South African Paediatric Surgical Outcomes Study:

A 14-day prospective, observational cohort study of paediatric surgical patients

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Abstract

Background: Children comprise a large proportion of the population in Sub-Saharan Africa. The burden of paediatric surgical disease exceeds available resources in Africa, potentially increasing morbidity and mortality. There are few prospective paediatric perioperative outcomes studies, especially in low and middle-income countries (LMICs).

Methods: We conducted a 14-day, multicentre, prospective observational cohort study of paediatric patients (aged <16 years) undergoing surgery in 43 government-funded hospitals in South Africa. The primary outcome was the incidence of in-hospital postoperative complications. The study was registered on ClinicalTrials.gov (NCT03367832).

Results: We recruited 2024 patients at 43 hospitals. The overall incidence of postoperative complications was 9.7% (95% confidence interval [CI] 8.4-11.0) The most common postoperative complications were infective (7.3%, 95% CI 6.2-8.4%). In-hospital mortality rate was 1.1% (95% CI 0.6-1.5) of which nine of the deaths (40.9%), were in American Society of Anesthesiologists Physical Status (ASA PS) I and II patients. The preoperative risk factors independently associated with postoperative complications were ASA PS, urgency of surgery, severity of surgery and an infective indication for surgery.

Conclusions: The risk factors for, the frequency of, and type of complications following paediatric surgery differ between LMICs and high-income countries (HICs). The in-hospital mortality is ten times greater than in HICs. These findings should be used to develop strategies to improve paediatric surgical outcomes in LMICs, and support the need for larger prospective, observational paediatric surgical outcomes research in LMICs.

Keywords

Postoperative Complications; Outcome Assessment (Health Care); Hospital mortality; Paediatrics; Prospective Studies; Developing Countries/statistics & numerical data; Surgery

Clinical Registry Number

ClinicalTrials.gov. (NCT03367832)

Introduction

Children comprise more than 40% of the Sub-Saharan African population.[1] Despite a shift towards prioritising surgical care as an essential[2-4] and cost-effective[5-7] public health intervention, deficits in human and material resources contribute to lack of access and poor outcomes for paediatric surgery in Africa.[8-12] In parts of Africa, less than one in three children, and less than one in twenty neonates receive necessary surgery.[8, 10]

For those children who do receive surgical care, there are few prospective studies reporting perioperative outcomes. These studies are limited to predominantly high-income countries (HICs)[13] or to a single operative procedure.[14] Although, there is a paucity of data from low and middle-income countries (LMICs), we expect the incidence of perioperative complications and mortality to be higher,[14] and the patient risk profile to differ,[15] which may result in a potential difference in the type and incidence of perioperative complications, when compared to HICs.

In LMICs paediatric surgery spans most hospitals, and data from tertiary paediatric surgical services alone do not necessarily reflect the majority of paediatric surgeries and their associated outcomes in a country.[16] Therefore, prospective countrywide data of paediatric surgical patients which identify risk factors and associated complications are needed in order to improve paediatric surgical outcomes in LMICs.

The primary objectives of this study were to provide prospective benchmark data for: i) the incidence of in-hospital postoperative complications, ii) day-of-surgery and in-hospital mortality, and iii) the incidence of critical care (ICU) admissions in paediatric surgical patients in South Africa. The secondary objectives were to identify risk factors associated with in-hospital postoperative complications, describe the case profile, workforce and hospital bed resources.

Methods

Study design, setting, participants

This 14-day, multicentre, prospective observational cohort study of paediatric patients (aged <16 years) undergoing surgery was registered on ClinicalTrials.gov (NCT03367832). Primary ethics approval was obtained from the University of KwaZulu-Natal Biomedical Research Ethics Committee (BE593/16). Further ethics approvals and appropriate gate-keeper permissions were obtained for all sites. Five university research ethics committees waived written informed patient consent. Two university research ethics committees (University of the Witwatersrand and University of Free State) required written informed consent from the parents or legal guardians and assent from the patients, with approval of deferred consent for patients who could not give consent prior to surgery.

To obtain a representative sample across the country, all South African university departments and their affiliated hospitals were invited to participate. Additional sites were invited using professional contacts, society newsletters and existing contact databases from similar adult studies.[15, 17] Participating sites selected a single 14-day recruitment period between 22 May 2017 and 22 August 2017, from 07h00 on the first day to 06h59 on the final recruitment day. Patients were followed to hospital discharge or censored at 30-days postoperatively if still in hospital. Participating sites were provided with support via a study website (www.sapsos.co.za) which included all relevant documentation, including outcome definitions and frequently asked questions, and by selected site visits by AT and LC.

