Safety and equity in scaling minimally invasive surgery worldwide in 109 countries using cholecystectomy as a tracer procedure: a prospective cohort study

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Summary

Background Minimally invasive surgery is rapidly expanding globally, yet there is insufficient knowledge of how to scale this technology safely and equitably across diverse health systems. We aimed to identify health-system factors associated with safe implementation of minimally invasive surgery globally, using minimally invasive cholecystectomy as a tracer procedure.

Methods We conducted a multicentre, prospective cohort study of consecutive adults undergoing cholecystectomy between July 31 and Nov 19, 2023, in 1218 hospitals across 109 countries. Data were collected by more than 10 000 health-care workers using a core measurement set mapped to the WHO Health System Building Blocks and the Global Patient Safety Action Plan. The primary outcome was 30-day procedure-specific complications, with multilevel logistic regression used to examine associations between health-system features and patient outcomes. This study is registered on ClinicalTrials.gov (NCT06223061).

Findings Among 52 187 included patients, the adjusted procedure-specific complication rate varied 40-fold between hospitals, from 0·3% in the lowest risk quintile to 12·1% in the highest risk quintile. Despite large structural differences across income groups in access to minimally invasive surgery, diagnostics, and emergency services, country income level was not independently associated with complication rates (adjusted odds ratio [OR] 0·81 [95% CI 0·59–1·10] for upper-middle income *vs* high income and 0·99 [0·70–1·39] for lower-middle income or low income *vs* high income). Three modifiable hospital-level factors were strongly associated with safer outcomes: establishment of local simulation-based training facilities (adjusted OR 0·78 [0·71–0·86]; p<0·0001), adoption of intraoperative safety and communication strategies (0·87 [0·79–0·96]; p=0·0046), and on-site CT diagnostics (0·79 [0·65–0·97]; p=0·0220). Training facilities showed the greatest benefit in hospitals with limited infrastructure and an inexperienced workforce: the number needed to treat to prevent a procedure-specific complication was 21 (95% CI 14–35; p<0·0001).

Interpretation Safe implementation of minimally invasive surgery varies widely worldwide but is not defined by national income level; differences in outcomes reflect the ability of health systems to adopt and safely deploy new surgical techniques. We identified for the first time that the presence of local simulation-based training facilities is independently associated with improved patient outcomes. Simulation appears to be fundamental to the safe delivery of minimally invasive surgery, particularly in resource-constrained settings. Together with safety systems and diagnostic capacity, these findings offer actionable targets for health systems seeking to equitably scale up essential surgical technologies.

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See Online for appendix

Introduction

The development of medical technologies holds transformative potential for health systems globally, particularly in the diagnosis and treatment of complex conditions.[1–3] Despite their recognised importance in improving health-care quality, access, and outcomes, the global implementation of these technologies remains inequitable.[4,5] Low-income and middle-income countries (LMICs) are disproportionately affected by these disparities, particularly given their growing burden of non-communicable diseases such as ischaemic heart disease and cancer.[6–8]

As the global demand for advanced medical solutions increases, there is an urgent need for strategic and equitable expansion of complex health technologies,[5,9] alongside robust evaluations of their integration within health systems.[9–12] Minimally invasive surgery represents one such crucial technology.[13,14] The recent *Lancet* Commissions on diagnostics[1] and global cancer surgery[8] have emphasised the importance of minimally invasive technologies in advancing cancer,[8] maternal,[15] and surgical[14] care globally.[1,2,8,14] Minimally invasive surgery techniques, such as laparoscopy, provide substantial advantages over open surgery, including fewer

Research in context

Evidence before this study

Minimally invasive surgery is recognised as an essential health technology, with the potential to improve outcomes, reduce recovery time, and address the growing burden of non-communicable diseases such as cancer. However, most of the evidence on minimally invasive surgery comes from high-income settings, and its safe and equitable adoption across diverse global health systems remains poorly understood. We searched PubMed and MEDLINE for articles published from database inception to June 1, 2024, using combinations of terms including "minimally invasive surgery", "laparoscopic", "implementation", "global surgery", "health system", and "low- and middle-income countries". No studies were found that prospectively assessed the safety of minimally invasive surgery on a global scale or examined how health-system factors influence outcomes across different income settings. Existing reports, including the *Lancet* Commission on diagnostics (2021) and the *Lancet* Commission on global cancer surgery (2023), highlight the importance of technological access and system-level enablers in strengthening surgical care. However, to the best of our knowledge, no previous work has examined a broad spectrum of modifiable health-system features and patient outcomes in the context of minimally invasive surgery implementation at this scale.

Added value of this study

This is, to the best of our knowledge, the first global, prospective study to assess the safe implementation of minimally invasive surgery across diverse health systems. Using minimally invasive cholecystectomy as a tracer procedure, we collected standardised, validated data from more than 52 000 patients in 1218 hospitals across 109 countries. The scale and diversity of this cohort enabled us to examine how specific health-system features influence patient outcomes. We found that, despite high adoption of minimally invasive surgery in this self-selecting sample, there was a 40-fold variation in complication rates between hospitals. Importantly, national income level was not associated with outcomes, suggesting that modifiable health-system factors, rather than economic status alone, influence safe delivery of minimally invasive surgery. For the first time, we show that the presence of simulation training facilities is independently associated with improved patient outcomes, alongside diagnostic capacity and structured safety systems. These findings identify actionable priorities for governments and health systems aiming to scale up minimally invasive surgery safely and equitably.

Implications of all the available evidence

Minimally invasive surgery is increasingly central to addressing the global burden of non-communicable diseases. Although global health strategies emphasise the importance of technology in strengthening surgical systems, our study is the first to identify specific, modifiable hospital-level factors—such as simulation training, safety practices, and diagnostic capacity—that are associated with improved minimally invasive surgery outcomes at scale. These findings shift the conversation from access alone to the quality and safety of implementation. Equitable surgical scale-up depends not only on introducing technologies, but on ensuring that systems are in place to support their safe use. Multisectoral investment in training infrastructure, system-wide safety initiatives, and diagnostic support is now essential. This evidence provides a roadmap for governments, funders, and providers (such as local surgical teams) to deliver minimally invasive surgery safely and sustainably, particularly in resource-constrained settings.

postoperative complications, shorter hospital stays, and faster recovery times.[8,16] These benefits are particularly relevant in LMICs, where the economic and social consequences of prolonged recovery can be catastrophic.[17,18] Despite these clear benefits, global monitoring of the adoption, quality, and safety of minimally invasive surgery remains inconsistent, with most data confined to single-country or regional studies.[19–21] A comprehensive, system-wide evaluation is urgently needed to identify factors supporting successful scaling up of these technologies across diverse health-care contexts.

In this study, we used minimally invasive cholecystectomy—the most commonly performed minimally invasive surgery procedure worldwide[22]—as a tracer to evaluate the safe and equitable implementation of minimally invasive surgery across global health systems.[23] Minimally invasive surgery for gallbladder disease provides a clear model to investigate key factors influencing technology adoption, safety, and outcomes.

For the **study documents** see https://globalsurgeryunit.org

By developing and applying a conceptual framework aligned with the WHO Health System Building Blocks[24] and the Global Patient Safety Action Plan,[25] this study aimed to identify actionable targets for improving the safe, scalable integration of minimally invasive surgery and offer important insights into how global health systems can address challenges in the adoption and implementation of such complex technologies in an equitable and sustainable manner.

Methods

Study design and setting

We conducted an international, multicentre, prospective cohort study of people undergoing surgery for gallbladder diseases.[26] All study documents, including the full protocol and training materials, were made available online before commencement. Teams of local investigators were coordinated by a network of national lead investigators. The collaborative network methodology has been described in detail elsewhere.[27,28]

Local principal investigators from participating sites obtained local institutional or national ethical approval, or both, according to local regulations. Any health-care facility (ie, first referral, secondary, or tertiary hospitals) providing elective or emergency surgery for gallbladder disease worldwide was eligible to voluntarily participate. This study is registered with ClinicalTrials.gov (NCT06223061).

