

Prospective observational cohort study on grading the severity of postoperative complications in global surgery research

International Surgical Outcomes Study (ISOS) group*

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Background: The Clavien–Dindo classification is perhaps the most widely used approach for reporting postoperative complications in clinical trials. This system classifies complication severity by the treatment provided. However, it is unclear whether the Clavien–Dindo system can be used internationally in studies across differing healthcare systems in high- (HICs) and low- and middle-income countries (LMICs).

Methods: This was a secondary analysis of the International Surgical Outcomes Study (ISOS), a prospective observational cohort study of elective surgery in adults. Data collection occurred over a 7-day period. Severity of complications was graded using Clavien–Dindo and the simpler ISOS grading (mild, moderate or severe, based on guided investigator judgement). Severity grading was compared using the intraclass correlation coefficient (ICC). Data are presented as frequencies and ICC values (with 95 per cent c.i.). The analysis was stratified by income status of the country, comparing HICs with LMICs.

Results: A total of 44 814 patients were recruited from 474 hospitals in 27 countries (19 HICs and 8 LMICs). Some 7508 patients (16.8 per cent) experienced at least one postoperative complication, equivalent to 11 664 complications in total. Using the ISOS classification, 5504 of 11 664 complications (47.2 per cent) were graded as mild, 4244 (36.4 per cent) as moderate and 1916 (16.4 per cent) as severe. Using Clavien–Dindo, 6781 of 11 664 complications (58.1 per cent) were graded as I or II, 1740 (14.9 per cent) as III, 2408 (20.6 per cent) as IV and 735 (6.3 per cent) as V. Agreement between classification systems was poor overall (ICC 0.41, 95 per cent c.i. 0.20 to 0.55), and in LMICs (ICC 0.23, 0.05 to 0.38) and HICs (ICC 0.46, 0.25 to 0.59).

Conclusion: Caution is recommended when using a treatment approach to grade complications in global surgery studies, as this may introduce bias unintentionally.



*Members of the ISOS group are co-authors and investigators of this study and are listed in *Appendix S1* (supporting information)

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Introduction

It is estimated that more than 300 million surgical procedures are carried out globally each year¹. Despite a population size five times that of high-income countries (HICs)^{2,3}, the rate of surgical intervention in low- and middle-income countries (LMICs) is at least ten times lower per head of population^{4,5}. Although surgical patients in LMICs tend to be younger with fewer perioperative risk factors than patients in HICs, they are twice as likely to die^{5,6}. Postoperative morbidity is important as a marker of the success of surgery in itself; consequently it is commonly used as an outcome measure in surgical research^{6,7}. Worldwide, the Clavien–Dindo classification⁸ is probably the most widely

used tool for assessing the severity of postoperative complications in clinical trials.

The Clavien–Dindo classification system was developed by a group of clinical researchers to address challenges in assessing the severity of postoperative complications, due to not only surgical care and the patient population, but also the inherent subjectivity of assessment^{9,10}. The system includes five categories (I–V) of increasing severity based on the clinical treatment of complications, for example pharmacological therapy (grade II) *versus* surgical intervention (grade III)¹¹. Clavien–Dindo has been used successfully in surgical studies in both HICs and LMICs, but not in international studies including LMICs in the global health context^{12,13}. The resources available to

treat postoperative complications may vary widely across LMICs, and this may introduce bias into severity grading using the Clavien–Dindo system.

Given the differences in the provision of surgical care in LMICs and HICs, the present authors were interested to explore whether complication severity grading based on treatments delivered was a reliable approach to the measurement of postoperative morbidity across countries with very different levels of healthcare resources. To this end, a simpler severity grading system was conceived that was used in the International Surgical Outcomes Study (ISOS) and the African Surgical Outcomes Study (ASOS)^{5,14}. Here, a prospective comparison of ISOS complication severity classification and the Clavien–Dindo classification is reported.