The aim was to include all consecutive eligible patients to eliminate selection bias. Inclusion criteria were all patients <16 years, admitted to participating centres during the study period

who underwent a surgical procedure, including day case surgery and operative procedures outside operating theatres where a general anaesthetic (GA) was performed. Exclusions were obstetric surgical procedures, and radiological or other procedures not requiring GA, or where general anaesthesia was provided but no procedure was performed e.g. GA during magnetic resonance imaging.

Data collection and variables

All definitions, including outcome definitions and measures were predefined (Appendix). Prior to study commencement, all participating sites documented hospital-specific data including service level, an estimation of the population served, number of hospital beds, operating rooms, critical care beds, nurse-to-patient ratios, and specialist surgical, anaesthetic and paediatric workforce.

The following variables were collected as part of the study: age, gender, weight, presence of comorbidities and American Society of Anesthesiologists Physical Status (ASA PS). The type, severity and urgency of operative procedure, primary indication for surgery (non-communicable, infective, traumatic or congenital), and anaesthetic technique and complications were also recorded. Postoperative outcome variables collected were: complications (graded as mild, moderate, or severe), length of stay, and status at hospital discharge which was censored at 30-days if still in hospital.

Data were collected for all patients on an operating room and postoperative paper case record form (CRF), with an additional CRF for any patient admitted to critical care during their hospital stay. Hospital site investigators transcribed data for each patient into a secure web-based application, [Research Electronic Data Capture (REDCap)][18] which generated an anonymised electronic patient record. Soft limits were set for data entry, prompting

investigators when data were entered outside these limits. The study was reported in accordance with the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) statement.[19]

Statistical analysis

Audit data submitted to the steering committee from potential participating sites prior to the study suggested it would be possible include 30 hospitals from six of the nine provinces and generate a sample size of approximately 2500 patients. A predicted recruitment of 95 % of eligible patients from these hospitals, would suggest that we could conservatively expect a sample size of at least 1750 paediatric surgical patients.

Incidences of categorical variables were calculated and reported as number and percentage. Differences were compared using $\chi 2$ or Fisher's exact tests as appropriate. Continuous variables were calculated and presented as mean and standard deviation (SD), or as median and interquartile range (IQR). A t-test for normally distributed data or Mann-Whitney U test for non-normally distributed data was used to compare differences in continuous variables. Binary outcome variables were presented as number (n) percentage (%) with 95% confidence intervals (CIs).

Prediction of preoperative risk factors for the development of postoperative complications was performed using bivariate logistic regression analysis and are presented as unadjusted univariate and adjusted multivariate odds ratios (ORs) and 95% CI. Based on our projected sample size, and to ensure that we did not violate the principle of 10 events per variable in a multivariate analysis of postoperative complications,[20] an a priori decision was taken to include the following candidate variables in a multivariate model based upon evidence from the available literature and biological plausibility; age; ASA PS; urgency of surgery (routine, urgent or emergency); primary indication for surgery (non-communicable, infective,

traumatic or congenital); presence of a preoperative comorbid disorder (cardiac disease, lower respiratory tract infection, pulmonary hypertension, human immunodeficiency virus and acquired immune deficiency syndrome (HIV/AIDS), or a congenital syndrome); severity of surgery (minor, intermediate or major); and type of surgery (cardiac- or neurosurgery). Factors were tested for collinearity and excluded if a variance-inflation factor was greater than two. With a predicted incidence of 5% for postoperative complications, the expected sample size would provide sufficient events to prevent model overfitting. As less than 5% of the data were missing for the primary outcomes, a complete case analysis was used.[21] Statistical analyses were performed using SPSS statistics version 25 (IBM, Chicago, IL, USA). For all analyses, p-values of less than 0.05 were considered statistically significant.

Results

Between 22 May 2017 and 22 August 2017, 2024 patients were recruited (Figure 1) from the 43 enrolled government-funded hospitals. One hospital withdrew on the first day of recruitment due to a fire in the theatre complex, leaving nine (21%) primary-level, 17 (41%) secondary-level, 7 (17%) tertiary-level and 9 (21%) central (tertiary-level acting as main university teaching platform) hospitals. Only two of the hospitals were dedicated paediatric hospitals (one tertiary, and one district) while the others provided mixed adult and paediatric surgical care. Six of the nine national provinces were represented, providing coverage of approximately 75% of the overall population in South Africa, with participating hospitals serving an estimated paediatric population of 8.5 million children.[22]

Cohort characteristics

The mean patient age was 5.9 (4.2) years with a majority of males in the cohort (Table 1). Most patients had a low preoperative risk profile, 66.4% were graded as ASA PS I. The most common acute comorbidity was an upper respiratory tract infection (4.4%), while congenital syndromes (6.5%) and congenital heart disease (4.5%) were the most common chronic comorbidities. HIV/AIDS was present in 2.5% (51) of patients.