Participants

Adults undergoing gallbladder surgery were included from one or more 14-day consecutive study periods between July 31 and Nov 19, 2023, with 30-day follow-up conducted for all. A period of data validation followed and was completed on April 30, 2024. Inclusion criteria were: age 18 years or older and undergoing elective or emergency cholecystectomy; undergoing first surgical procedure for the treatment of gallbladder disease; and requiring a skin incision performed under general or neuraxial (eg, regional, epidural, or spinal) anaesthesia. All individuals fulfilling the inclusion criteria within the defined period were enrolled. A 14-day period was chosen to balance sample size requirements and pragmatism for working clinicians enrolling patients and contributing data. Exclusion criteria were those having cholecystectomy as a part of another surgical procedure (eg, liver or pancreas resection) or those with known gallbladder cancer.

Measurement set for evaluating technologies within health systems

At present, no comprehensive framework exists to evaluate safe implementation of technologies within health-care systems globally. To address this gap, we developed a conceptual framework aligned with the key principles of the WHO Health System Building Blocks[24] and Global Patient Safety Action Plan.[25] This framework aimed to take a whole-systems approach in capturing both patient-level and hospital-level data, building on our previous work in this area.[23] Co-production was through several rounds of consultation with a Study Management Group (SMG) to maximise face and content validity. The SMG was composed of a diverse group of stakeholders, including health-care workers, health service researchers, and methodologists with expertise in global health research. Key domains within the conceptual framework were: technologies; service delivery; workforce; leadership, governance, and financing; and training and safety. Within each of these domains, the SMG prioritised several measures deemed important as part of a whole-system assessment (appendix p 4).

To address technologies, we measured the availability of minimally invasive surgery (defined as laparoscopic or robotic-assisted cholecystectomy), critical care facilities, and on-site diagnostics. To address health service delivery, we measured time from first symptom to diagnosis, time from the decision to operate to surgery, and urgency of surgery (defined as elective or emergency). To address the workforce, we measured grade of operator, experience of operator, and anaesthetic type. To address leadership, governance, and financing, we measured hospital funding and hospital type. To address training and safety of technology use, we measured training and simulation facilities, intraoperative cholangiogram use, and critical view of safety. Safety was defined as the absence of procedure-specific complications (appendix p 5). Overall complications were defined according to the Clavien–Dindo grade of complications.[12] The relationship between each key measure on patient safety is summarised in a simplified directed acyclic graph (figure 1).

Data collection

The SMG selected variables to be objective, standardised, and internationally relevant, to maximise data completeness and accuracy.[26] Data were collected over four stages. First, principal investigators identified a team of local investigators who underwent study-specific training. Second, local investigators identified patients, collected data, and uploaded de-identified records to a secure Research Electronic Data Capture system.[29] Third, the lead investigator at each site checked the accuracy of all cases before final data submission. Fourth, a centralised real-time quality assessment was done, and inconsistencies highlighted to local teams for review. Online data visualisation tools were developed to aid this process. Once vetted, the record was accepted into the dataset for analysis.

Data validation

On completion of data collection, data were validated by independent investigators (ie, doctors or nurses who were not part of the data collection team) in two stages across a representative sample of centres, according to a prespecified protocol (appendix pp 34–39).[26] First, case ascertainment and sampled data accuracy were assessed. Second, eligible individuals missing from the local dataset were identified and missing data collected. These data were used to ascertain whether data were missing at random.

Sample size

As described in the protocol,[26] sample sizes were estimated on the basis of income groups. The primary outcome was 30-day procedure-specific complications. Estimates for 30-day postoperative complications following cholecystectomy were established from the CholeS and CholeCOVID studies[30,31] in both high-income countries (2·7–10·8%) and LMICs (5·0–21·8%). An indicative sample size calculation using the smaller of these estimates suggests around 587 individuals per group at 80% power (2·0% *vs* 5·0%, α=0·05) or 786 individuals per group at 90% power would be required to conclude a difference in complication rate

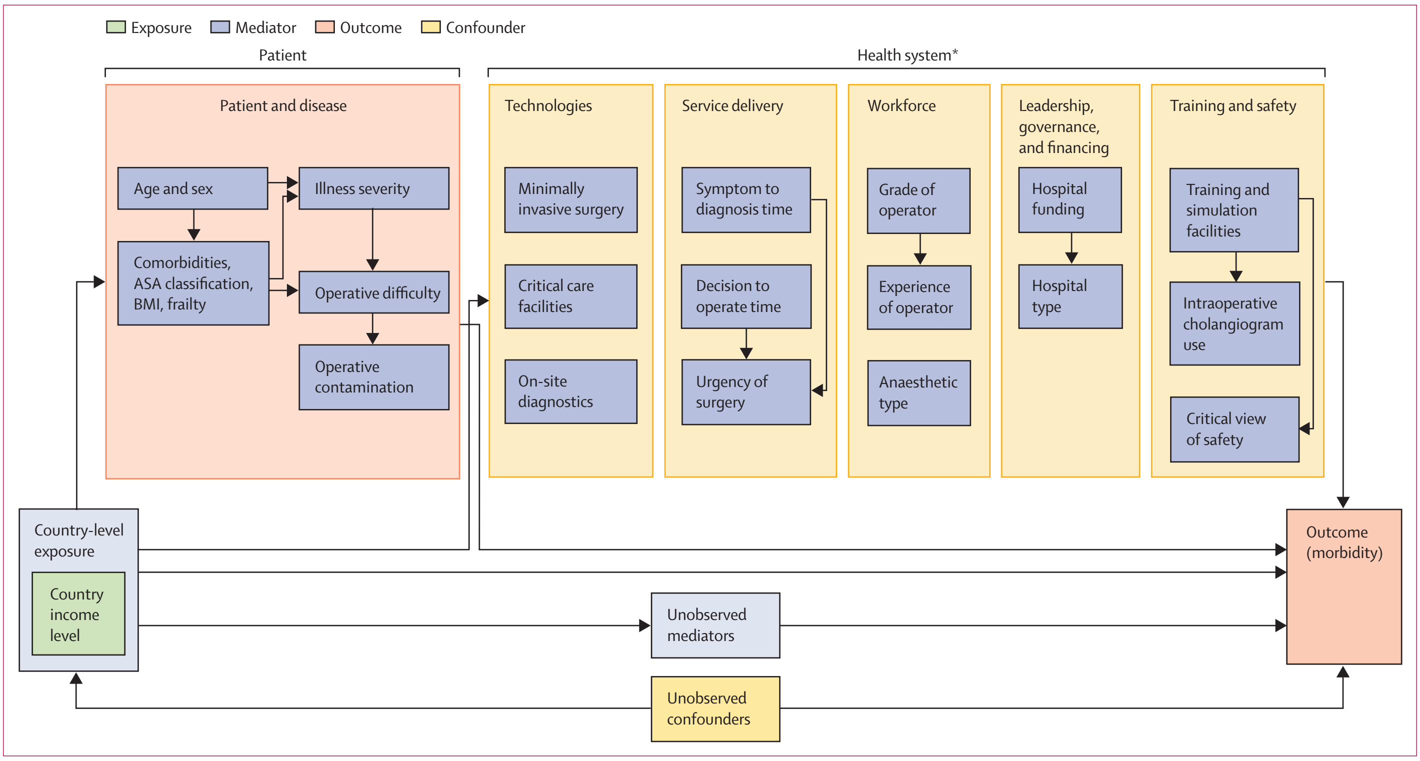

Figure 1: **Conceptual framework for technology adoption in global health systems using minimally invasive gallbladder surgery as tracer procedure**
ASA=American Association of Anesthesiologists. *Directed acyclic graph of components as a function of the health system (defined as the WHO Health System Building Blocks and Global Patient Safety Action Plan).

between income groups. The sample size was based on this outcome measure since it is a single standardised safety measure consistent across previous studies that can be used as a benchmark.

