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ORIGINAL RESEARCH

The incidence of perioperative critical events in paediatric patients at a Johannesburg academic hospital

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Background: Critical events in anaesthesia are defined as events requiring immediate intervention to prevent major disability or death. South African research on risk factors predisposing our vulnerable paediatric patients to critical events is limited.

Methods: A prospective, observational, cross-sectional study was conducted at Rahima Moosa Mother and Child Hospital (RMMCH) in Johannesburg. The study included 206 paediatric patients up to the age of 12 years undergoing anaesthesia for elective and emergency procedures. The study aimed to describe the incidence and management of perioperative critical events, determine risk factors, and describe the immediate postoperative outcomes.

Results: The median age of patients with a critical event was four years with a weight of 13 kg. The cumulative incidence of critical events was 34% (95% confidence interval [CI] 27 to 40), with hypoglycaemia having the highest incidence of 21% (95% CI 16 to 27). The incidence of respiratory critical events was 11% (95% CI 7 to 16), emergence delirium 2.4% (95% CI 0.90 to 5.9), cardiovascular events 1.9% (95% CI 0.62 to 5.2), and temperature abnormalities 0.5% (95% CI 0.03 to 3.1). Risk factors associated with respiratory events included younger age and using endotracheal tubes (ETT). The management of the events varied according to physician preference. Of the patients included, 87% were discharged to the ward.

Conclusion: The cumulative incidence of critical events was more than double the number previously reported in a large South African multicentre study. Hypoglycaemia continues to be the biggest contributor. To improve patient outcomes, attention should be given to improving in-service training and continuous medical education (CME).

Keywords: paediatric, critical events, adverse events, anaesthesia, perioperative outcomes

Introduction

Critical events in anaesthesia are defined as events requiring immediate intervention to prevent major disability or death.[1] Critical events in anaesthesia are not uncommon, and care should be taken to avoid critical events in the vulnerable paediatric population to avoid morbidity and mortality.

Patient, surgical, and anaesthetic risk factors predisposing patients to critical events have been identified in numerous studies.[1-3] Patient-related risk factors include higher American Society of Anesthesiologists (ASA) scores, patients less than six years of age, with the highest risk in the neonatal population, and patients with sensitised airways with inflammation.[4] Physical conditions such as prematurity, a history of snoring, having a fever, taking treatment, and having a mental or physical disability were also identified as risk factors.

Anaesthetic-related risk factors include less experienced anaesthetists using inhalational induction, airway manipulation such as endotracheal intubation, and the use of supraglottic airways.[1,2] Some studies have found that intubation without muscle relaxants is a risk factor.[3] Emergency cases have a higher incidence of critical events.[1] An upper respiratory tract infection less than two weeks before the procedure, a history of night-time coughing and wheezes, a family history of atopy, asthma and eczema, and secondary smoking can increase respiratory adverse events.[2]

Studies to determine the incidence of critical events have been conducted globally.[1,5-8] The results of these studies may differ as the definitions of perioperative critical and adverse events are not standardised. There is a paucity of data concerning critical events in South Africa. A study conducted by Cronjé et al. in 2017 examined severe anaesthetic-related critical incidents (SARCI) and perioperative cardiac arrests in paediatrics.[8] This study found that the incidence of SARCI was 15.9% and that critical incidents were three times higher than in high-income countries.[8]

Establishing the status quo regarding critical events in a paediatric setting is necessary to provide insight into the current service provision. The objective of this study was to determine the incidence of perioperative critical events in paediatric patients undergoing anaesthesia for surgical procedures, to determine the patient, surgical, and anaesthetic factors associated with severe critical events, and to describe the management and immediate postoperative outcomes of patients where critical events under anaesthesia occurred.

Methods

This was a prospective, observational, cross-sectional study conducted at Rahima Moosa Mother and Child Hospital (RMMCH), a regional hospital in Johannesburg, South Africa. It

was conducted on 206 paediatric patients up to the age of 12 years old, over four months (October 2022 to February 2023).

A questionnaire based on the study conducted by Habre et al. was adapted with permission and underwent face and content validation by 10 specialist anaesthetists at the University of the Witwatersrand.[1] The study was approved by the senior clinical executive of RMMCH and registered on the National Research Database (NHRD) GP_202208_068. Ethical clearance was obtained from the Human Research Ethics Committee (Medical) at the University of the Witwatersrand (M220813). Parental or guardian consent for participation in the study was obtained for all children and additional assent obtained from children older than seven years.

An adequate sample size of 205 was calculated using the formulas reported by Sharma et al., using the cumulative incidence data from Cronjé et al., assuming an incidence of 15.9%, and allowing for a 5% margin of error. Non-probability consecutive convenience sampling was used.[8,9] A total of 217 patients were recruited, and 11 patients were excluded due to incomplete questionnaires or the study's age restriction. A total of 206 cases were assessed.

