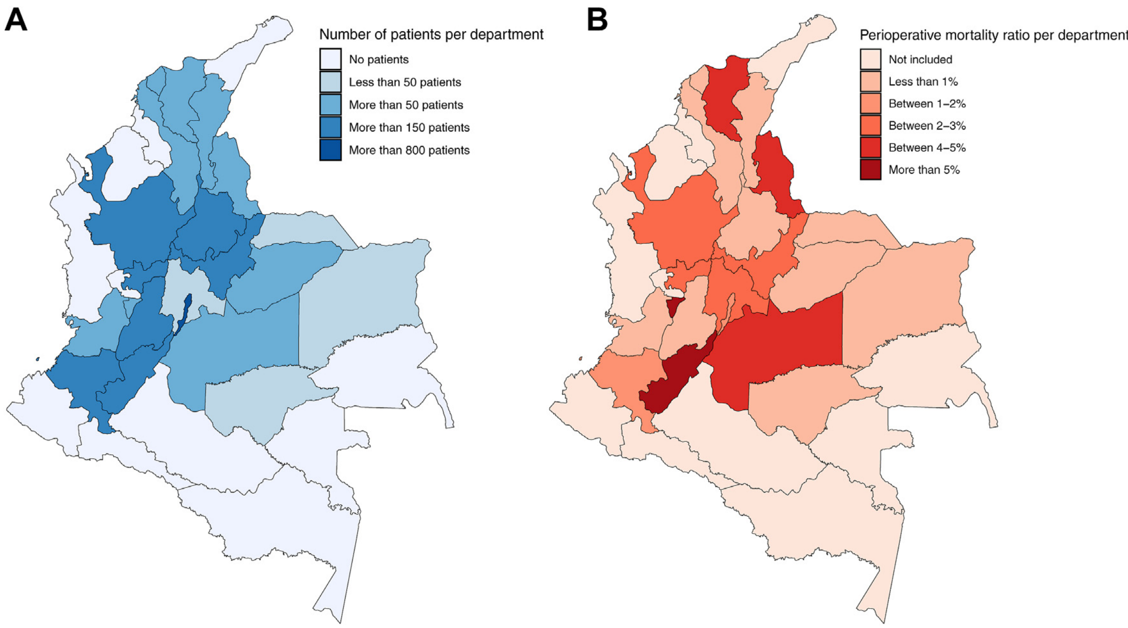

Fig. 3: Colombian map demonstrates disparate POMR distribution between regions (A) Number of Patients per department, and (B) POMR per department.

factor for postoperative complications.[32] In fact, various authors hypothesized that it is caused by the obesity paradox, which proposes that in stressful situations such as in the postoperative period and its complications, adipose tissue supplies the energy requirements[33]; others consider that the chronic inflammation of obesity limits excessive acute inflammation in the postoperative period.[34] However, our data suggest that increasing BMI units reduces mortality risk. Still, the results clearly show that it is not overweight and obesity acting as protective factors, but low weight as a significant risk factor.

The results confirm that age increases the mortality risk, similar to those published by Jawad and colleagues,[31] who reported an unadjusted odds ratio of 1.04 (1.01–1.08, p 0.006). This risk factor is supported by evidence in multiple populations and is believed to be related to the accumulation of comorbidities,[31,35–38] a pattern also found in our sensitivity analysis. However, our multivariate analysis indicates that age persists as a risk factor even when adjusted by BMI, ASA, and comorbidities. Therefore, we consider other unmeasured factors that could contribute, such as frailty. This is a common syndrome in the elderly characterized by an age-related cumulative decline, which conditions less functional reserve to undergo a surgical procedure. Moreover, the frailty index is a better predictor than chronological age for operative outcomes, like 30-day mortality, especially in patients older than 75 years.[39] Therefore, frailty and nutritional status should be measured and controlled in older surgical patients.

On the other hand, comorbidities were also a risk factor in our study. An ASA score of IV generated ten times the risk of perioperative mortality compared to ASA I. Likewise, being diagnosed with COPD increased the risk of mortality by more than 200%. Findings are similar to Swesos,[31] with unadjusted ORs of 9.74 (CI 4.47–21.2) for ASA values, 28.1 (CI 3.64–217) for those who had a single chronic disease, 27.8 (CI 2.8–271.3) and 50.4 (CI 4.43–575) for those who had two or more than three chronic diseases, respectively. On the contrary, a meta-analysis published in 2019 reported that COPD was related to a higher incidence of postoperative complications but not to a higher risk of mortality.[40]

In light of the COVID-19 pandemic and post-pandemic, our results suggest that patients with acute COVID-19 infections face a nearly double risk of perioperative mortality. These findings align with international cohort studies that showed mortality rates of 24% and postoperative pulmonary complications of 51% in acute infected patients.[41] However, it's worth noting that mortality rates among this population have decreased, potentially due to the availability of vaccinations. Prasad et al.[42] found that vaccinated patients experienced better outcomes, lower mortality rates, and fewer postoperative complications than unvaccinated patients, although the difference in mortality rates was not statistically significant.

