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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 yrs) undergoing surgery in 43 government-funded hospitals in South Africa. The primary outcome was the incidence of in-hospital postoperative complications.
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 (41%) were in ASA physical status 1 and 2 patients. The preoperative risk factors independently associated with postoperative complications were ASA physcial status, urgency of surgery, severity of surgery, and an infective indication for surgery.
Conclusions: The risk factors, frequency, and type of complications after paediatric surgery differ between LMICs and high-income countries. The in-hospital mortality is 10 times greater than in high-income countries. These findings

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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.

Clinical trial registration: NCT03367832.

Keywords: anesthesiology; developing countries; hospital mortality; outcome assessment (healthcare); pediatrics; postoperative complications; prospective studies; specialties, surgical

Editor's key points

- Access to safe paediatric surgery is an ongoing challenge in lower- and middle-income countries.
- This large study conducted in South Africa found that one in 10 paediatric patients suffer a postoperative complication; most complications were infective.
- There are important differences in the pattern and incidence of postoperative complications after paediatric surgery in lower- and middle-income countries when compared with high-income countries.

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 20 neonates receive necessary surgery.[8,10]

For those children who do receive surgical care, there are few prospective studies that report 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 with 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, and describe the case profile, workforce, and hospital bed resources.

Methods

Study design, setting, and participants

This 14-day multicentre, prospective, observational cohort study of paediatric patients (aged <16 yrs) 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 gatekeeper 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 before 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 May 22, 2017 and August 22, 2017, from 0700 hours on the first day to 0659 hours on the final recruitment day. Patients were followed to hospital discharge or censored at 30 days after operation if still in the 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 A.T. and L.C.

The aim was to include all consecutive eligible patients to eliminate selection bias. Inclusion criteria were all patients <16 yrs and 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; radiological or other procedures not requiring GA; or where general anaesthesia was provided, but no procedure was performed (e.g. GA during MRI).

Data collection and variables

All definitions, including outcome definitions and measures, were predefined (Supplementary Data). Before the 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 co-morbidities, and ASA physical status (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 (LOS), and status at hospital discharge, which was censored at 30 days if still in the 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),[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 (Strengthening the Reporting of Observational Studies in Epidemiology) statement.[19]

Statistical analysis

Audit data submitted to the steering committee from potential participating sites before the study suggested it would be possible to 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 χ^2 or Fisher's exact tests as appropriate. Continuous variables were calculated and presented as mean and standard deviation, or as median and inter-quartile 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 *n*, (%) with 95% confidence intervals (CIs).

Prediction of preoperative risk factors for the development of postoperative complications was performed using bivariate logistic regression analysis and is presented as unadjusted univariate and adjusted multivariate odds ratios 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 physical status; urgency of surgery (routine, urgent, or emergency); primary indication for surgery (non-communicable, infective, traumatic, or congenital); presence of a preoperative co-morbid 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 >2. With a predicted incidence of 5% for postoperative complications, the expected sample size would provide sufficient events to prevent model overfitting. As <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, $P>0.05$ was considered statistically significant.

Results

Between May 22, 2017 and August 22, 2017, 2024 patients were recruited (Fig. 1) from the 43 enrolled government-funded hospitals. One hospital withdrew on the first day of recruitment because of a fire in the theatre complex, leaving nine (21%) primary-level, 17 (41%) secondary-level, seven (17%) tertiary-level, and nine (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), whilst 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 (range 0–15.9) yrs with a majority of males in the cohort (Table 1). Most patients had a low preoperative risk profile; 66% were graded as ASA PS 1. The most common acute co-morbidity was an upper respiratory tract infection (4.4%), whilst congenital syndromes (6.5%) and congenital heart disease (4.5%) were the most common chronic co-morbidities. HIV/AIDS was present in 2.5% (51) of patients.