Statistical analysis

Variation across different international health settings was assessed by stratifying countries according to World Bank country group classifications: high-income, upper-middle-income, and lower-middle-income or low-income countries, as previously described.[28,32,33] Differences between these groups were tested with the Pearson χ^2 test for categorical variables and the Kruskal–Wallis test for continuous variables. Non-normally distributed data were summarised as medians with IQRs, and group differences tested with the Mann–Whitney *U* test. Normally distributed data were summarised as means with SDs.

Multilevel logistic regression was used to explore associations between country income and outcomes, incorporating population stratification by hospital and country of residence as random intercepts. Logistic regression was also used for exploratory analyses of the measurement set (figure 1) and outcomes. Results are presented as total effects from univariable analyses and direct effects from multivariable analyses that incorporate all variables;[34] coefficients should be interpreted accordingly. Statistical approaches to variable selection and variable-specific mediation analysis were not undertaken in this part of the study. Coefficients are presented as odds ratios (ORs) and 95% CIs.

Risk-adjusted hospital-level outcomes were assessed with a logistic regression model of patient and disease factors only. For each hospital, we calculated an observed-to-expected ratio of outcomes and then scaled this ratio by the cohort complication rate to obtain an adjusted hospital complication proportion. Hospitals were then ranked and divided into five quintiles of risk, balanced by patient counts (rather than hospital counts).

Simulations were undertaken on models incorporating specific first-order, second-order, and third-order interactions, defined post hoc through data exploration. Bootstrap replications of models (stable at n=2000) were used to ascertain outcome probabilities at varying levels of covariates of interest, with other covariates held at their mode unless stated otherwise. Comparisons between outcomes of interest were made for each bootstrap and relative and absolute risk differences calculated, together with 95% CIs and a two-side p value. The number needed to treat was defined as 1 divided by the absolute risk difference.

A complete-case analysis was pre-planned if missing data were minimal (<5%) and missing at random.[35] For missingness exceeding 5%, multiple imputation by chained equations was planned, assuming data were missing at random or completely at random, as outlined in the study protocol. Statistical significance was defined as a p value less than 0·05. Data were analysed in R (version 3.2.2), with the finalfit, dplyr, ggplot2, and survival packages.

Role of the funding source

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

Results

Between July 31, 2023, and Nov 19, 2023, 53 708 people were enrolled from 1262 hospitals across 110 countries. Following quality control, 1521 (2·8%) did not fulfil the inclusion criteria, leaving 52 187 records for the final analysis (figure 2). These people were from 1218 hospitals across 109 countries. When stratified by World Bank country income groups, 27 943 (53·5%) individuals were from 627 hospitals in 44 high-income countries, 11 560 (22·1%) were from 280 hospitals in 33 upper-middle-income countries and 12 684 (24·3%) were from 311 hospitals in 32 lower-middle-income or low-income countries. Overall rates of missing data were low, and no patterns were seen when comparing included and missing data (appendix p 6).

Patients in upper-middle-income and lower-middle-income or low-income countries were younger, had lower BMI, fewer pre-existing illnesses, were less frail, and more likely to have acute cholecystitis compared with those in high-income countries (table). A summary of health-system characteristics highlights differences across the income spectrum (figure 3).

The overall rate of minimally invasive surgery for gallbladder disease was 95·7%, which was higher in high-income countries (98·6%) than in upper-middle-income countries (93·8%) or lower-middle-income or low-income countries (90·9%, p<0·0001; table). Access to on-site diagnostics such as CT was also higher in high-income countries (99·1%) than in upper-middle-income countries (90·2%) and lower-middle-income or low-income countries (90·3%).

Procedures were more likely to be performed in the emergency setting in high-income countries (40·0%) than in upper-middle-income (29·0%) and lower-middle-income and low-income countries (15·5%; table). Individuals in high-income countries (12·6%) were more likely to wait more than 6 months for surgery from the decision to operate than those in upper-middle-income (3·9%) and lower-middle-income and low-income countries (3·5%).

The primary operator was more likely to be a consultant or attending physician in lower-middle-income and low-income countries (77·4%) than in high-income countries (65·0%) or upper-middle-income countries (66·9%; table). Inhaled general anaesthesia was more common in lower-middle-income and low-income countries (74·8%) than in upper-middle-income countries (60·7%) and high-income countries (46·2%).

In this cohort, surgery was more commonly performed in public hospitals in high-income countries (80·5%) and upper-middle-income countries (75·4%) than in lower-middle-income or low-income countries (54·4%). These hospitals, however, were more commonly found in a non-rural district setting in high-income countries (23·6%) than in upper-middle-income countries (15·0%) and lower-middle-income or low-income countries (7·1%; table).

Local training and simulation facilities were available for 43·3% of individuals undergoing surgery, which varied between country income groups (44·8% in high-income countries, 36·2% in upper-middle-income countries, and 46·2% in lower-middle-income or low-income countries; table). An intraoperative timeout to assess the critical view of safety was documented in the operation note more frequently in lower-middle-income or low-income countries (59·3%) and upper-middle-income countries (57·9%) than in high-income countries (44·3%).

Patient, disease, and health-system characteristics stratified by minimally invasive surgery and open surgery are provided in the appendix (pp 7–9). Among those undergoing minimally invasive surgery (n=49 937), differences in patient, disease, and health-systems characteristics are presented in the appendix (pp 10–12).

The overall rate of procedure-specific complications in those undergoing minimally invasive cholecystectomy