Methods

Study design and setting

Prospective secondary analysis was undertaken of ISOS, a 7-day observational cohort study of in-hospital perioperative outcomes conducted in 474 hospitals in 27 countries. The principal methods and results have been published previously^{14–18}. Regulatory requirements varied according to country, with some requiring research ethics approval and some requiring only data governance approval. In the UK, the study was reviewed and approved by the Yorkshire and Humber Research Ethics Committee (13/YH/0371)¹⁵. Reporting is consistent with the STROBE guidelines¹⁹ for observational research and the principles of the Declaration of Helsinki.

Participants and data collection

Participants were all adults (aged at least 18 years) at participating centres undergoing planned surgical procedures with at least one intended overnight stay in hospital. Patients undergoing day-case procedures, interventional radiology procedures or emergency surgery were excluded. The study was led in each country by a national coordinator, who selected a single national data collection week between April and August 2014. This approach is now widely adopted by surgical research collaboratives^{12,13}. Data were collected for consecutive surgical patients over a 1-week period at each centre, using standard case report forms; patients were followed up for 30 days or until hospital discharge. The data set included demographic information, surgical procedure category, perioperative care and details of any postoperative complications. Data were censored at 30 days after surgery for the small minority of patients who remained in hospital. Anonymized

data were entered on to a secure internet database, which included automated checks for consistency, plausibility and completeness^{14,15}. Data were collected prospectively, allowing the severity of complications to be graded by both the Clavien–Dindo and ISOS systems, to allow subsequent comparison.

Variables

The variables of interest were postoperative complications graded according to the Clavien–Dindo and ISOS classifications. The Clavien–Dindo system categorizes complications into five main groups: grade I, any deviation from the normal postoperative course, without pharmacological, surgical, endoscopic or radiological intervention; grade II, a complication requiring pharmacological treatment, other than drugs allowed for grade I; grade III, a complication requiring surgical, endoscopic or radiological intervention; grade IV, a life-threatening complication; and grade V, death. The ISOS system categorizes complications into three categories (mild, moderate and severe) according to disease-specific criteria^{14,20}. Although the ISOS system references the need for clinical treatment, it also includes other factors such as prolongation of hospital stay and potential for long-term harm. Unlike the Clavien–Dindo system, ISOS severity grading is not related to the specific type of clinical treatment administered. In general, a mild complication is one that results in only temporary harm and does not usually require specific clinical treatment; a moderate complication is more serious, but does not usually result in permanent harm or functional limitation, and usually requires clinical treatment; and a major complication is one that results in significant prolongation of hospital stay and/or permanent functional limitation or death, and almost always requires clinical treatment. However, there were also additional specific criteria for some complications. Investigators at each site classified postoperative complications according to the ISOS severity grading system. In addition, data were also collected regarding treatment for postoperative complications to allow the retrospective classification of complications according to the Clavien–Dindo system.

Statistical analysis

This was a planned secondary analysis of the ISOS cohort to compare the severity grading of postoperative complications by the Clavien–Dindo system with severity grading by the ISOS system. STATA[®] version 14 (Stata-Corp, College Station, Texas, USA) was used to analyse the data. The analysis was restricted to patients who

suffered a complication or died within the follow-up period. Missing data were handled by list-wise deletion. First, the relative severity of complications according to each grading system was compared using a 3×5 table and a χ^2 test. Second, to facilitate comparison, cases were stratified into three groups according to the ISOS classification (mild, moderate and severe) and into three groups according to the Clavien–Dindo system (I, II and III–V), to produce two ordinal categorical variables each with three levels. Clavien–Dindo grades III, IV and V were grouped together for analysis to avoid a single group with a very small number of cases and to produce a single stratum of major complications that it was hoped would be broadly equivalent to the ISOS severe category.

First, the proportion of patients in each group was compared between classification systems and subjected to χ^2 testing. This was repeated, taking each complication in turn. Second, the intraclass correlation coefficient (ICC) was used with a two-way random-effects model for absolute agreement, to measure the reliability of assignment of complication severity between the classification systems. This method is commonly used to compare the reliability of diagnostic tests^{21,22}. The ICC was calculated for the whole sample, and repeated after stratifying the sample by complication type. The results are presented as ICC with 95 per cent confidence intervals. An ICC of zero suggests no agreement between classification systems, and an ICC of 1 suggests complete agreement²¹. ICC values were interpreted based on the schema presented by Koo and Li²²: more than 0.90, excellent; 0.76–0.90, good; 0.50–0.75, moderate; less than 0.5, poor.