Most surgeries were minor, scheduled surgery. Overall, only 7.5% of patients had major surgery, although this proportion doubled in patients presenting for emergency surgery. The primary indication for surgery was evenly distributed, but surgery for congenital and infective indications was associated with increased complications. Orthopaedic and ear, nose and throat (ENT) surgery were most common. Cardiac- and neurosurgery represented 2.6%

and 4.4% of operative procedures respectively. A surgical checklist (SC) was used in 70.9% of cases.

Primary outcomes

Outcome data were complete for 97.6 % of patients for postoperative complications, 99.5% for mortality, and 100% for critical care admission. A total of 346 postoperative complications occurred in 192 patients, an overall incidence of 9.7% (95% CI 8.4-11.0) (Table 2). Twenty-five percent of complications were mild, 38% moderate and 37% severe. The most common postoperative complications were infective (146/1999; 7.3%, 95% CI 6.2-8.4%), of which surgical site infections (SSI) were the most common (4.7%, 95% CI 3.8-5.6). A re-operation to treat a complication occurred in 81/2008 (4.0%, 95% CI=3.2-4.9) of patients.

In-hospital mortality rate was 1.1% (95% CI 0.6-1.5; n=22/2014), which is equivalent to an in-hospital perioperative mortality rate (POMR) of 109 per 100 000 cases (95% CI=88.5-129.4). Mortality on the day of surgery was 14.8 per 100 000 cases (95% CI=7.2-22.3), and one third of all deaths occurred within one day of surgery (34.8 per 100 000 case [95% CI=23.2-46.3]). The median time of death was 4 days (IQR 1.0-8.0). Of the 22 deaths, the majority occurred at a tertiary facility (20/22), with a single death each at a primary-level and at a secondary-level facility. Nine of the deaths (40.9%), were in ASA PS I and II patients. The majority of patients who died were not admitted to a critical care ward (54.5%, n=12/22) at any stage during their hospital stay.

One hundred and sixty patients were admitted to critical care (ICU) (7.9%, 95% CI=6.7-9.0). Almost all of these admissions (96%) were immediately following surgery and 40.5% were unplanned.

Preoperative factors associated with complications

The ASA PS, urgency of surgery, severity of surgery and an infective indication for surgery were independently associated with postoperative complications and are shown in Table 3.

Process measures

The median length of stay (LOS) was 1 day (1-5), with three quarters of the cohort having an overnight hospital admission. Postoperative complications, major surgery or an ICU admission significantly increased hospital LOS. The median LOS for patients without a complication was 1 day (0-3) increasing to 15 days (6-30) for patients with a postoperative complication ($p<0.001$). Major surgery increased LOS to 8 days (5-15.8) compared to 1 day (0-2) for minor surgery ($p<0.001$). Patients admitted to ICU had an overall hospital LOS of 13 days (6-25) ($p<0.001$).

Hospital and workforce indicators

Hospitals had a median of 499 (304-867) hospital beds, and five operating rooms (4-10). Approximately half the hospitals (23/42) had a paediatric critical care bed, with a median of four (2-7) critical care beds in these hospitals. Hospitals were staffed by a median of three (0.75-8) specialist paediatricians (n=256), three (1-6) specialist surgeons (n=221) and three (1-5.75) specialist anaesthetists (n=208). The median surgical and anaesthetic specialist workforce was 6.0 (2-10.25) specialists per hospital (n=429), equivalent to 5 to 6 specialists per 100 000 paediatric population. The median number of surgical procedures performed was

31(10-65.5) per hospital in the study weeks, an estimated rate of 619 (95% CI 570-667) procedures per 100 000 paediatric population per year.

Discussion

This prospective observational study of perioperative outcomes in South African paediatric surgical patients, reports that one in 10 patients suffer a postoperative complication, with an in-hospital mortality of one in 100. Most of the complications were infective, with one in 22 patients developing a surgical site infection (SSI). Almost half of deaths occurred in ASA PS I and II patients and one third occurred within one day of surgery.