Most surgeries were minor scheduled surgeries. 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 surgeries were most common. Cardiac and neurosurgery represented 2.6% and 4.4% of operative procedures, respectively. A surgical checklist 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%

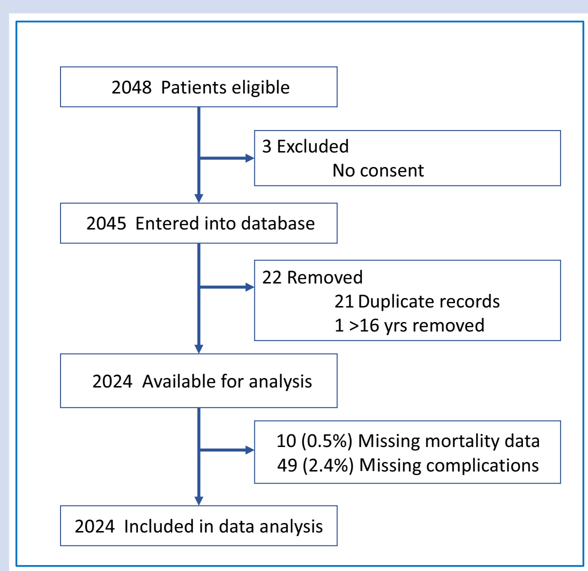

Fig 1. Patient recruitment and analysis.

Table 1 Baseline characteristics of the South African Paediatric Surgical Outcomes Study patient cohort. Data are mean (range), median (IQR). Denominators vary with the completeness of the data. ENT, ear, nose, and throat; GIT, gastrointestinal tract; HD, heart disease; HIV/AIDS, human immunodeficiency virus and acquired immune deficiency syndrome; IQR, inter-quartile range; OSA, obstructive sleep apnoea; RTI, respiratory tract infection.