Secondary analyses

To determine whether any observed difference in complication grading severity was influenced by economic status, the cohort was stratified by the World Bank economic classification (high-income and low–middle-income) according to the country of origin, and repeated the primary analysis²³. A sensitivity analysis was also conducted to test alternative comparisons. In the primary analysis, the ISOS moderate grade was compared with Clavien–Dindo grade II, and the ISOS severe grade was compared with Clavien–Dindo grades III–V. However, it is possible that any observed differences between the two classification systems could be due to this analysis strategy. Therefore, the data were recoded, comparing the ISOS moderate grade with Clavien–Dindo grades II–III, and the ISOS severe grade with Clavien–Dindo grades IV–V, and then repeating the primary analysis.

The analysis was a pragmatic one based on the complication severity grading by local investigators. The ISOS

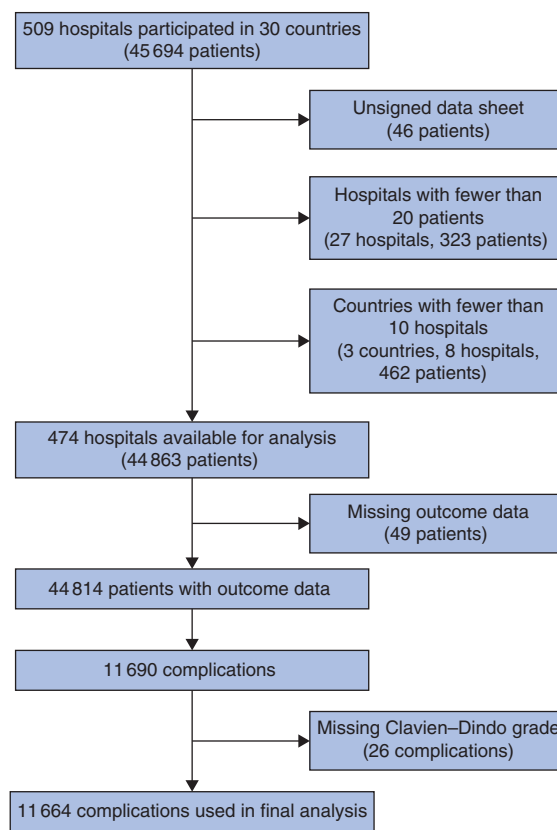


Fig. 1 Flow diagram showing the number of cases included in the analysis

severity grading did not mandate that a patient with a complication received a treatment in order for it to be classified as either moderate or severe, unlike Clavien–Dindo grade II or above. However, the authors were interested to know what proportion of complications graded using the ISOS system received treatment. Similarly, it was expected, for patients with a complication who subsequently died, that the complication would have been graded as severe. To test this, the proportion of patients who died according to each ISOS severity grade was tabulated. To account for potential bias by misclassification of severe complications due to coding of patients who died, patients who died were removed and the analysis was repeated.

Results

The ISOS included 44 814 patients, recruited from 474 hospitals in 27 countries worldwide during a single week in 2014. Eight countries were categorized as LMICs (including 134 hospitals), and 19 were classed as HICs (including 340 hospitals)¹⁴. Forty-nine participants with

Table 1 Postoperative complications stratified by ISOS and Clavien–Dindo severity grading systems