This study identified three important differences regarding postoperative complications following paediatric surgery in LMICs, when compared to HICs. Firstly, the dominant complications differ. In HICs, the majority of postoperative complications are non-infective,[14, 23] while in this study infective complications predominated. Secondly, the incidence of postoperative complications was more frequent in this study of a MIC than that reported in HICs (1.1-6.2 % of patients),[14, 23, 24] but lower than that seen in LICs.[14, 23] However, it remains difficult to directly compare postoperative complication rates between countries due to varying study definitions, a lack of national data reports, and reports which are limited to specific surgical procedures.[14, 23-26]

Thirdly the identified risk factors for complications were different to those found in HICs.[23] Identification of risk factors for perioperative complications may guide potential clinical decision-making, interventions and the allocation of resources needed to decrease these complications. Weinberg and colleagues[23] investigated risk factors for postoperative complications and mortality in paediatric surgical patients in a HIC, and were able to construct and validate[27] a preoperative and overall risk score model for these outcomes. They identified six independent preoperative variables (gestational age, ASA PS score >3, a history

of cardiovascular comorbidities, and cardiovascular, neurological or orthopaedic surgical procedures) as predictors of postoperative complications. In comparison, in our study, four preoperative risk factors were identified: infection as an indication for surgery; ASA PS; surgical urgency; and severity of surgery. Age, type of surgery, and comorbidities were not independently associated with postoperative complications. This suggests that perioperative risk stratification in paediatric surgical patients in LMICs may differ from that of HICs. This study supports previous studies which highlight the impact of emergency surgery and infection on paediatric surgical morbidity in Africa.[14, 28, 29] In addition, it demonstrates that infection as an indication for surgery is an important predictor of risk.

Paediatric surgical mortality in LMICs has been reported to be two to ten times that of HICs,[14, 25, 26] and 100-fold higher for certain low-income countries (LICs). [25, 26, 29-32] However, the majority only report 24-hour mortality. It is possible that the retrospective estimates of paediatric outcomes in LMICs are potentially conservative. In South Africa, a retrospective study of the perioperative mortality of one tertiary, dedicated paediatric surgical service was reported to have a similar mortality to retrospective studies in HICs.[16, 33, 34] The perioperative mortality in our study is ten times that of a prospective study in HICs.[13] The potential reasons for this difference in mortality would be multifactorial and speculative. Poor access resulting in delayed presentation to specialist care could be one of the reasons. While in Europe, only 12% of deaths at 30 days occur in ASA PS I and II patients (Data extracted from the Anaesthesia Practice In Children Observational Trial [APRICOT] Study)[13], in South Africa 40% of deaths occur in these low risk patient categories. It is possible that these deaths may follow a missed critical incident or postoperative complication resulting in 'failure to rescue'. These are important signals and further work is needed to determine what the potential drivers are for paediatric perioperative mortality in LMICs.

Strengths

The strength of this study is that the simple pragmatic design ensured high compliance in a resource-constrained environment, with a good representation of the paediatric population, with more than half of the potential paediatric surgical population in South Africa represented. These data therefore reflect the broader paediatric surgical service of a MIC, and illustrate the differences in risk factors, and outcomes when compared to HICs.

Weaknesses

The majority of hospitals and doctors in LMICs provide a service to a mixed adult and paediatric population, and it was therefore difficult to report on the specialist workforce density and bed resources for paediatric surgical patients as planned. As the specialist paediatric surgical provision is limited in LMICs, it is therefore important that a new definition of an adequacy of paediatric surgical provision is agreed upon for LMICs, to address this shortcoming.

Based on the small numbers associated with mortality, the missing outcomes data for mortality may have affected our results. Should all these missing patients (n=10) have died then the mortality for the cohort would be 32/2024 (1.7%, 95% CI 1.1-2.3). The impact of the missing complication outcomes data is markedly less on the interpretation of the data presented, as it was less than 2.5% of the dataset, and hence would not adversely affect our whole case analysis of associations with postoperative complications.[21]

Finally, the data submitted was not validated, with the exception of the soft data limits at the time of data submission, and the queries to investigators of data outliers during data cleaning.

We believe the results from this study are generalisable to the South African public service, however, further work is needed to determine whether it is generalisable to other LMICS. In LMICs the burden of surgical disease in children is high, with a reported surgical need in almost 20% of children, of which 62% are unmet.[8] Globally the reported surgical need per capita is 4664 per 100 000 population per year, which increases to 7000 per 100 000 population per year in Africa.[35] As children (less than 15 years old) constitute 40% of the Sub-Saharan African population, we therefore estimate that the surgical need in children is between 2000 – 3000 operations /100 000 population per year.[36] This study further indicates that South Africa is currently achieving between a 1/3 and 1/5 of its predicted met surgical need in paediatric patients.

Furthermore, in order to benchmark paediatric outcomes globally, universal definitions of paediatric perioperative outcomes are needed. The Paediatric Perioperative Outcomes Group has started work on developing paediatric perioperative core outcome sets.[37]

Finally, the differences between risk factors for, the type of, and the frequency of perioperative complications between South Africa, and the literature from HICs, suggests that further prospective studies are needed from LMICs, which may result in the development of a risk prediction tool specific for the LMIC paediatric surgical environments. Only once we understand the risk factors for paediatric surgical morbidity in this environment, will we be able to target interventions with potential therapeutic benefit.