Regarding perioperative complications, our investigation revealed that 11.7% of the procedures exhibited some form of major complication, as per the Clavien Dindo classification, which encompasses minor

Predictors	Perioperative mortality		
	OR	CI (95%)	P-Value
(Intercept)	0.00	0.00–0.00	<0.0001[b]
Age (Years)	1.02	1.00–1.04	0.032[a]
Smoke history [Yes]	1.39	0.71–2.74	0.33
BMI [Reference: normal 18.5–24.9 kg/m^2]			
Low weight (<18.5 kg/m^2)	4.82	2.02–11.55	0.0004[b]
Overweight (25–29.9 kg/m^2)	1.22	0.65–2.30	0.53
Obese grade I (30–34.9 kg/m^2)	0.86	0.27–2.68	0.79
Obese grade II (35–39.9 kg/m^2)	0.78	0.10–6.36	0.82
Obese grade III (≥40 kg/m^2)	0.00	0.00–Inf	0.99
Hypertension [Yes]	1.22	0.62–2.41	0.55
Cardiac arrhythmia [Yes]	1.37	0.50–3.77	0.54
Cardiac failure [Yes]	0.47	0.18–1.22	0.12
Diabetes mellitus [Yes]	0.68	0.33–1.42	0.31
COPD [Yes]	3.98	1.85–8.58	0.0041[b]
CKD [Yes]	1.79	0.73–4.42	0.20
COVID 19 infection [Yes]	1.96	1.02–3.77	0.044[a]
Healthcare affiliation [Reference Subsidized]			
Contributively	0.45	0.25–0.83	0.0099[b]
Special regimen	1.02	0.33–3.15	0.96
Prepaid insurance	0.65	0.14–3.03	0.58
Cash	0.00	0.00–Inf	0.99
International insurance	2.86	0.07–115	0.57
SOAT	1.08	0.08–14.83	0.95
None	0.92	0.09–9.51	0.94
ASA score [Reference I]			
II	1.32	0.44–3.94	0.62
III	3.69	1.20–11.34	0.022
IV	10.33	3.05–34.96	<0.0001[b]
V	0.00	0.00–Inf	0.99
Surgical complexity [Reference Low]			
Medium	1.68	0.72–3.94	0.22
High	0.97	0.24–3.93	0.96
Surgery urgency [Elective]	0.41	0.20–0.82	0.012[a]
Preoperative hemodynamical instability [Yes]	6.57	3.01–14.35	<0.0001[b]
Preoperative cardiac arrest [Yes]	1.58	0.10–24.99	0.74
Surgical categories [Reference No]			
Orthopaedic [Yes]	3.89	1.17–12.93	0.026[a]
Gynaecology and obstetrics [Yes]	0.00	0.00–Inf	0.99
Breast surgery [Yes]	0.00	0.00–Inf	0.99
Gastrointestinal [Yes]	6.23	1.84–21.10	0.0032[b]
Coloproctology [Yes]	4.44	0.66–29.92	0.12
Hepatobiliary [Yes]	0.45	0.05–3.89	0.46
Urology [Yes]	6.09	1.29–28.76	0.022[a]
Vascular [Yes]	2.05	0.55–7.71	0.28
Cardiovascular [Yes]	2.08	0.31–13.96	0.45
Thoracic [Yes]	7.21	1.64–31.71	0.0089[b]
Head and neck [Yes]	1.64	0.27–9.95	0.59
Plastic [Yes]	2	0.40–9.97	0.39
Transplant [Yes]	0.00	0.00–Inf	0.99

(Table 4 continues on next column)

Predictors	Perioperative mortality		
	OR	CI (95%)	P-Value
(Continued from previous column)			
Neurosurgery [Yes]	4.99	1.12–22.29	0.035[a]
Otorhinolaryngology [Yes]	15.69	1.16–212.29	0.038[a]
Ophthalmology [Yes]	0.00	0.00–Inf	0.99
Abdominal wall [Yes]	5.13	0.49–53.46	0.17
Soft tissues [Yes]	0.00	0.00–Inf	0.99
Surgical approach [Reference Open]			
Video-assisted	0.69	0.30–1.57	0.37
Endovascular	5.28	1.09–25.47	0.038[a]
Open/video-assisted	0.00	0.00–Inf	0.99
Open/endovascular	0.00	0.00–Inf	0.99
Robot assisted	0.00	0.00–Inf	0.99
Percutaneous	0.00	0.00–Inf	0.99
Vaginal	0.00	0.00–Inf	0.99
Other	0.00	0.00–Inf	0.99
Random Effects			
σ2			3.29
τ00 region			0.00
ICC			0.29
N region			5
Marginal R2/Conditional R2			0.964
AIC			549.191

Odds ratios were constructed with a multilevel mixed-effects multilevel modelling regression. SOAT: Mandatory medical insurance for vehicle accidents. [a]Statistically significant P value < 0.05. [b]Statistically very significant P value < 0.005.