	ISOS system			Clavien–Dindo system				
	Mild	Moderate	Severe	I	II	III	IV	V
Infection								
Superficial surgical site	679 (51.6)	516 (39.2)	122 (9.3)	402 (30.5)	531 (40.3)	218 (16.6)	149 (11.3)	17 (1.3)
Deep surgical site	118 (21.0)	250 (44.4)	195 (34.6)	81 (14.4)	185 (32.9)	156 (27.7)	113 (20.1)	28 (5.0)
Body cavity	97 (28.5)	136 (40.0)	107 (31.5)	45 (13.2)	117 (34.4)	65 (19.1)	89 (26.2)	24 (7.1)
Pneumonia	239 (33.8)	325 (46.0)	143 (20.2)	73 (10.3)	269 (38.0)	71 (10.0)	239 (33.8)	55 (7.8)
Urinary tract	293 (43.2)	332 (48.9)	54 (8.0)	152 (22.4)	353 (52.0)	82 (12.1)	79 (11.6)	13 (1.9)
Bloodstream	140 (33.7)	160 (38.6)	115 (27.7)	55 (13.3)	156 (37.6)	55 (13.3)	101 (24.3)	48 (11.6)
Cardiovascular								
Myocardial infarction	45 (32.4)	43 (30.9)	51 (36.7)	29 (20.9)	33 (23.7)	13 (9.4)	38 (27.3)	26 (18.7)
Arrhythmia	467 (38.3)	566 (46.5)	185 (15.2)	250 (20.5)	481 (39.5)	115 (9.4)	298 (24.5)	74 (6.1)
Pulmonary oedema	127 (38.5)	141 (42.7)	62 (18.8)	33 (10.0)	121 (36.7)	31 (9.4)	111 (33.6)	34 (10.3)
Pulmonary embolism	17 (22)	33 (42)	28 (36)	13 (17)	28 (36)	13 (17)	19 (24)	5 (6)
Stroke	31 (27.9)	28 (25.2)	52 (46.8)	22 (19.8)	23 (20.7)	14 (12.6)	34 (30.6)	18 (16.2)
Cardiac arrest	n.a.	n.a.	153 (100)	13 (8.5)	9 (5.9)	2 (1.3)	38 (24.8)	91 (59.5)
Other								
Gastrointestinal bleed	95 (47.3)	66 (32.8)	40 (19.9)	47 (23.4)	61 (30.3)	29 (14.4)	40 (19.9)	24 (11.9)
Acute kidney injury	423 (54.4)	203 (26.1)	152 (19.5)	186 (23.9)	228 (29.3)	92 (11.8)	196 (25.2)	76 (9.8)
Postoperative bleed	n.a.	1143 (84.2)	214 (15.8)	191 (14.1)	635 (46.8)	211 (15.5)	265 (19.5)	55 (4.1)
ARDS	46 (32.4)	41 (28.9)	55 (38.7)	17 (12.0)	10 (7.0)	13 (9.2)	68 (47.9)	34 (23.9)
Anastomotic leak	52 (25.0)	62 (29.8)	94 (45.2)	22 (10.6)	35 (16.8)	61 (29.3)	69 (33.2)	21 (10.1)
Other	1339 (45.7)	1197 (40.9)	392 (13.4)	831 (28.4)	1044 (35.7)	499 (17.0)	462 (15.8)	92 (3.1)

Values in parentheses are percentages. ISOS, International Surgical Outcomes Study; n.a., not available; ARDS, acute respiratory distress syndrome.

Table 2 Postoperative complications according to the ISOS severity classification and stratified by the Clavien–Dindo classification

ISOS system	Clavien–Dindo system					Total
	I	II	III	IV	V	
Mild	1687 (68.5)	2216 (51.3)	579 (33.3)	848 (35.2)	174 (23.7)	5504 (47.2)
Moderate	576 (23.4)	1858 (43.0)	810 (46.6)	861 (35.8)	139 (18.9)	4244 (36.4)
Severe	199 (8.1)	245 (5.7)	351 (20.2)	699 (29.0)	422 (57.4)	1916 (16.4)
Total	2462	4319	1740	2408	735	11 664

Values in parentheses are percentages. ISOS, International Surgical Outcomes Study. $P < 0.001$ (χ^2 test for trend).

missing outcome data were excluded, leaving 7508 of 44 814 participants (16.8 per cent) who sustained at least one postoperative complication, including the 207 (0.5 per cent) who died. For this analysis, 26 complications with a missing Clavien–Dindo grade were excluded, giving a total of 11 664 individual complications for analysis, accounting for some participants who sustained multiple complications (*Fig. 1*).