Conclusion

The risk factors for, the frequency of, and the type of postoperative complications differ

between paediatric surgical patients in LMICs and HICs. These findings have implications for developing strategies to improve paediatric surgical outcomes in LMICs, and support the need for larger prospective, observational paediatric surgical outcomes research in LMICs.

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The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the paper. The corresponding author (AT), LC, JT, BB and RR had full access to all the data in the study.

Author's contributions

Study design/planning: A.T., L.C., J.T., B.B.

Study conduct: A.T., L.C., J.T., H.M., A.B., J.D., C.C., H.K., B.M., M.K., R.R., B.B, SAPSOS investigators (see Appendix)

Data analysis: A.T., L.C., R.R., B.B.

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Declaration of Interest

None declared

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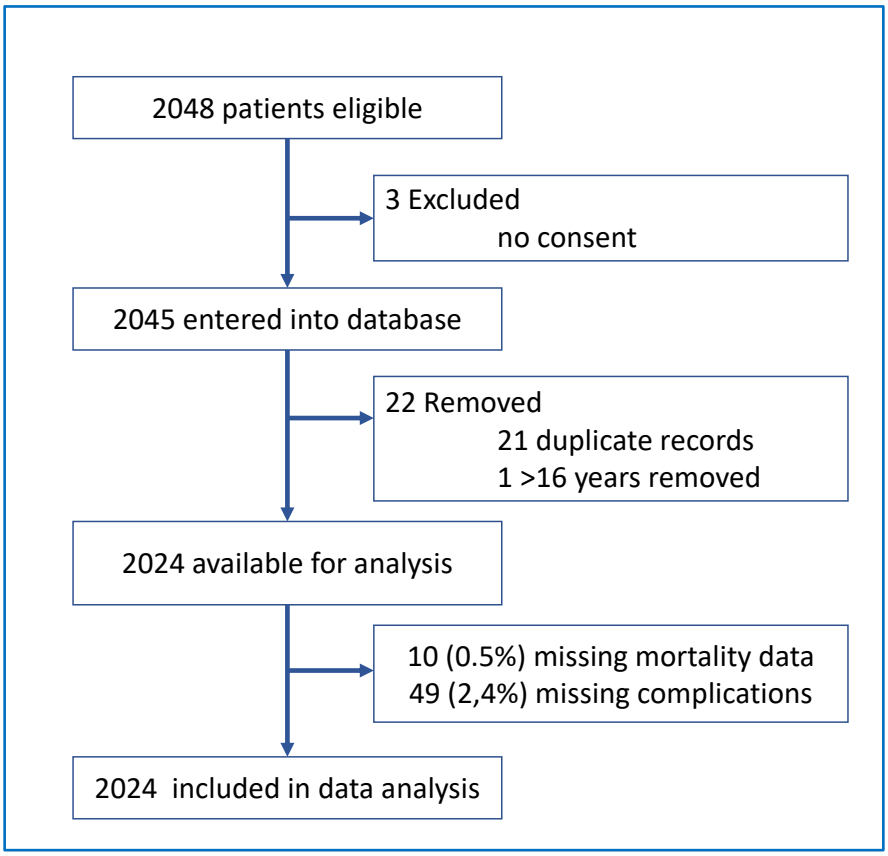

Fig. 1. Patient recruitment and analysis

Table 1. Baseline characteristics of the South African Paediatric Surgical Outcomes Study patient cohort

Variable	**All patients (n=2024)**	**Patients with complications (n=192)**	**Patients without complications (n=1975)**	**Univariate Odds Ratio (95%CI)**	**p**
Age Mean (SD)	5.86 (4.20)	5.1 (4.8)	5.9 (4.1)	-	-
Gender					
Male	1215/2015 (60.3)	120/1191 (10.1)	1071/1191 (89.9)	reference	
Female	800/2015 (39.7)	72/775 (9.3)	703/775 (90.7)	0.914 (0.672-1.243)	0.567
Age categories					
0-28 days	58/2024 (2.9)	21/52 (40.4)	31/52 (59.6)	5.377 (2.515-11.494)	<0.001
29 days- <1 year	212/2024 (10.5)	43/206 (20.9)	163/206 (79.1)	2.094 (1.127-3.889)	0.019
1- <4 years	495/2024(24.5)	34/485 (7.0)	451/485 (93.0)	0.598 (0.320-1.119)	0.108
4- <13 years	1109/2024 (54.8)	78/1089 (7.2)	1011/1089 (92.8)	0.612 (0.347-1.081)	0.091
13- <16 years	150/2024 (7.4)	16/143 (11.2)	127/143 (88.8)	reference	
ASA PS					
I	1339/2017 (66.4)	66/1308 (5.0)	1242/1308 (95.0)	reference	
II	418/2017 (20.7)	36/408 (8.8)	378/408 (91.2)	1.821 (1.194-2.778)	0.005