Variable	All patients (n=2024)	Patients with complications (n=192)	Patients without complications (n=1975)	Univariate odds ratio (95% CI)	*P*-value
Age, mean (range)	5.86 (0–15.9)	5.1 (0.01–15.9)	5.9 (0–15.9)	—	—
Sex					
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)	0.91 (0.67–1.24)	0.57
Age categories					
0–28 days	58/2024 (2.9)	21/52 (40.4)	31/52 (59.6)	5.38 (2.52–11.49)	<0.001
29 days to <1 yr	212/2024 (10.5)	43/206 (20.9)	163/206 (79.1)	2.09 (1.13–3.89)	0.019
1 to <4 yrs	495/2024 (24.5)	34/485 (7.0)	451/485 (93.0)	0.60 (0.32–1.12)	0.11
4 to <13 yrs	1109/2024 (54.8)	78/1089 (7.2)	1011/1089 (92.8)	0.61 (0.35–1.08)	0.091
13 to <16 yrs	150/2024 (7.4)	16/143 (11.2)	127/143 (88.8)	Reference	
ASA physical status					
1	1339/2017 (66.4)	66/1308 (5.0)	1242/1308 (95.0)	Reference	
2	418/2017 (20.7)	36/408 (8.8)	378/408 (91.2)	1.82 (1.19–2.78)	0.005
3	218/2017 (10.8)	65/213 (30.5)	148/213 (69.5)	9.21 (6.31–13.45)	<0.001
4–5	42/2017 (2.1)	17/41 (41.5)	24/41 (58.5)	17.92 (9.26–34.70)	<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)	3.27 (2.28–4.70)	<0.001
Emergency	305/2024 (15.1)	59/294 (20.1)	235/294 (79.9)	4.32 (2.98–6.27)	<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)	2.58 (1.82–3.67)	<0.001
Major	151/2017 (7.5)	47/144 (32.6)	97/144 (67.4)	9.06 (5.82–14.08)	<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)	2.25 (1.47–3.43)	<0.001
Trauma	449/2017 (22.3)	36/434 (8.3)	398/434 (91.7)	1.18 (0.75–1.87)	0.47
Congenital	556/2017 (27.6)	59/545 (10.8)	486/545 (89.2)	1.59 (1.06–2.36)	0.025
Type of surgery					
Orthopaedic	428/2016 (21.1)	18/410 (4.4)	392/410 (95.6)	0.37 (0.22–0.60)	<0.001
Cardiac	50/2016 (2.5)	17/45 (37.8)	28/45 (62.2)	6.09 (3.27–11.35)	<0.001
ENT	260/2016 (12.8)	14/259 (5.4)	245/259 (95.3)	0.49 (0.28–0.87)	0.014
Gynaecological	7/2016 (0.3)	0/7 (0.0)	7/7 (100.0)	0.00 (0.00–0.00)	>0.99
Vascular	6/2016 (0.3)	0/6 (0.0)	6/6 (100.0)	0.00 (0.00–0.00)	>0.99
Kidney/urological	148/2016 (7.3)	11/147 (7.5)	136/147 (92.5)	0.74 (0.39–1.39)	0.34
Upper GIT	59/2016 (2.9)	7/58 (11.5)	51/58 (87.9)	1.29 (0.58–2.87)	0.54
Thoracic	34/2016 (1.7)	7/33 (21.2)	26/33 (78.8)	2.56 (1.10–5.97)	0.030
Ophthalmology	170/2016 (8.4)	4/168 (2.4)	164/168 (97.6)	0.21 (0.08–0.57)	0.002
Lower GIT	206/2016 (10.2)	38/202 (18.8)	164/202 (81.2)	2.44 (1.65–3.60)	<0.001
Maxillofacial/dental	194/2016 (9.6)	1/192 (0.5)	191/192 (99.5)	0.04 (0.01–0.31)	0.002
Plastic/cutaneous	162/2016 (8.0)	13/156 (8.3)	143/156 (91.7)	0.83 (0.46–1.50)	0.54
Hepatobiliary	17/2016 (0.8)	4/17 (23.5)	13/17 (76.5)	2.90 (0.94–8.97)	0.065
Neurosurgery	89/2016 (4.4)	25/87 (28.7)	62/87 (71.3)	4.16 (2.54–6.79)	<0.001
Burns	66/2016 (3.3)	16/63 (25.4)	47/63 (74.6)	3.36 (1.87–6.05)	<0.001
Other	120/2016 (5.9)	16/117 (13.7)	101/117 (87.3)	1.51 (0.87–2.62)	0.14
Surgical checklist	1381/2014 (70.9)	129/1381 (9.3)	1252/1381 (90.7)	0.90 (0.65–1.25)	0.54
Any co-morbidity	774/2024 (38.2)	111/754 (14.7)	643/754 (85.3)	2.43 (1.80–3.29)	<0.001
Co-morbid disorder					
Congenital HD	92/2024 (4.5)	25/84 (29.8)	59/84 (70.2)	4.37 (2.67–7.17)	<0.001
Other HD	9/2024 (0.4)	2/9 (22.2)	7/9 (77.8)	2.67 (0.55–12.95)	0.22
Muscle disorder	4/2024 (0.2)	0/4 (0.0)	4/4 (100.0)	0.00 (0.00–0.00)	>0.99
Endocrine	9/2024 (0.4)	0/9 (0.0)	9/9 (100.0)	0.00 (0.00–0.00)	>0.99
Cancer	61/2024 (3.0)	15/60 (25.0)	45/60 (75.0)	3.27 (1.79–5.99)	<0.001
Cerebral palsy	30/2024 (1.5)	4/30 (13.3)	26/30 (86.7)	1.44 (0.50–4.16)	0.50
Snoring	73/2024 (3.6)	5/72 (6.9)	67/72 (93.1)	0.69 (0.27–1.72)	0.42
Asthma/atopy	492 024 (2.4)	2/49 (4.1)	47/49 (95.9)	0.39 (0.09–1.61)	0.19
HIV/AIDS	51/2024 (2.5)	5/51 (9.8)	46/51 (90.2)	1.01 (0.40–2.57)	0.98
OSA	25/2024 (1.2)	2/25 (8.0)	23/25 (92.0)	0.81 (0.19–3.44)	0.77
Current/recent upper RTI	89/2024 (4.4)	4/87 (4.6)	83/87 (95.4)	0.44 (0.16–1.20)	0.11
Current/recent lower RTI	57/2024 (2.8)	13/55 (23.6)	42/55 (76.4)	3.01 (1.56–5.71)	0.001
Pulmonary hypertension	13/2024 (0.6)	5/13 (38.5)	8/13 (61.5)	5.93 (1.92–18.32)	0.002
Acute liver disease	4/2024 (0.2)	2/4 (50.0)	2/4 (50.0)	9.37 (1.31–66.93)	0.026
Chronic liver disease	11/2024 (0.5)	2/11 (18.2)	9/11 (81.8)	2.08 (0.45–9.67)	0.35