Baseline characteristics of the cohort, stratified by complication grading, are shown in *Table S1* (supporting information). Each type of complication, stratified by complication grading, is shown in *Table 1*. The single most common complication was postoperative bleeding (1357 of 11 664, 11.6 per cent), followed by superficial surgical-site infection (1317 of 11 664, 11.3 per cent).

Comparison of Clavien–Dindo and ISOS severity classifications

Using the ISOS classification, 5504 of 11 664 complications (47.2 per cent) were graded as mild, 4244 (36.4 per cent) as moderate and 1916 (16.4 per cent) as severe. Using the Clavien–Dindo classification, 2462 of 11 664 complications (21.1 per cent) were graded as I, 4319 (37.0 per cent) as II, 1740 (14.9 per cent) as III, 2408 (20.6 per cent) as IV and 735 (6.3 per cent) as V. The 735 complications that occurred in patients who died were incorporated into the severe category of the ISOS classification. The proportion of complications categorized as mild, moderate or severe using the ISOS classification and categorized as grade I, II, III, IV or V using the Clavien–Dindo classification is shown in *Table 2*. Hypothesis testing using a χ^2 test suggested a difference in proportions ($P < 0.001$).

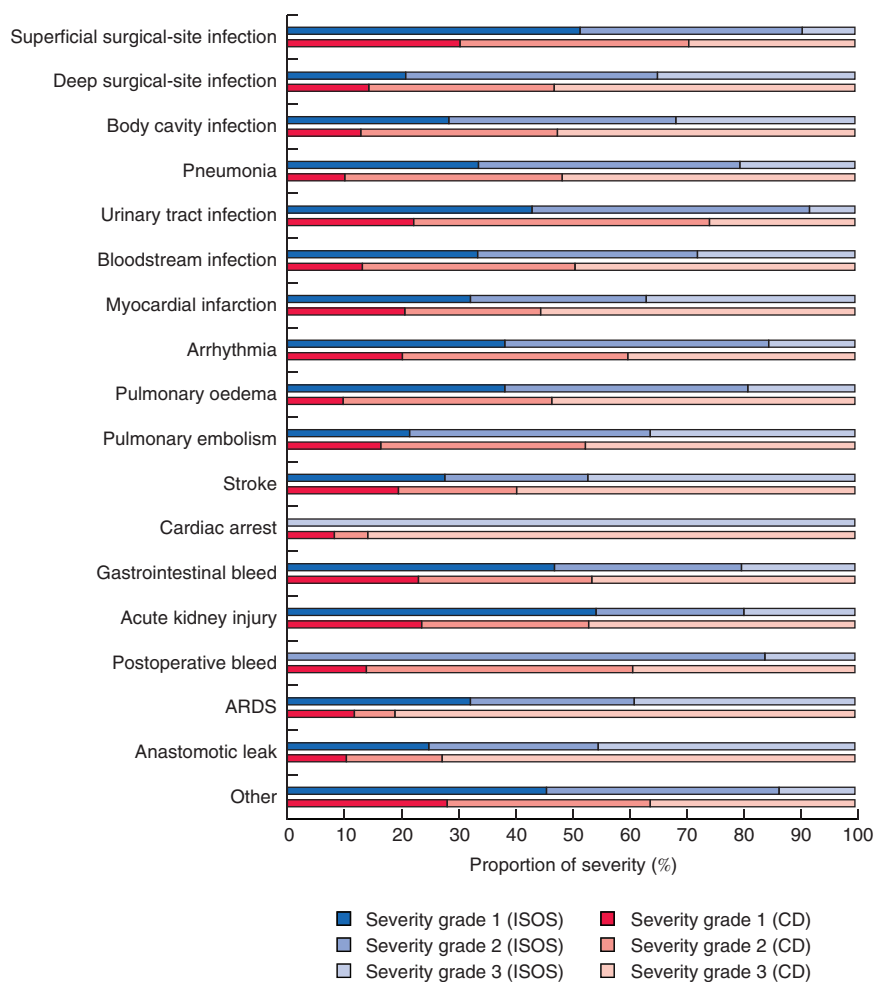


Fig. 2 Relative proportions of severity for each complication using ISOS and Clavien–Dindo classifications. International Surgical Outcomes Study (ISOS) classification: mild, grade 1; moderate, grade 2; severe, grade 3. Clavien–Dindo (CD) classification: I, grade 1; II, grade 2; III–V, grade 3. ARDS, acute respiratory distress syndrome

Complications were coded into three groups (Table S2, supporting information), and the relative proportions are shown in Fig. 2. ICC analysis found poor agreement between classification systems (ICC 0.41, 95 per cent c.i. 0.20 to 0.55) across the whole cohort, which was replicated when specific complications were tested individually (Table 3). Several complication categories (myocardial infarction, pulmonary embolism, stroke, acute respiratory distress syndrome and anastomotic leak) had a negative ICC, suggesting divergence between groups.

Low- and middle-income versus high-income countries

Of the 11 664 complications included in this analysis, 3009 (25.8 per cent) occurred in LMICs. Individual complications stratified by income status are shown in Table

S3 (supporting information). Comparison of complication categorization by tabulation (Table S4, supporting information) suggests a difference in proportions for both HICs and LMICs ($P < 0.001$). ICC analysis stratified by income status found poor agreement in both LMICs (ICC 0.23, 95 per cent c.i. 0.05 to 0.38) and HICs (ICC 0.46, 0.25 to 0.59) (Table 3).