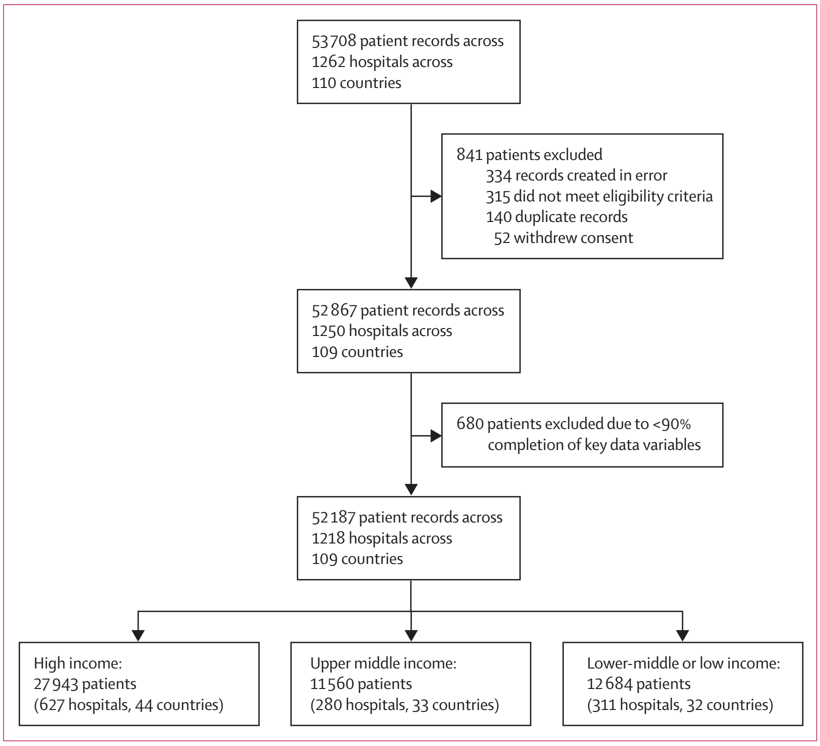

Figure 2: **Patient flowchart**

	High income (n=27 943; 53·5%)	Upper-middle income (n=11 560; 22·2%)	Lower-middle income and low income (n=12 684; 24·3%)	Total (n=52 187)	p value
Patient and disease factors					
Age, years					
18–30	2912 (10·4%)	1605 (13·9%)	2221 (17·5%)	6738 (12·9%)	<0·0001
31–50	9188 (32·9%)	4791 (41·4%)	6021 (47·5%)	20 000 (38·3%)	..
51–70	10 480 (37·5%)	4028 (34·8%)	3750 (29·6%)	18 258 (35·0%)	..
≥71	5363 (19·2%)	1136 (9·8%)	692 (5·5%)	7191 (13·8%)	..
Missing	0 (0·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	..
Sex at birth					
Female	18 131 (64·9%)	8162 (70·6%)	9186 (72·4%)	35 479 (68·0%)	<0·0001
Male	9812 (35·1%)	3396 (29·4%)	3497 (27·6%)	16 705 (32·0%)	..
Missing	0 (0·0%)	2 (0·0%)	1 (0·0%)	3 (0·0%)	..
ASA grade					
I	4618 (16·5%)	3519 (30·4%)	6178 (48·7%)	14 315 (27·4%)	<0·0001
II	15 942 (57·1%)	6501 (56·2%)	5615 (44·3%)	28 058 (53·8%)	..
III	6672 (23·9%)	1386 (12·0%)	831 (6·6%)	8889 (17·0%)	..
IV	411 (1·5%)	77 (0·7%)	38 (0·3%)	526 (1·0%)	..
V	20 (0·1%)	3 (0·0%)	0 (0·0%)	23 (0·0%)	..
Unknown	271 (1·0%)	74 (0·6%)	21 (0·2%)	366 (0·7%)	..
Missing	9 (0·0%)	0 (0·0%)	1 (0·0%)	10 (0·0%)	..
Body mass index, kg/m²					
<18·5	255 (0·9%)	132 (1·1%)	224 (1·8%)	611 (1·2%)	<0·0001
18·5–24·9	7146 (25·6%)	3498 (30·3%)	5600 (44·2%)	16 244 (31·1%)	..
25·0–29·9	9094 (32·5%)	4357 (37·7%)	4063 (32·0%)	17 514 (33·6%)	..
30·0–34·9	5732 (20·5%)	2035 (17·6%)	1657 (13·1%)	9424 (18·1%)	..
35·0–39·9	2588 (9·3%)	607 (5·3%)	436 (3·4%)	3631 (7·0%)	..
≥40·0	1496 (5·4%)	207 (1·8%)	123 (1·0%)	1826 (3·5%)	..
Unknown	1624 (5·8%)	724 (6·3%)	579 (4·6%)	2927 (5·6%)	..
Missing	8 (0·0%)	0 (0·0%)	2 (0·0%)	10 (0·0%)	..
Number of comorbidities					
None	15 533 (55·6%)	7279 (63·0%)	8530 (67·3%)	31 342 (60·1%)	<0·0001
1	7068 (25·3%)	2790 (24·1%)	2815 (22·2%)	12 673 (24·3%)	..
2	3274 (11·7%)	1124 (9·7%)	1049 (8·3%)	5447 (10·4%)	..
≥3	2035 (7·3%)	348 (3·0%)	258 (2·0%)	2641 (5·1%)	..
Missing	33 (0·1%)	19 (0·2%)	32 (0·3%)	84 (0·2%)	..
Clinical frailty score					
1–3	22 660 (81·1%)	9890 (85·6%)	11 781 (92·9%)	44 331 (84·9%)	<0·0001
4–6	2961 (10·6%)	909 (7·9%)	741 (5·8%)	4611 (8·8%)	..
7–9	250 (0·9%)	68 (0·6%)	23 (0·2%)	341 (0·7%)	..
Unknown	2062 (7·4%)	687 (5·9%)	135 (1·1%)	2884 (5·5%)	..
Missing	10 (0·0%)	6 (0·1%)	4 (0·0%)	20 (0·0%)	..
History of acute cholecystitis or cholangitis					
No	19 473 (69·7%)	7052 (61·0%)	7683 (60·6%)	34 208 (65·5%)	<0·0001
Yes	8466 (30·3%)	4505 (39·0%)	5001 (39·4%)	17 972 (34·4%)	..
Missing	4 (0·0%)	3 (0·0%)	0 (0·0%)	7 (0·0%)	..
Operative contamination					
Clean-contaminated	25 825 (92·4%)	11 034 (95·4%)	12 231 (96·4%)	49 090 (94·1%)	<0·0001
Contaminated	1704 (6·1%)	436 (3·8%)	397 (3·1%)	2537 (4·9%)	..
Dirty	390 (1·4%)	79 (0·7%)	52 (0·4%)	521 (1·0%)	..
Missing	24 (0·1%)	11 (0·1%)	4 (0·0%)	39 (0·1%)	..

(Table continues on next page)

	High income (n=27 943; 53·5%)	Upper-middle income (n=11 560; 22·2%)	Lower-middle income and low income (n=12 684; 24·3%)	Total (n=52 187)	p value
(Continued from previous page)					
Operative difficulty (Nassar grade)					
I	10 079 (36·1%)	3894 (33·7%)	5580 (44·0%)	19 553 (37·5%)	<0·0001
II	6495 (23·2%)	3355 (29·0%)	3222 (25·4%)	13 072 (25·0%)	..
III	5055 (18·1%)	1752 (15·2%)	1424 (11·2%)	8231 (15·8%)	..
IV	1595 (5·7%)	495 (4·3%)	383 (3·0%)	2473 (4·7%)	..
V	100 (0·4%)	101 (0·9%)	43 (0·3%)	244 (0·5%)	..
Unknown	3576 (12·8%)	1030 (8·9%)	628 (5·0%)	5234 (10·0%)	..
Missing	1043 (3·7%)	933 (8·1%)	1404 (11·1%)	3380 (6·5%)	..
Technology					
Operative approach					
Open	371 (1·3%)	703 (6·1%)	1152 (9·1%)	2226 (4·3%)	<0·0001
Minimally invasive surgery	27 558 (98·6%)	10 848 (93·8%)	11 531 (90·9%)	49 937 (95·7%)	..
Missing	14 (0·1%)	9 (0·1%)	1 (0·0%)	24 (0·0%)	..
Critical care facilities					
No	1299 (4·6%)	991 (8·6%)	604 (4·8%)	2894 (5·5%)	<0·0001
Yes	26 644 (95·4%)	10 569 (91·4%)	12 080 (95·2%)	49 293 (94·5%)	..
Missing	0 (0·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	..
On-site CT					
No	249 (0·9%)	1138 (9·8%)	1229 (9·7%)	2616 (5·0%)	<0·0001
Yes	27 694 (99·1%)	10 422 (90·2%)	11 455 (90·3%)	49 571 (95·0%)	..
Missing	0 (0·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	..
Service delivery					
Urgency					
Elective	16 768 (60·0%)	8202 (71·0%)	10 703 (84·4%)	35 673 (68·4%)	<0·0001
Emergency	11 164 (40·0%)	3353 (29·0%)	1972 (15·5%)	16 489 (31·6%)	..
Missing	11 (0·0%)	5 (0·0%)	9 (0·1%)	25 (0·0%)	..
Symptom onset *vs* diagnosis					
0 days	5472 (19·6%)	1236 (10·7%)	508 (4·0%)	7216 (13·8%)	<0·0001
1–2 days	6094 (21·8%)	1755 (15·2%)	1181 (9·3%)	9030 (17·3%)	..
3–7 days	4660 (16·7%)	1986 (17·2%)	1997 (15·7%)	8643 (16·6%)	..
1–2 weeks	1364 (4·9%)	685 (5·9%)	805 (6·3%)	2854 (5·5%)	..
2–4 weeks	1235 (4·4%)	817 (7·1%)	814 (6·4%)	2866 (5·5%)	..
1–6 months	5721 (20·5%)	3479 (30·1%)	5170 (40·8%)	14 370 (27·5%)	..
>6 months	3128 (11·2%)	1596 (13·8%)	2207 (17·4%)	6931 (13·3%)	..
Missing	269 (1·0%)	6 (0·1%)	2 (0·0%)	277 (0·5%)	..
Diagnosis *vs* decision to operate					
0 days	7996 (28·6%)	2867 (24·8%)	1928 (15·2%)	12 791 (24·5%)	<0·0001
1–2 days	4558 (16·3%)	2037 (17·6%)	2869 (22·6%)	9464 (18·1%)	..
3–7 days	2590 (9·3%)	1490 (12·9%)	2170 (17·1%)	6250 (12·0%)	..
1–2 weeks	1427 (5·1%)	760 (6·6%)	1197 (9·4%)	3384 (6·5%)	..
2–4 weeks	1645 (5·9%)	842 (7·3%)	883 (7·0%)	3370 (6·5%)	..
1–6 months	6540 (23·4%)	2645 (22·9%)	3002 (23·7%)	12 187 (23·4%)	..
>6 months	3024 (10·8%)	913 (7·9%)	632 (5·0%)	4569 (8·8%)	..
Missing	163 (0·6%)	6 (0·1%)	3 (0·0%)	172 (0·3%)	..
Decision to operate *vs* operation					
0 days	3333 (11·9%)	1001 (8·7%)	552 (4·4%)	4886 (9·4%)	<0·0001
1–2 days	5295 (18·9%)	2847 (24·6%)	2929 (23·1%)	11 071 (21·2%)	..
3–7 days	2365 (8·5%)	1950 (16·9%)	2461 (19·4%)	6776 (13·0%)	..
1–2 weeks	1344 (4·8%)	960 (8·3%)	1250 (9·9%)	3554 (6·8%)	..