Continued

Table 1 Continued

Variable	All patients (n=2024)	Patients with complications (n=192)	Patients without complications (n=1975)	Univariate odds ratio (95% CI)	P-value
Congenital syndrome	132/2024 (6.5)	25/129 (19.4)	104/129 (80.6)	2.42 (1.52–3.85)	<0.001
Other	231/2024 (11.4)	37/222 (16.7)	185/222 (83.3)	2.06 (1.40–3.04)	<0.001
Neurological disorder	63/2024 (3.1)	11/62 (17.7)	51/62 (82.3)	2.06 (1.06–4.03)	0.034

(95% CI: 8.4–11.0) (Table 2). Overall, 25% 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 (SSIs) were the most common (4.7%; 95% CI: 3.8–5.6). A reoperation 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 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 1 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 1 and 2 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 after 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 the 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 the LOS to 8 days (5–15.8) compared with 1 day (0–2) for minor surgery (P<0.001). Patients admitted to the ICU had an overall hospital LOS of 13 days (6–25) when compared with others (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 (from two to seven) critical care beds in these hospitals. Hospitals were staffed by a median of three (0.75–8) specialist paediatricians (n = 256), three (from one to six) 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 five to six 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 an SSI. Almost half of deaths occurred in ASA physical status 1 and 2 patients, and one-third occurred within 1 day of surgery.

This study identified three important differences regarding postoperative complications after paediatric surgery in LMICs, when compared with HICs. Firstly, the dominant complications differ. In HICs, the majority of postoperative complications are non-infective,[14,23] whilst in this study, infective complications predominated. Secondly, the incidence of postoperative complications was more frequent in this study of a middle-income country (MIC) than that reported in HICs (1.1–6.2% of patients),[14,23,24] but lower than that seen in low-income countries (LICs).[14,23] However, it remains difficult to directly compare postoperative complication rates between countries as a result of varying study definitions, a lack of national data reports, and reports that 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 the risk factors for postoperative complications and mortality in paediatric surgical patients in an 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 physical status >3; a history of cardiovascular co-morbidities; 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 physical status, surgical urgency, and severity of surgery. Age, type of surgery, and co-morbidities 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 that 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.

Table 2 Incidence and severity of complications. Denominators vary with the completeness of the data. ARDS, acute respiratory distress syndrome; NA, not applicable; SSI, surgical site infection

Variable	Patients without complications, *n*/*N* (%)	Patients with complications, *n*/*N* (%)	Complications by severity		
			Mild, *n*/*N* (%)	Moderate, *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					
Gastrointestinal 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)

Paediatric surgical mortality in LMICs has been reported to be from two to 10 times that of HICs,[14,25,26] and 100-fold higher for certain LICs.[25,26,29–32] However, the majority only report 24 h 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 10 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. Whilst in Europe, only 12% of deaths at 30 days occur in ASA physical status 1 and 2 patients (data extracted from the Anaesthesia Practice in Children Observational Trial 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 with 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 < 2.5% of the data set, and hence, would not adversely affect our whole case analysis of associations with postoperative complications.[21]