Sensitivity analyses

When the analysis categories were recoded to compare ISOS moderate grade with Clavien–Dindo grade II–III, and ISOS severe grade with Clavien–Dindo grade IV–V, the results were similar (Table S5, supporting information). Of the 7488 patients with a total of 11 664 complications graded by ISOS classification, 5425 (72.4 per cent) received

Table 3 Agreement between ISOS and Clavien–Dindo classifications using intraclass correlation coefficient

	ICC		
	Whole cohort	LMICs	HICs
Complication			
Superficial SSI	0.3 (0.16, 0.40)	0.004 (–0.09, 0.09)	0.36 (0.24, 0.46)
Deep SSI	0.15 (0.06, 0.23)	–	0.07 (–0.03, 0.16)
Body cavity infection	0.13 (0.03, 0.22)	0.05 (–0.12, 0.20)	–
Pneumonia	0.10 (0.02, 0.18)	–	0.19 (0.07, 0.29)
Urinary tract infection	0.04 (–0.05, 0.12)	–	0.19 (0.08, 0.28)
Bloodstream infection	0.01 (–0.08, 0.09)	–	–
Arrhythmia	0.25 (0.11, 0.36)	0.008 (–0.09, 0.10)	0.35 (0.20, 0.46)
Pulmonary oedema	–	–	0.08 (–0.03, 0.17)
Gastrointestinal bleed	–	–	0.001 (–0.19, 0.16)
Acute kidney injury	0.25 (0.11, 0.36)	–	0.34 (0.16, 0.47)
Postoperative bleed	0.19 (–0.01, 0.35)	–	0.26 (–0.02, 0.45)
Other	0.41 (0.23, 0.53)	0.17 (0.05, 0.28)	0.46 (0.27, 0.58)
Overall	0.41 (0.20, 0.55)	0.23 (0.05, 0.38)	0.46 (0.25, 0.59)

Values in parentheses are 95 per cent confidence intervals. Classification systems were divided into three groups (International Surgical Outcomes Study (ISOS) classification: mild, 1; moderate, 2; severe, 3; Clavien–Dindo classification: I, 1; II, 2; III–V, 3). Negative intraclass correlation coefficient (ICC) values, indicating divergence (included myocardial infarction, pulmonary oedema, pulmonary embolism, stroke, cardiac arrest, acute respiratory distress syndrome and anastomotic leak) are not presented. LMIC, low- and middle-income country; HIC, high-income country; SSI, surgical-site infection.

treatment (Table S6, supporting information). Of the 207 participants who died, 16 (7.7 per cent) had a mild complication, 24 (11.6 per cent) had a moderate complication and 167 (80.7 per cent) had a major complication (Table S7, supporting information). When the primary ICC analysis was repeated excluding patients who died, the results were similar (Table S8, supporting information). A *post hoc* sensitivity analysis was performed of interrater reliability of the two classification systems using the κ statistic. The results suggest that the two systems would be expected to agree in 30.3 per cent of cases ($P < 0.001$).