All children (age 0-12 years old) who received an elective or emergency anaesthetic for a procedure in theatre were eligible to be part of the study. The study included ASA I-IV patients undergoing sedation, regional and general anaesthesia for paediatric gastroenterology, dental, ear nose and throat (ENT), gynaecological, urological, plastic surgical and orthopaedic procedures. Children that were already intubated prior to arrival to theatre and remote site anaesthesia were excluded from this study.

Critical events included respiratory, cardiac, metabolic, neurological events, as well as drug errors. Respiratory critical events included difficult bag valve mask ventilation (BMV) and was defined as the inability of an unassisted anaesthesiologist to maintain oxygen saturation of > 92% or to prevent or reverse signs of inadequate ventilation during positive-pressure mask ventilation.[10] Multiple intubations were defined as two or more attempts with a laryngoscope. Other respiratory events included laryngospasm, bronchospasm, aspiration, severe hypoxia (a peripheral saturation of < 80% on pulse oximetry, or clinical impression of hypoxia in the absence of a pulse oximeter) and postoperative stridor.[11]

Cardiac events included bradycardia (defined as a heart rate below the lowest normal value for age, newborns to 3 month old < 80 bpm, 3 month to 2 years < 75 bpm, 2-10 years < 60 bpm, older than 10 years < 50 bpm), arrhythmias, hypotension (a blood pressure reading below the lowest value for the patient's age from the paediatric advanced life support guidelines by American Heart Association) and cardiac arrest.[11,12]

Metabolic events included hypoglycaemia and was defined as a haemoglucose test (HGT) level of < 3.6 mmol/L in infants and children.[11] Haemoglucose levels were tested at induction of anaesthesia with a VivaChek Ino glucometer that has a test range of 0.6–33.3 mmol/L. In this study hypothermia was defined as a temperature of < 36 °C, hyperthermia as a temperature > 38 °C.

Patient factors included the age, weight and ASA classifications. Surgical factors included the urgency of surgery (elective or emergencies), the surgical discipline and the type of procedure. Anaesthetic factors included the level of training of anaesthetists, type of anaesthesia (general, regional or sedation), the airway device used, whether a muscle relaxant was used and deep or awake extubation. Immediate postoperative outcomes of the patients were also assessed whether discharged home, to the ward or to a high care or intensive unit.

Data analysis

After recruitment, the data from the questionnaires were entered anonymously into an electronic spreadsheet and analysed using R v4.2.2. Continuous data are reported as medians (interquartile range [IQR]). Categorical data are reported as counts and percentages.

The cumulative incidence of critical events was calculated as the number of patients with at least one critical event during surgery divided by the total number of patients in the cohort. A bootstrap CI (99 999 resamples) was calculated for the cumulative incidence. For univariate comparisons, Wilcoxon rank-sum tests were used to compare the critical event and no critical event groups for continuous variables, while Fisher's exact or chi-square tests (the test was chosen based on expected frequencies) were used to compare the critical event and no critical event groups for categorical variables. Multivariable logistic regression was used to model risk factors for having a critical event; independent variables included age (years), weight (kg), ASA status, and surgical discipline. Multivariable logistic regression was also used to assess associations between the immediate postoperative outcome and surgical discipline, age, weight, and ASA status. Descriptive statistics were used to document the management responses to critical events, and p-values < 0.05 were considered statistically significant.

To assess whether the concentration of dextrose solution administered was dependent on haemoglucose concentration, haemoglucose was categorised into three groups: very low haemoglucose (< 2.6 mmol/l), low haemoglucose (2.6–3.5 mmol/l), and haemoglucose > 3.5 mmol/l, and then quantile regression (conditional median), followed by pairwise comparisons, was performed.

Logistic regression was performed to assess whether the presence of hypoglycaemia (yes/no) was associated with patient characteristics or the type of intervention (only procedures performed ≥ 10 times were used in the analysis: adenotonsillectomy, dental extraction, other dental procedures, gastroscopy, and tongue tie release).

Results

A total of 217 patients were recruited, three patients were excluded due to the age restriction and eight removed due to incomplete questionnaires or duplicate records. A total of 206 cases were analysed (Figure 1).

The patient, anaesthetic, and surgical characteristics of participants are summarised in Table I. A total of 206 surgeries were assessed. The median (IQR) age for the study was four years (2.2–5.8). All but one patient received a general anaesthetic. Regional techniques were combined with general anaesthesia in 13 (6.3%) patients. Caudal blocks were done in seven patients, supraclavicular in three, followed by one fascia iliaca block, penile block, and wrist block each.