III	218/2017 (10.8)	65/213 (30.5)	148/213 (69.5)	9.212 (6.311-13.446)	<0.001
IV-V	42/2017 (2.1)	17/41 (41.5)	24/41 (58.5)	17.922 (9.258-34.694)	<0.001
Urgency of surgery					
Routine	1311/2024 (64.8)	71/1293 (5.5)	1222/1293 (94.5)	reference	
Urgent	408/2024 (20.2)	62/388 (16.0)	326/388 (84.0)	3.273 (2.279-4.701)	<0.001
Emergency	305/2024 (15.1)	59/294 (20.1)	235/294 (79.9)	4.321 (2.978-6.271)	<0.001
Severity of surgery					
Minor	1107/2017(54.9)	55/1083 (5.1)	1028/1083 (94.9)	reference	
Intermediate	759/2017 (37.6)	90/741(12.1)	651/741 (87.9)	2.584 (1.822-3.665)	<0.001
Major	151/2017 (7.5)	47/144 (32.6)	97/144 (67.4)	9.056 (5.824-14.083)	<0.001
Primary indication for surgery					
Non-communicable disease	643/2017 (31.9)	45/634 (7.1)	589/634 (92.9)	reference	
Infective	369/2017 (18.3)	52/355 (14.6)	303/355 (85.4)	2.246 (1.472-3.427)	<0.001
Trauma	449/2017 (22.3)	36/434 (8.3)	398/434 (91.7)	1.184 (0.750-1.869)	0.468
Congenital	556/2017 (27.6)	59/545 (10.8)	486/545 (89.2)	1.589 (1.059-2.385)	0.025

Type of surgery					
Orthopaedic	428/2016 (21.1)	18/410 (4.4)	392/410 (95.6)	0.367 (0.223-0.604)	<0.001
Cardiac	50/2016 (2.5)	17/45 (37.8)	28/45 (62.2)	6.089 (3.268-11.345)	<0.001
ENT	260/2016 (12.8)	14/259 (5.4)	245/259 (95.3)	0.494 (0.282-0.865)	0.014
Gynaecological	7/2016 (0.3)	0/7 (0.0)	7/7 (100.0)	0.000 (0.000-0.000)	0.999
Vascular	6/2016 (0.3)	0/6 (0.0)	6/6 (100.0)	0.000 (0.000-0.000)	0.999
Kidney/urological	148/2016 (7.3)	11/147 (7.5)	136/147 (92.5)	0.736 (0.391-1.389)	0.343
Upper GIT	59/2016 (2.9)	7/58 (11.5)	51/58 (87.9)	1.285 (0.575-2.872)	0.541
Thoracic	34/2016 (1.7)	7/33 (21.2)	26/33 (78.8)	2.557 (1.095-5.972)	0.030
Ophthalmology	170/2016 (8.4)	4/168 (2.4)	164/168 (97.6)	0.210 (0.077-0.057)	0.002
Lower GIT	206/2016 (10.2)	38/202 (18.8)	164/202 (81.2)	2.436 (1.650-3.597)	<0.001
Maxillo-facial/ dental	194/2016 (9.6)	1/192 (0.5)	191/192 (99.5)	0.044 (0.006-0.313)	0.002
Plastic/cutaneous	162/2016 (8.0)	13/156 (8.3)	143/156 (91.7)	0.833 (0.462-1.500)	0.542
Hepatobiliary	17/2016 (0.8)	4/17 (23.5)	13/17 (76.5)	2.897 (0.935-8.974)	0.065
Neurosurgery	89/2016 (4.4)	25/87 (28.7)	62/87 (71.3)	4.155 (2.544-6.788)	<0.001
Burns	66/2016 (3.3)	16/63 (25.4)	47/63 (74.6)	3.358 (1.865-6.046)	<0.001
Other	120/2016 (5.9)	16/117 (13.7)	101/117 (87.3)	1.514 (0.874-2.623)	0.139