(Table continues on next page)

	High income (n=27 943; 53·5%)	Upper-middle income (n=11 560; 22·2%)	Lower-middle income and low income (n=12 684; 24·3%)	Total (n=52 187)	p value
(Continued from previous page)					
2–4 weeks	2115 (7·6%)	1152 (10·0%)	972 (7·7%)	4239 (8·1%)	··
1–6 months	9927 (35·5%)	3196 (27·6%)	4074 (32·1%)	17 197 (33·0%)	··
>6 months	3514 (12·6%)	448 (3·9%)	439 (3·5%)	4401 (8·4%)	··
Missing	50 (0·2%)	6 (0·1%)	7 (0·1%)	63 (0·1%)	··
Workforce					
Grade of primary operator					
Consultant or attending	18 175 (65·0%)	7738 (66·9%)	9816 (77·4%)	35 729 (68·5%)	<0·0001
Non-consultant	9752 (34·9%)	3814 (33·0%)	2864 (22·6%)	16 430 (31·5%)	··
Missing	16 (0·1%)	8 (0·1%)	4 (0·0%)	28 (0·1%)	··
Experience of operator (number of procedures)					
0–50	3714 (13·3%)	1911 (16·5%)	2008 (15·8%)	7633 (14·6%)	<0·0001
51–100	3339 (11·9%)	1498 (13·0%)	1578 (12·4%)	6415 (12·3%)	··
101–200	4426 (15·8%)	1319 (11·4%)	1639 (12·9%)	7384 (14·1%)	··
>200	16 395 (58·7%)	6821 (59·0%)	7458 (58·8%)	30 674 (58·8%)	··
Missing	69 (0·2%)	11 (0·1%)	1 (0·0%)	81 (0·2%)	··
Anaesthetic					
General (inhaled)	12 923 (46·2%)	7018 (60·7%)	9490 (74·8%)	29 431 (56·4%)	<0·0001
TIVA or other anaesthetic	14 994 (53·7%)	4530 (39·2%)	3190 (25·1%)	22 714 (43·5%)	··
Missing	26 (0·1%)	12 (0·1%)	4 (0·0%)	42 (0·1%)	··
Leadership, governance, and financing					
Hospital funding					
Public	22 501 (80·5%)	8713 (75·4%)	6906 (54·4%)	38 120 (73·0%)	<0·0001
Private	2212 (7·9%)	1799 (15·6%)	3855 (30·4%)	7866 (15·1%)	··
Mixed	3230 (11·6%)	1048 (9·1%)	1923 (15·2%)	6201 (11·9%)	··
Missing	0 (0·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	··
Hospital type					
Tertiary (teaching or university hospital)	19 629 (70·2%)	9119 (78·9%)	11 583 (91·3%)	40 331 (77·3%)	<0·0001
District (rural)	1732 (6·2%)	703 (6·1%)	195 (1·5%)	2630 (5·0%)	··
District (non-rural)	6582 (23·6%)	1738 (15·0%)	906 (7·1%)	9226 (17·7%)	··
Missing	0 (0·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	··
Training and safety					
Local simulation training facilities					
No	15 415 (55·2%)	7372 (63·8%)	6824 (53·8%)	29 611 (56·7%)	<0·0001
Yes	12 528 (44·8%)	4188 (36·2%)	5860 (46·2%)	22 576 (43·3%)	··
Missing	0 (0·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	··
Intraoperative cholangiogram use					
Not available	1375 (4·9%)	1262 (10·9%)	2782 (21·9%)	5419 (10·4%)	<0·0001
Selective use	22 015 (78·8%)	9139 (79·1%)	8211 (64·7%)	39 365 (75·4%)	··
Routine use	4546 (16·3%)	1159 (10·0%)	1691 (13·3%)	7396 (14·2%)	··
Missing	7 (0·0%)	0 (0·0%)	0 (0·0%)	7 (0·0%)	··
Intraoperative safety timeout (CVS)					
No	7800 (27·9%)	3108 (26·9%)	3204 (25·3%)	14 112 (27·0%)	<0·0001
Yes	12 365 (44·3%)	6693 (57·9%)	7524 (59·3%)	26 582 (50·9%)	··
Unknown	7778 (27·8%)	1759 (15·2%)	1956 (15·4%)	11 493 (22·0%)	··
Missing	0 (0·0%)	0 (0·0%)	0 (0·0%)	0 (0·0%)	··

Data are n (%). ASA=American Society of Anesthesiologists. TIVA=total intravenous anesthesia. CVS=critical view of safety.

Table: **Patient-level, disease-level, and health-system-level characteristics of individuals undergoing gallbladder surgery, stratified by country income group**

was 5·8% (2912 of 49 937; appendix pp 13–15), which was comparable across income settings when adjusted for patient and disease characteristics (appendix p 16). Similar results were seen for overall complications (7336 [14·7%] of 49 937; appendix pp 24–27). Individual hospital procedure-specific complications differed almost 40-fold between those in the lowest risk quintile (31 [0·3%] of 9768) and those in the highest quintile (1172 [12·1%] of 9708; appendix pp 17–18).

To understand the actionable targets for safe implementation of minimally invasive surgery technology within health systems, we studied the direct associations between health-system characteristics and the immediate outcomes of surgery, adjusting for patient and disease factors. We present our key outcome measure here (procedure-specific complications) and include overall complication data in the appendix (pp 28–30).