The airway management included 125 (61%) endotracheal tubes (ETT) intubations, 49 (24%) with supraglottic device insertions, and 32 (16%) patients who received a general anaesthetic with a facemask technique. A muscle relaxant was used for one patient for intubation, and 122 (70%) patients were extubated while awake. From the theatre complex, 25 (12%) patients went directly home, and 181 (88%) went to the ward to be discharged from the hospital at a later stage. Discharge dates and postoperative complications in the ward were not studied.

Critical events

Of the 206 surgeries, 70 (34%) were associated with the occurrence of at least one critical event. Details about the critical events are presented in Table II.

Table I: Participant demographic characteristics

Characteristic	Overall *n* (%)	No critical event *n* (%)	Critical event *n* (%)	*p*-value
Patient factors				
Weight (kg)				0.11
< 10	34 (17)	24 (18)	10 (14)	
10–20	115 (56)	69 (51)	46 (66)	
≥ 20	57 (28)	43 (32)	14 (20)	
ASA classification				0.6
I	156 (76)	104 (76)	52 (74)	
II	37 (18)	25 (18)	12 (17)	
III	13 (6.3)	7 (5.1)	6 (8.6)	
IV and V	0 (0)	0 (0)	0 (0)	
Anaesthetic and surgical factors				
Anaesthetist level of experience				0.3
Consultant	182 (88)	119 (88)	63 (90)	
Senior registrar (years 3 and 4)	13 (6.3)	11 (8.1)	2 (2.9)	
Junior registrar (years 1 and 2)	10 (4.9)	5 (3.7)	5 (7.1)	
Medical officer	1 (0.5)	1 (0.7)	0 (0)	
Airway management				0.14
ETT	125 (61)	76 (56)	49 (70)	
Facemask	32 (16)	24 (18)	8 (11)	
Supraglottic device	49 (24)	36 (26)	13 (19)	
Urgency of surgery				0.013
Elective	177 (86)	111 (82)	66 (94)	
Emergency	29 (14)	25 (18)	4 (5.7)	
Time of surgery				0.7
In hours (07:00–16:00)	200 (97)	131 (96)	69 (99)	
After hours (16:00–07:00)	6 (2.9)	5 (3.6)	1 (1.4)	
Surgical discipline				0.3
Dental	40 (19)	24 (18)	16 (23)	
Ear, nose, and throat	63 (31)	41 (30)	22 (31)	
Gastroenterology	21 (10)	11 (8.1)	10 (14)	
Gynaecology	1 (0.5)	1 (0.7)	0 (0)	
Orthopaedic	43 (21)	33 (24)	10 (14)	
Plastic surgery	25 (12)	19 (14)	6 (8.6)	
Urology	13 (6.3)	7 (5.1)	6 (8.6)	

ASA – American Society of Anesthesiologists, ETT – endotracheal tube

Management of critical events

The treatment strategies of critical events are summarised in Table III.

The management of the respiratory events is summarised in Table IV.