Finally, the data submitted were 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% is 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 (<15 yrs old) constitute 40% of the sub-Saharan African population, we therefore estimate that the surgical need in

Table 3 Multivariate risk factors for postoperative complications. Preoperative cardiac disease (congenital heart disease and other cardiac disease). CI, confidence interval; HIV/AIDS, human immunodeficiency virus and acquired immune deficiency syndrome; LRTI, lower respiratory tract infection

Preoperative risk factors	Univariate analysis		Multivariate analysis	
	Odds ratio (95% CI)	P-value	Odds ratio (95% CI)	P-value
Age				
0–28 days	5.38 (2.52–11.49)	<0.001	2.47 (0.99–6.14)	0.052
29 days to <1 yr	2.09 (1.13–3.89)	0.019	1.46 (0.70–3.02)	0.31
1 to <4 yrs	0.60 (0.32–1.12)	0.118	0.84 (0.42–1.68)	0.62
4 to <13 yrs	0.61 (0.35–1.08)	0.091	0.78 (0.42–1.45)	0.430
13–16 yrs	Reference		Reference	
ASA physical status				
1	Reference		Reference	
2	1.82 (1.19–2.78)	0.005	1.69 (1.05–2.71)	0.031
3	9.21 (6.31–13.45)	<0.001	6.23 (3.80–10.22)	<0.001
4–5	17.82 (9.26–34.70)	<0.001	7.12 (3.07–16.52)	<0.001
Urgency of surgery				
Routine	Reference		Reference	
Urgent	3.27 (2.28–4.70)	<0.001	2.08 (1.36–3.20)	0.001
Emergency	4.32 (2.98–6.27)	<0.001	2.28 (1.42–3.65)	<0.001
Severity of surgery				
Minor	Reference		Reference	
Intermediate	2.58 (1.82–3.67)	<0.001	1.71 (1.16–2.53)	0.007
Major	9.06 (5.82–14.08)	<0.001	2.55 (1.41–4.61)	0.002
Primary indication for surgery				
Non-communicable disease	Reference		Reference	
Infective	2.25 (1.47–3.43)	<0.001	1.99 (1.20–3.31)	0.008
Trauma	1.18 (0.75–1.87)	0.47	1.27 (0.74–2.19)	0.38
Congenital	1.59 (1.06–2.39)	0.025	0.72 (0.42–1.24)	0.24
Type of surgery				
Cardiac	6.09 (3.27–11.35)	<0.001	1.79 (0.56–5.66)	0.32
Neurosurgery	4.16 (2.54–6.79)	<0.001	1.50 (0.83–2.69)	0.18
Co-morbid disorder				
Preoperative cardiac disease	4.14 (2.56–6.70)	<0.001	1.04 (0.43–2.49)	0.93
Pulmonary hypertension	5.93 (1.92–18.32)	0.001	1.67 (0.43–6.42)	0.46
HIV/AIDS	1.01 (0.40–2.57)	0.98	0.52 (0.18–1.46)	0.21
Congenital syndrome	2.42 (1.52–3.85)	<0.001	1.22 (0.66–2.24)	0.53
Current/recent LRTI	3.01 (1.59–5.71)	0.001	0.90 (0.42–1.95)	0.80

children is between 2000 and 3000 operations/100 000 population per year.[36] This study further indicates that South Africa is currently achieving between one-third and one-fifth 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, type, and frequency of perioperative complications between South Africa and the literature from HICs suggest 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.[38] 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.

The risk factors, frequency, and 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.

Authors' contributions

Study design/planning: AT, LC, JT, BB.
Study conduct: all authors, South African Paediatric Surgical Outcomes Study investigators (see Supplementary Data).
Data analysis: AT, LC, RR, BB.
Writing paper: AT, LC, RR, BB.
Critical revision of paper: all authors.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2018.11.015.

Declaration of interest

The authors declare that they have no conflicts of interest.

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