Surgical checklist	1381/2014 (70.9)	129/1381 (9.3)	1252/1381 (90.7)	0.902 (0.651 – 1.251)	0.538
Any comorbidity	774/2024 (38.2)	111/754 (14.7)	643/754 (85.3)	2.430 (1.796-3.287)	<0.001
Comorbid disorder					
Congenital HD	92/2024 (4.5)	25/84 (29.8)	59/84 (70.2)	4.374 (2.669-7.169)	<0.001
Other HD	9/2024 (0.4)	2/9 (22.2)	7/9 (77.8)	2.671 (0.551-12.948)	0.223
Muscle disorder	4/2024 (0.2)	0/4 (0.0)	4/4 (100.0)	0.000 (0.000)	0.999
Endocrine	9/2024 (0.4)	0/9 (0.0)	9/9 (100.0)	0.000 (0.000)	0.999
Cancer	61/2024(3.0)	15/60 (25.0)	45/60 (75.0)	3.273 (1.788-5.991)	<0.001
Cerebral Palsy	30/2024 (1.5)	4/30 (13.3)	26/30 (86.7)	1.438 (0.496-4.164)	0.503
Snoring	73/2024 (3.6)	5/72 (6.9)	67/72 (93.1)	0.685 (0.273-1.720)	0.420
Asthma/atopy	492024 (2.4)	2/49 (4.1)	47/49 (95.9)	0.389 (0.094-1.613)	0.193
HIV/AIDS	51/2024 (2.5)	5/51 (9.8)	46/51 (90.2)	1.010 (0.396-2.572)	0.984
OSA	25/2024 (1.2)	2/25 (8.0)	23/25 (92.0)	0.805 (0.188-3.443)	0.770

Current/recent Upper RTI	89/2024 (4.4)	4/87 (4.6)	83/87 (95.4)	0.436 (0.158-1.202)	0.109
Current/recent Lower RTI	57/2024 (2.8)	13/55 (23.6)	42/55 (76.4)	3.011 (1.586-5.714)	0.001
Pulmonary hypertension	13/2024 (0.6)	5/13 (38.5)	8/13 (61.5)	5.932 (1.921-18.318)	0.002
Acute liver disease	4/2024 (0.2)	2/4 (50.0)	2/4 (50.0)	9.374 (1.313-66.925)	0.026
Chronic liver disease	11/2024 (0.5)	2/11 (18.2)	9/11 (81.8)	2.075 (0.445-9.673)	0.353
Congenital syndrome	132/2024 (6.5)	25/129 (19.4)	104/129 (80.6)	2.417 (1.519-3.846)	<0.001
Other	231/2024 (11.4)	37/222 (16.7)	185/222 (83.3)	2.062 (1.397-3.044)	<0.001
Neurological disorder	63/2024 (3.1)	11/62 (17.7)	51/62 (82.3)	2.064 (1.057-4.031)	0.034

Data are mean (SD), median (IQR). Denominators vary with the completeness of the data.

ASA PS=American Society of Anesthesiologists physical status. ENT=ear, nose and throat. GIT=gastrointestinal tract. HD=heart disease. HIV/AIDS= human immunodeficiency virus and acquired immune deficiency syndrome. OSA=obstructive sleep apnoea. RTI=respiratory tract infection.

Table 2: Complications by severity and total

Variable	**Patients without complications n/N (%)**	**Patients with complications n/N (%)**	**Complications by severity**		
			Mild n/N (%)	**Mod n/N (%)**	**Severe n/N (%)**
Any complication	1783/1975 (90.3%)	192/1975 (9.7%)	87/346 (25%)	132/346 (38%)	127/346 (37%)
Infective complications	1853/1999 (92.7%)	146/1999 (7.3%)	-	-	-
Cardiovascular complications	1971/1988 (99.1%)	17/1988 (0.9%)	-	-	-
Other complications	1906/1992 (95.7%)	86/1992 (4.3%)	-	-	-
Type of complication					
Infective complications					
Superficial SSI	1942/2002 (97.0%)	60/2002 (3.0%)	26/2002 (1.3%)	28/2002 (1.4%)	6/2002(0.3%)
Deep SSI	1959/2003 (97.8%)	44/2003 (2.2%)	7/2003 (0.35%)	18/2003 (0.9%)	19/2003 (0.9%)

Body cavity infection	1982/2004 (98.9%)	22/2004 (1.1%)	4/2004 (0.2%)	8/2004 (0.4%)	10/2004 (0.5%)
Pneumonia	1962/2001 (98.1%)	39/2001 (1.9%)	6/2001 (0.3%)	16/2001 (0.8%)	17/2001 (0.8%)
Urinary tract infection	1985/2002 (99.2%)	17/2002 (0.8%)	8/2002 (0.4%)	6/2002 (0.3%)	3/2002 (0.1%)
Bloodstream infection	1964/2004 (98.0%)	40/2004 (2.0%)	8/2004 (0.4%)	11/2004 (0.5%)	21/2004 (1%)
Cardiovascular complications					
Arrhythmia	1992/2002 (99.5%)	10/2002 (0.5%)	2/2002 (0.1%)	5/2002 (0.2%)	3/2002 (0.1%)
Pulmonary oedema	1999/2001 (99.9%)	2/2001 (0.1%)	1/2001 (0.05)	0 /2001(0%)	1/2001 (0.05%)
Pulmonary embolism	2001/2001 (100%)	0/2001 (0%)	0/2001 (0%)	0/2001 (0%)	0/2001(0%)
Cardiac Arrest	1979/1991 (99.4%)	12/1991 (0.6%)	NA	NA	12/1991 (0.6%)
Other complications					
Gastro-intestinal bleed	2000/2002 (99.9%)	2/2002 (0.1%)	1/2002 (0.05%)	0/2002 (0%)	1/2002 (0.05%)
Acute kidney injury	1991/2002 (99.5%)	11/2002 (0.5%)	3/2002 (0.15%)	5/2002 (0.2%)	3/2002 (0.15%)