In an adjusted multilevel model accounting for variables in the conceptual model (figure 1), no difference between country income and procedure-specific complications was seen (upper-middle income *vs* high income: OR 0·81 [95% CI 0·59–1·10], p=0·1727; lower-middle or low income *vs* high income: 0·99 [0·70–1·39], p=0·9546). The strongest modifiable characteristic associated with lower procedure-specific complications was the presence of local training and simulation facilities (training and safety domain; OR 0·78 [95% CI 0·71–0·86], p<0·0001; figure 4; appendix pp 19–21). The use of an intraoperative timeout in the identification of the critical view of safety was also associated with fewer complications (OR 0·87 [95% CI 0·79–0·96], p=0·0046), independent of the presence of training facilities. The

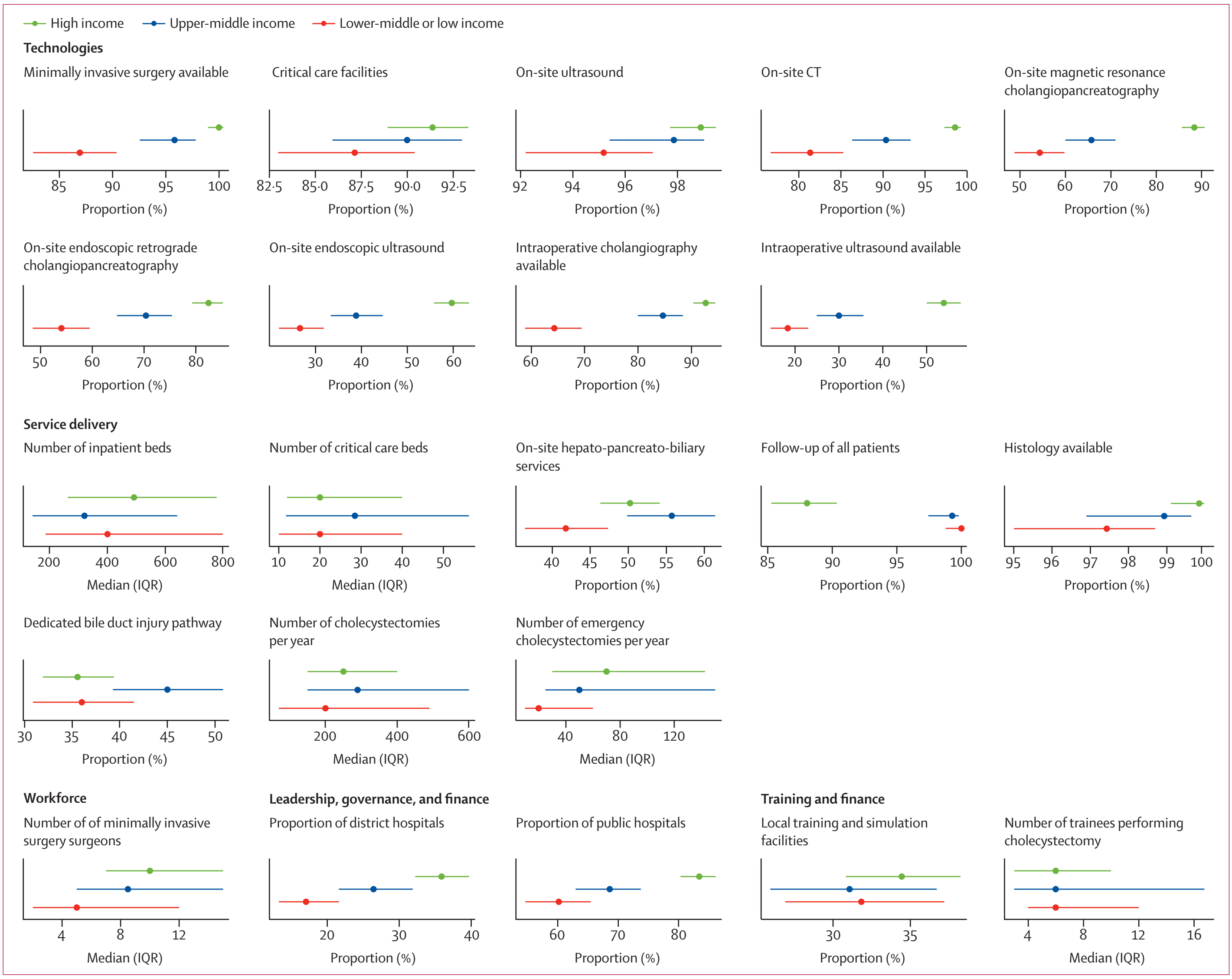

Figure 3: **Hospital-level characteristics stratified by country income level**

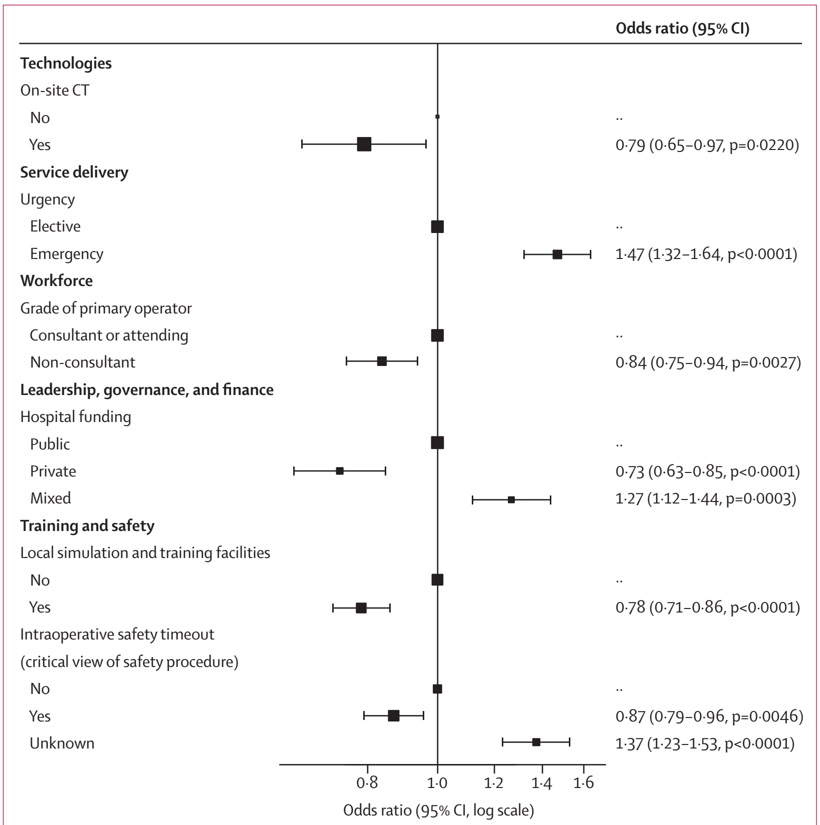

***Figure 4:* Direct effects of specific care characteristics on 30-day procedure-specific complications in patients undergoing laparoscopic cholecystectomy across high-income, upper-middle-income, and lower-middle-income or low-income countries**

Multilevel logistic regression model accommodating country clustering and adjusted for all variables presented in the table. The full model is provided in the appendix (pp 19–21). Point-estimate box size proportional to group size.

availability of on-site CT (technology domain; OR 0·79 [95% CI 0·65–0·97], p=0·0220) was also associated with fewer complications. Similar findings were seen in models for overall complications, with operator experience (workforce domain) also showing a significant association with fewer complications (>200 procedures *vs* ≤50 procedures, OR 0·88 [95% CI 0·79–0·97], p=0·0141; appendix pp 28–30).

The relationships between training and safety, disease severity, workforce, and technological infrastructure were explored in extended multivariable models, incorporating interactions. In almost all scenarios examined, local training and simulation facilities were associated with lower risk of procedure-specific complications (figure 5; appendix pp 22–23). This association was stronger when the workforce had less experience (relative risk [RR] with local training facilities and low operator experience [0–50 procedures] 0·48 [95% CI 0·35–0·65], *vs* high operator experience [>200 procedures] 0·88 [0·76–1·00], with low disease severity [no acute cholecystitis] and with on-site CT available). Similarly, hospitals with lower levels of technological infrastructure (on-site CT as indicator) had a stronger association between training and procedure-specific complications (RR 0·38 [95% CI 0·20–0·61]) than hospitals with higher levels of infrastructure (0·88 [0·76–1·00]; with low disease severity (no acute cholecystitis) and operator experience >200 procedures).