Discussion

The principal finding of this analysis was that postoperative complications tend to be graded as less severe in LMICs when using the Clavien–Dindo classification compared with the ISOS classification. This is most likely because the use of less expensive treatments to treat complications reduces the apparent severity in resource-poor LMIC hospitals. Access to surgical treatments (Clavien–Dindo grade III) and ICUs (Clavien–Dindo grade IV) is often limited in these countries. The agreement between classification systems was much better for HICs than for LMICs. When the cohort was stratified by the income status of each country, there was an exaggerated difference between classification systems for LMICs compared with HICs, perhaps due to lower availability of specific treatments for postoperative complications in the former compared with the latter²⁴. This could lead to underestimation of the incidence of postoperative complications in LMICs, introducing bias

into the findings of international trials in the global surgery context. Conversely, complications may be overtreated in HICs, which may introduce similar bias.

Postoperative morbidity and mortality are major public health concerns^{25–29}. Worldwide, over 312 million surgical procedures are carried out each year, associated with an estimated approximately seven million postoperative complications^{1,14,30}. Over the last decade, the Clavien–Dindo system has been the dominant method for grading complications. However, although the rate of postoperative complications is thought to vary between HICs and LMICs, it is not known how these estimates may be biased by the measurement system^{5,13}. The differences observed here in the incidence and severity of postoperative complications in the ISOS cohort, particularly with regard to LMICs, suggest that the universal application of the Clavien–Dindo grading system may not be reliable. The recent ASOS adopted a complication grading system similar to that used in ISOS; this approach could be adopted by future studies in LMICs⁵.

The strengths of this study are the prospective design, the detailed and standardized data set, and the large sample size, which included hospitals from both HICs and LMICs. There are also limitations to the approach. To compare the two complication grading systems, the severity of complications in each classification system was coded into three strata. It is possible that translating the Clavien–Dindo system into three categories for analysis could have influenced the results. However, when the data were recorded using a different method, the results were similar. In the Clavien–Dindo system, death is considered the most

severe complication, by definition. However, this is not implicit in the ISOS classification, where it is possible for a patient to die following a complication of mild or moderate severity. Of the 207 participants who died, 16 (7.7 per cent) had a mild complication, 24 (11.6 per cent) had a moderate complication and 167 (80.7 per cent) had a major complication. When patients who died were excluded from the analysis, the results were again similar.

The present findings may have implications for future perioperative and surgical research in the global health context. First, these data suggest that use of the Clavien–Dindo classification may bias measurement of the severity of postoperative complications in LMICs, or when comparisons are made between HICs and LMICs. Second, an alternative option is to use complication-specific definitions of severity, for example the severity grading used by the ASOS⁵. Alternatively, it may be more appropriate to use standardized definitions of postoperative complications, derived using a consensus approach that incorporates severity grading, for example the Delphi-derived definitions developed by the StEP (Standardised Endpoints in Perioperative Medicine) collaboration, although these are not designed for use in LMIC settings³¹. Third, it may be helpful for future studies in LMICs to collect complication data using alternative systems, to allow assessment of bias between alternative complication severity classifications.

There are apparent differences in the incidence and severity of complications according to the severity grading system used. This difference is more pronounced in LMICs. Future surgical research in the global health context requires careful consideration of the optimal approach to evaluating complications, especially in international studies including healthcare systems with widely differing levels of resources.

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Supporting information

Additional supporting information can be found online in the Supporting Information section at the end of the article.