Postoperative bleed	1985/2000 (99.3%)	15/2000 (0.8%)	6/2000 (0.3%)	4/2000 (0.2%)	5/2000 (0.3%)
ARDS	1994/2001 (99.7%)	7/2001 (0.3%)	4/2001 (0.2%)	1/2001 (0.05%)	2/2002 (0.1%)
Anastomotic breakdown	1996/2000 (99.8%)	4/2000 (0.2%)	0/2000 (0%)	2/2000 (0.1%)	2/2000 (0.1%)
Other	1935/1996 (96.9%)	61/1996 (3.1%)	11/1996 (0.6%)	28/1996 (1.4%)	22/1996 (1.1%)

Denominators vary with the completeness of the data. SSI=surgical site infection. ARDS= acute respiratory distress syndrome. NA = not applicable.

Table 3: Multivariate risk factors for postoperative complications

Pre-operative risk factors	**Univariate analysis**		**Multivariate analysis**	
	Odds Ratio (95% CI)	**p value**	**Odds Ratio (95% CI)**	**p value**
Age				
0-28 days	5.377 (2.515-11.494)	<0.001	2.468 (0.991-6.143)	0.052
29 days to < 1 year	2.094 (1.127-3.889)	0.019	1.457 (0.704-3.015)	0.310
1 to <4 years	0.598 (0.320-1.119)	0.108	0.840 (0.419-1.680)	0.621
4 to < 13 years	0.612 (0.347-1.081)	0.091	0.780 (0.421-1.445)	0.429
13 to 16 years	reference		reference	
ASA PS				
I	reference		reference	
II	1.821 (1.194-2.778)	0.005	1.686 (1.049-2.711)	0.031
III	9.212 (6.311-13.446)	<0.001	6.228 (3.797-10.218)	<0.001
IV-V	17.822 (9.258-34.694)	<0.001	7.118 (3.068-16.516)	<0.001
Urgency of surgery				
Routine	reference		reference	
Urgent	3.273 (2.279-4.701)	<0.001	2.084 (1.358-3.198)	0.001
Emergency	4.321 (2.978-6.271)	<0.001	2.276 (1.419-3.652)	<0.001
Severity of Surgery				
Minor	reference		reference	
Intermediate	2.584 (1.822-3.665)	<0.001	1.714 (1.162-2.527)	0.007
Major	9.056 (5.824-14.083)	<0.001	2.546 (1.408-4.605)	0.002

Primary indication for surgery				
Non-communicable disease	reference		reference	
Infective	2.246 (1.472-3.427)	<0.001	1.992 (1.200-3.305)	0.008
Trauma	1.184 (0.750-1.869)	0.468	1.274 (0.743-2.185)	0.379
Congenital	1.589 (1.059-2.385)	0.025	0.723 (0.423-1.237)	0.237
Type of Surgery				
Cardiac surgery	6.089 (3.268-11.345)	<0.001	1.786 (0.564-5.659)	0.324
Neurosurgery	4.155 (2.544 -6.788)	<0.001	1.498 (0.834-2.691)	0.176
Comorbid disorder				
Preoperative cardiac disease	4.140(2.557-6.703)	<0.001	1.039 (0.433-2.493)	0.932
Pulmonary hypertension	5.932 (1.921-18.318)	0.001	1.666 (0.432-6.417)	0.458
HIV/AIDS	1.010 (0.396-2.572)	0.984	0.516 (0.183-1.458)	0.211
Congenital Syndrome	2.417 (1.519-3.846)	<0.001	1.218 (0.663-2.236)	0.525
Current/recent LRTI	3.011 (1.586-5.714)	0.001	0.904 (0.419-1.950)	0.797

ASA PS=American Society of Anesthesiologists physical status. Preoperative cardiac disease = congenital heart disease and other cardiac disease. HIV/AIDS= human immunodeficiency virus and acquired immune deficiency syndrome. LRTI – lower respiratory tract infection