Finally, with a higher baseline risk of complications associated with increased disease severity, absolute risk differences associated with training were generally higher in acute cholecystitis (–4·15% [95% CI –5·86 to –2·50]) compared with the absence of acute cholecystitis (–2·07% [–3·04 to –1·11]; operator experience >200 procedures, no on-site CT available). Where training was most beneficial (inexperienced workforce, worse disease, poor infrastructure), the number needed to treat for training facilities was 21 (95% CI 14 to 35; p<0·0001) to prevent a procedure-specific complication (appendix p 22).

Data were validated in 1217 hospitals across 109 countries (2434 hospital weeks of data collection). 12 124 individuals fulfilled inclusion criteria compared with 10 841 (89·4%) in the primary dataset (appendix pp 34–35). Accuracy was high for the validated continuous predictor (Pearson's correlation coefficient 0·99; appendix p 36). Agreement for categorical predictors was good (gender, operative approach, urgency, and critical view of safety; appendix p 35). Agreement was good for overall complications (κ 0·72; appendix p 37).

Discussion

This study offers a comprehensive analysis—across 109 countries—of the adoption and implementation of minimally invasive gallbladder surgery, used here as a tracer procedure to evaluate system-level factors that influence the safe scaling up of this essential surgical intervention. By developing a robust framework, we have identified actionable targets for technology adoption, including strengthening diagnostics, expanding training opportunities such as simulation facilities, and implementing safety and communication initiatives. These findings serve as a guide for policy makers, offering insights into the broader challenges of scaling and adopting similar technologies, which are prone to comparable weaknesses.[1,3,9] Neglecting these crucial system-wide factors during technology adoption risks patient harm and increased health-care costs, particularly in LMICs, where health systems might already be under considerable strain.

Cholecystectomy is among the most commonly performed surgical procedures worldwide, both in elective and emergency settings, for which minimally invasive surgery is considered the gold standard.[36] Like all complex technologies, its successful implementation relies on a multifaceted interplay of human and technical dynamics, increasingly framed within the context of digital transformation.[37] Although delivering such an intervention clearly requires a workforce and infrastructure capable of performing the necessary anaesthetic and surgical procedures, it is the broader characteristics of a health system that ultimately establish the safety and effectiveness of its implementation. The aim of this study was neither to capture the many important cultural and contextual factors influencing local implementation,[38] nor was it to perform a comprehensive end-to-end health technology assessment.[39] Rather, the focus was to quantitively identify patterns of care within a broad health-system framework and to link these directly to patient-level outcomes on a global scale. The findings of this study could be generalised across procedural interventions such as surgery, endoscopy, interventional radiology, and percutaneous cardiac interventions, and the framework is likely to be applicable across broad health-care settings.

With specific regard to minimally invasive cholecystectomy, the variation in outcomes across individual hospitals was striking: the risk of complications varied almost 40-fold between average hospitals in the lowest quintile (0·3%) and those in the highest quintile (12·1%) of procedure-specific complication risk after adjustment for patient and disease characteristics. This substantial institutional variation was explained in part by health-system factors, but unexplained variation remains. Despite this variability, outcomes in LMICs were found to be equivalent to those in high-income countries. Although this conclusion is true for hospitals contributing to this study, it should not be generalised beyond this convenience sample, which was enriched with tertiary care centre enthusiasts with established surgical programmes. What these findings do show is that within this context, minimally invasive cholecystectomy can be delivered by health systems in the global south with equivalent outcomes to that seen in the global north. This observation underscores the importance of focusing on health-system factors, rather than economic classification alone, in global health equity efforts.

Our study highlights the important role of training and safety in relation to patient outcomes. Hospitals with access to procedure-specific training resources and attention to systems of safety, such as intraoperative timeouts, had lower rates of postoperative complications. These observations could be confounded, meaning that the association between simulation facilities and better outcomes could be influenced by other, as-yet undefined

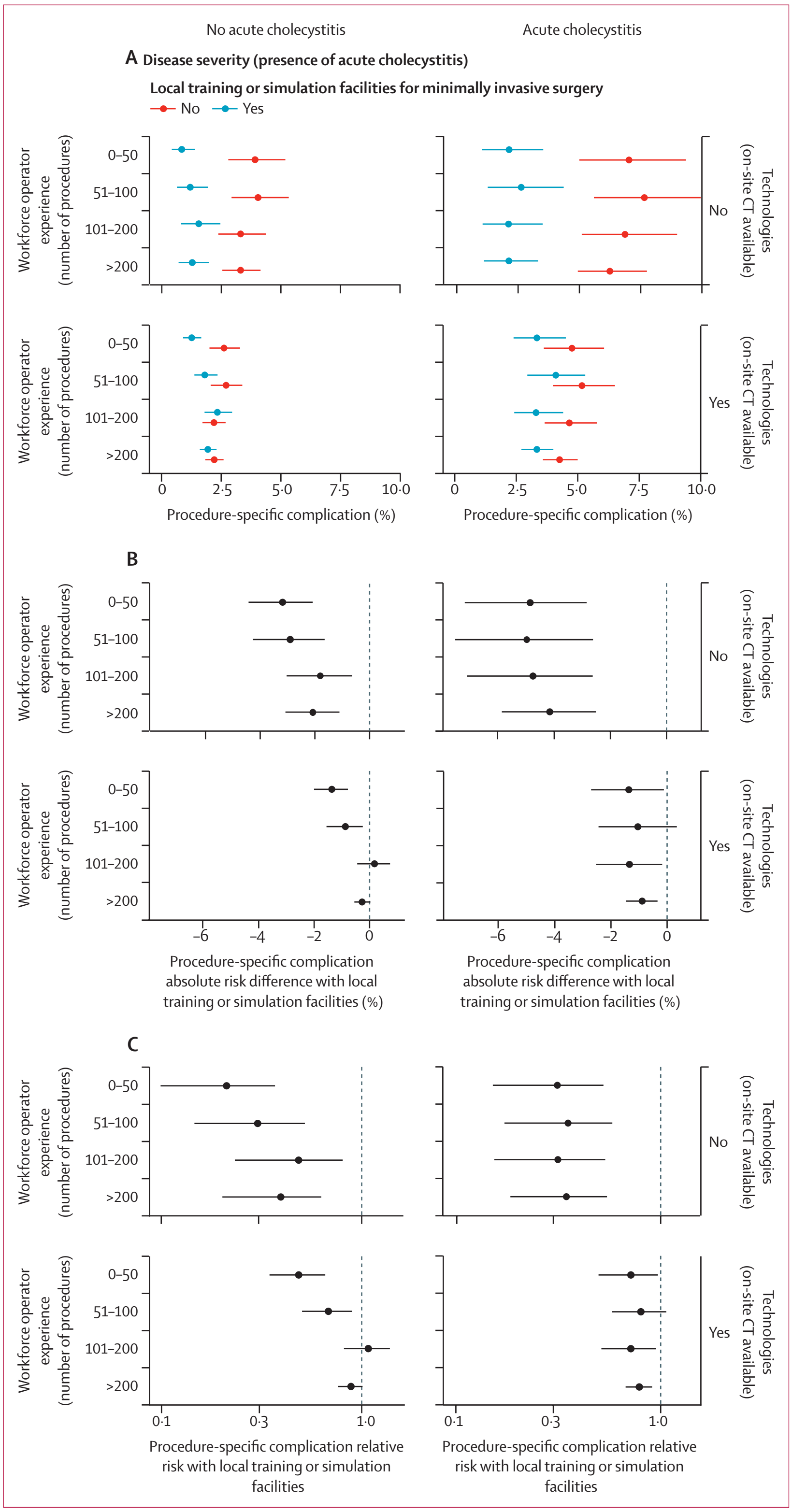

***Figure 5*: Relationship between training and safety, disease severity, workforce, and technological infrastructure**

(A) Procedure-specific complications after laparoscopic cholecystectomy and association with the presence of local training and simulation facilities (training and safety domain), stratified by disease severity (patient or disease domain, defined as the presence of acute cholecystitis), on-site CT availability (technology domain), and operator experience (workforce domain). (B) Absolute risk difference between presence and absence of local training and simulation facilities. (C) Relative risk of presence and absence of local training and simulation facilities. Multivariable logistic regression adjusted for age, sex, American Association of Anesthesiologists grade, frailty, BMI, critical care facilities, decision to operation time, operator grade, anaesthetic type, hospital funding, hospital type, and World Bank income level. Bootstrapped models (n=2000) with co-variates held constant set at their mode and income level at low or lower middle.