Table 4: **Multivariate analysis of protective and risk factors for perioperative mortality.**

complications classified as I-II and major complications categorized as ≥III. This rate is significantly lower compared to other cohorts, such as ASOS (18.2%), niSOS (18.5%), and ISOS (16.8%).[12,20,24] This difference may be attributed to various factors, including disparities in the complexity of the procedures performed across the cohorts. In addition, our study revealed that the most common complication was surgical site infection (SSIs) at a rate of 3%, mirroring findings reported in the ASOS study.[12] Given the significant morbidity associated with this outcome, it is imperative to advocate for strategies that can prevent SSIs. The ChEETAh Trial exemplifies one such strategy, emphasizing the routine change of gloves and instruments by the entire scrub team before wound closure to mitigate complications effectively.[43]

Strengths and limitations

Considering the study's methodology, notable strengths include a substantial participant pool, approximately 2.8 times the calculated lower limit sample size, prospective methodology, and the first multicentre study nationwide led by Colombian researchers. With this sample size assured, we expect to control the bias introduced by convenience sampling to the maximum extent, aiming to prevent skewing the study results and making them less generalisable. Additionally, it may overlook critical perspectives and characteristics within the population. Rigorous data quality assurance measures were taken, and previously unconsidered variables, such as migration status and socioeconomic stratum, were collected. Some variables had missing values, but imputation showed no significant differences in sensitivity analysis. Perioperative mortality was adjusted for baseline predictive factors, and a statistical model considered multilevel conditions.

One significant limitation concerns data accessibility from peripheral population hospitals in Colombia, which often lack the resources and infrastructure to participate in comprehensive research studies. This situation leads to underrepresenting or excluding certain demographic groups and geographic regions, particularly those with lower surgical volumes. However, it is noteworthy that the departments included represent most of the procedures, especially high and medium complexity, made in the country. The departments that were not included have lower procedure volumes, as evidenced by previous research.[9,10] Additionally, it's important to acknowledge potential biases related to participation rates (where higher-performing facilities might be more inclined to participate). Also, there were challenges in making comparisons due to unclear national data. Despite these limitations, our study included the departments with the highest surgical volumes. Furthermore, it's worth noting that our sample had a higher representation of private institutions than public ones, similar to findings reported by previous studies.[9,10]

We acknowledge that the designated week for data collection at each hospital may not accurately reflect typical surgical volumes due to variables like surgical team availability or other temporal factors. To address this, hospitals were permitted to request a rescheduling of their data collection week for unforeseen circumstances, which were reviewed and approved based on each hospital's specific needs and availability. Our analysis also considers potential confounding factors introduced by these timing variations, such as seasonal and regional differences. Finally, data collection occurred during the COVID-19 pandemic and post-pandemic period, warranting consideration of the historical context in interpreting results.

In conclusion, adhering to Lancet Global Surgery Commission guidelines, this study reports a POMR in Colombia of 1.9%, providing a national and local understanding of surgical patterns. Associated factors, particularly those relevant to clinical practice, were identified, shedding light on the nuanced mortality risks faced by surgical patients. Notably, the findings prompt discussions about the subsidized regime and the low weight, indicating increased perioperative mortality risk. Moreover, the remarkably high complication rate underscores the imperative to delve into causative factors and modifiable elements for preventing postoperative complications. The study's outcomes lay a foundation for evidence-based policymaking, offering valuable insights to national and local decision-makers. Recognising surgery as a pivotal component of public health, these findings contribute to the potential development of a National Surgical, Obstetric, and Anaesthesia Plan (NSOAP) in Colombia.

Contributors

CJPR and NLS: Conceptualization, data curation, data acquisition, formal analysis, funding acquisition, investigation, methodology, project administration, resources, software, supervision, validation, visualization, writing—original draft, and writing—review editing. LBA and PAC: conceptualization, funding acquisition, investigation, methodology, supervision, validation, and writing—review editing. SVAM, MPBT, LGZ, DLE, LFRS, MPVC: Conceptualization, investigation, data acquisition, methodology, project administration, resources, validation, visualization, writing—original draft, and writing—review editing. CAPS and AVS: Conceptualization, data curation, funding acquisition, methodology, writing—original draft, and writing—review editing. All authors had full access to all the data in the study, accepted responsibility to submit for publication, and met the ICMJE recommendations for authors. CJPR and NLS have directly accessed and verified the underlying data reported in the manuscript. CJPR, NLS and LBA were responsible for the decision to submit the paper.

Data sharing statement

Confidential agreements between institutions protect the data. Therefore, individual patient and hospital data will not be shared. On the other hand, protocol, informed consent, data dictionary, and data analytic code will be available upon request immediately following publication, with no end date. The request should be directed to colombiansurg@gmail.com; requestors must sign an access agreement to gain access.

Editor note

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Declaration of interests

All authors declare there are no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lana.2024.100862.

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