characteristics of health systems. However, the association persisted in models accounting for many aspects of the variation in patients, diseases, and health systems (appendix pp 19–21), such as the availability of critical care and imaging facilities, service factors such as delays in care, and different funding models and hospital contexts. Any confounder of training and simulation facilities must be independent of these other characteristics.

The importance of such safety measures has been highlighted by WHO and other organisations,[40,41] yet there is a scarcity of high-quality global data on their relationship to broader health-system dynamics.[42,43] Simulation-based training has the potential to enhance the quality of technology adoption through various mechanisms, including improving both technical and non-technical performance within clinical teams. Over the past decade, the benefits of simulation-based training have been demonstrated, particularly in enhancing technical performance. For instance, a systematic review of 79 studies involving 7138 trainees showed that simulation training improved technical performance by increasing knowledge, skills, and procedural efficiency.[43] To the best of our knowledge, our study is the first to demonstrate, on a global scale, that simulation-based training is independently associated with improved patient outcomes. Simulation-based training can minimise patient risks[44] by fostering a safe working environment, improving interprofessional working relationships, providing a safe space for learners to make and learn from mistakes, and is a scalable, cost-effective way to support quality care, particularly in under-resourced systems.[18,45,46] These findings reinforce that while technology itself is essential, the systems that support its use—particularly around workforce development and safety—are equally important to achieving the desired outcomes.

The relationship between training and simulation facilities and complication rates, as influenced by other health-system factors, is compelling. The strength of this association varies by disease severity, the level of hospital infrastructure, and operator experience. Notably, the greatest potential benefit of training is observed among less experienced surgical teams operating in health systems with scarce infrastructure, particularly when managing patients with more severe disease. This finding emphasises the need to integrate surrounding infrastructure alongside the implementation of new interventions. Equally important is ensuring that robust systems for training and safety are established from the outset to maximise the effectiveness of these technologies. Intraoperative safety timeouts were reported more frequently in hospitals in LMICs than in those in high-income countries. This might reflect strong promotion of safety measures such as the WHO Surgical Safety Checklist as a global patient safety priority, with many LMIC hospitals adopting the intervention as a standard of care. By contrast, studies in high-income countries suggest variable or inconsistent checklist use despite earlier widespread implementation.[47] These findings emphasise that adoption of safety practices does not follow a simple income gradient, but is shaped by safety culture, leadership, and implementation support.

This study has several strengths. First, its prospective, multicentre design and the breadth of data collected provide a comprehensive, whole-system evaluation of technology adoption. By collecting patient-level and hospital-level data across diverse settings, we have developed one of the richest datasets in this area. Second, the co-development of our conceptual framework, based on the WHO Health System Building Blocks and the Global Patient Safety Action Plan, grounds the study in well established principles of health-system strengthening and patient safety. Third, we ensured data quality through robust measures including training modules, collaborator-facing web applications, real-time data quality assurance, and an independent data validation study to verify case ascertainment and data accuracy. The scarcity of high-quality data has hindered evaluations of technology adoption in resource-constrained settings.[19,20] This study addresses that gap, enabling meaningful comparisons across income settings with accurate case-mix adjustment and contributing valuable insights into technology adoption on a global scale.

However, there are several limitations to consider. First, although using minimally invasive cholecystectomy as a tracer procedure provided valuable insights, it might not fully capture the complexities and unique challenges associated with other health technologies. Second, selection bias was evident, as participating hospitals were predominantly tertiary care facilities, especially in LMICs, thus limiting the generalisability of these findings to smaller, district-level hospitals. This sampling also helps explain counter-intuitive patterns, such as the apparently high minimally invasive surgery rates in LMIC hospitals; these sites are more likely to have access to minimally invasive surgery infrastructure, training, and manage younger, elective caseloads, whereas hospitals from high-income countries in our network contributed a higher proportion of emergency presentations and older, comorbid patients. Differences in site type and case mix therefore plausibly account for the divergence from expectations. Third, we did not observe a relationship between country income level and outcomes, and so did not perform planned mediation analyses of potential intermediary variables identified a priori in the framework. Fourth, the requirement for an analysis of second-order and third-order interactions on specific variables was only identified in a post-hoc data analysis, and the results should be interpreted accordingly. Fifth, we did not have access to patients' financial data, which precludes an assessment of economic barriers to accessing minimally invasive surgery. This is particularly important in LMICs, where catastrophic health-care expenditures remain a major concern. Last, although the study comprised 109 countries, the applicability of our whole-system framework and findings should be interpreted with caution, as they might not generalise to countries or settings not represented in this cohort.

For both clinicians and policy makers, this study highlights the importance of investing not only in technologies themselves but also in the supporting health-system infrastructure required for their safe and effective use. Our findings highlight the pivotal role of diagnostic tools, such as CT imaging, along with robust training programmes and safety protocols, in achieving better outcomes. Policy makers should prioritise these foundational elements when introducing new technologies, particularly in resource-constrained settings where health systems might not have the necessary infrastructure. Strengthening these areas has the potential to promote more equitable outcomes across diverse health systems. Future research should aim to identify strategies for extending the benefits of minimally invasive surgery and other advanced health technologies to first-referral hospitals and rural settings, especially in LMICs. Additionally, investigating the performance and adoption of different types of minimally invasive surgery, including robotic surgery, across varying contexts would provide valuable insights for tailoring technology to diverse health-care environments.

In conclusion, this study highlights the importance of a whole-system approach to the adoption of essential surgical innovations such as minimally invasive surgery. Although the adoption of minimally invasive surgery was high among the hospitals in this study, the variability in outcomes shows that the mere availability of technology is insufficient to ensure success. Achieving equitable, high-quality health-care outcomes will require policy makers to strengthen the health-system infrastructure surrounding the technology, particularly in training, safety, and diagnostics. By addressing these factors, global health systems can more effectively scale up technologies such as minimally invasive surgery, ultimately improving patient outcomes and advancing health equity worldwide. Our findings provide a roadmap for how health systems, regardless of income level, can strengthen training, safety, and infrastructure to deliver safer and more equitable surgical care.

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The writing group and the statistical analysis group (SKK and EMH) contributed to writing, data interpretation, and critical revision of the manuscript. The writing group, steering group, national leads and dissemination committee contributed to study conception, protocol development, study delivery, and management. The collaborators contributed to data collection and study governance across included sites. All members of the writing group had full access to the data in the study. SKK, OK, RP, and EMH verified the underlying data in the study. SKK, EMH, and the writing group had final responsibility for the decision to submit for publication. Role descriptions of all collaborators are shown in the appendix.

Declaration of interests

We declare no competing interests.

Data sharing

Data sharing requests will be considered by the writing group upon written request via email to the corresponding author.

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