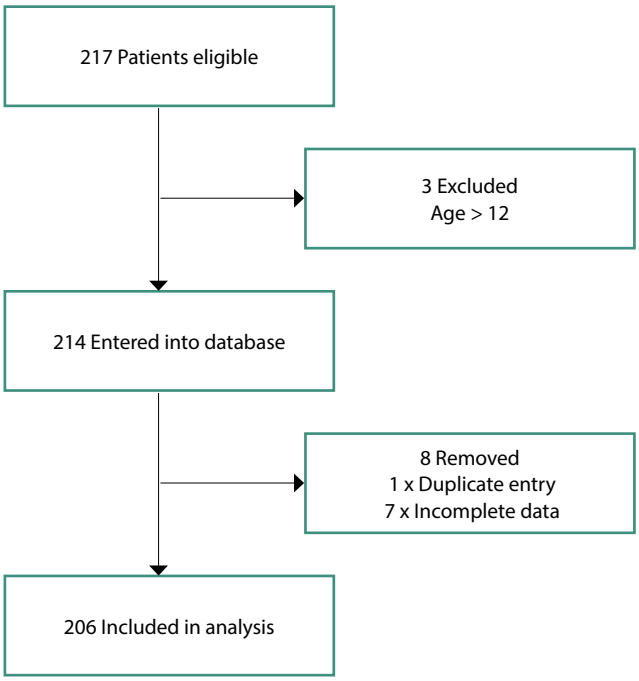


Figure 1: Flow chart of sample realisation

Table II: Cumulative incidence of critical events

Characteristic	*n* (%)	Cumulative incidence* % (95% CI)
Number of critical events		
1	61 (30)	30 (23 to 36)
2	7 (3.4)	3 (1 to 6)
3	2 (1)	1 (0.5 to 1.9)
Hypoglycaemia (HGT < 3.6 mmol/L)	43 (61)	21 (16 to 27)
Respiratory		
Laryngospasm	15 (21)	7.3 (4.3 to 12)
≥ 2 attempts at intubation	5 (7.1)	2.4 (0.90 to 5.9)
Bronchospasm	4 (5.7)	1.9 (0.62 to 5.2)
Difficult BMV	2 (2.9)	1 (0.17 to 3.8)
Stridor	1 (1.4)	0.5 (0.03 to 3.1)
Aspiration	0 (0)	0 (0.0 to 2.3)
Hypoxia	0 (0)	0 (0.0 to 2.3)
Cardiovascular		
Bradycardia	3 (4.3)	1.5 (0.38 to 4.5)
Hypotension	1 (1.4)	0.5 (0.03 to 3.1)
Arrhythmia	0 (0)	0 (0.0 to 2.3)
Cardiac arrest	0 (0)	0 (0.0 to 2.3)
Drug error	0 (0)	0 (0.0 to 2.3)
Temperature abnormality	1 (1.4)	0.5 (0.03 to 3.1)
Neurological event	0 (0)	0 (0.0 to 2.3)
Emergence delirium	5 (2.4)	2.4 (0.9 to 5.9)
Other (Unable to obtain IV access)	1 (1.4)	0.5 (0.03 to 3.1)

CI – confidence interval, BMV– bag mask ventilation, HGT – haemoglucose test, IV – intravenous
* Number of patients with events/number of patients

Table III: Management of critical events

Critical event management strategy			
Hypoglycaemia†	***n* (%)**	***n* (%)**	***n* (%)**
Dextrose solution	Very low haemoglucose (< 2.6 mmol/L) *n* = 12	Low haemoglucose (2.6–3.5 mmol/L) *n* = 31	Haemoglucose (>3 .5 mmol/L) *n* = 158
Nil	0 (0)	1 (3.2)	116 (73.4)
1% Dextrose	0 (0)	11 (35.5)	24 (15.2)
2% Dextrose	11 (92)	15 (48.4)	16 (10.1)
3% Dextrose	1 (8)	0 (0)	0 (0)
4% Dextrose	0 (0)	1 (3.2)	0 (0)
10% Dextrose	0 (0)	3 (9.7)	2 (1.3)
Emergence Delirium ‡			*n* = 5
Parental presence			2 (40)
Fentanyl and propofol			2 (40)
Propofol only			1 (20)
Reassurance			1 (20)
Cardiovascular Critical Events			*n* = 4
Bradycardia treated with atropine			3 (75)
Hypotension treated with vasopressors			1 (25)
Hyperthermia (> 38 °C)			*n* = 1
Bair hugger switched off			1 (100)
Hypothermia (< 36 °C)			*n* = 0
Treatment			0 (0)

† Count adds to less than 206 because of a malfunction with the HGT machine in 5 patients
‡ Count adds to greater than 5 because one patient received two interventions.

Table IV: Treatment of respiratory events

	Difficult BMV *n* = 2	Difficult intubation *n* = 5	Laryngospasm *n* = 15	Bronchospasm *n* = 4	Stridor *n* = 1
Treatment *n* (%)					
Positive pressure	..	2 (40)	11 (73)	1 (25)	..
OPA	1 (50)	3 (60)	8 (53)	..	1 (100)
Anaesthesia deepening	1 (50)	5 (100)	8 (53)	4 (100)	..
Propofol	1 (50)	5 (100)	12 (80)	2 (50)	..
Ketamine	..	..	2 (13)	2 (50)	..
Magnesium sulphate	..	..	1 (6.7)	1 (25)	..
Intubation	1 (50)	2 (40)	5 (33)	..	..
Bronchodilators	..	..	1 (6.7)	1 (25)	..
Adrenaline nebulisation	..	..	..	..	1 (100)
Suctioning	1 (50)	1 (20)	4 (27)	1 (25)	..
Steroids	1 (50)	2 (40)	4 (27)	2 (50)	..
Change laryngoscope blade/handle	..	1 (20)	1 (6.7)	..	..
Change ETT	..	2 (40)	..	..	..
Bag-mask ventilation	..	2 (40)	..	..	..
Consultant to take over airway	..	1 (20)	..	..	..
Escalate level of expertise	..	1 (20)	..	..	..

BMV – bag mask ventilation, ETT – endotracheal tube, OPA – oropharyngeal airway

Table V: Logistic regression summary of all the critical events and respiratory events

Characteristic	OR	95% CI	*p*-value
Logistic regression summary of all the critical events			
ASA classification			
I	—	—	
II	0.91	0.37 to 2.14	0.8
III	1.02	0.20 to 4.75	> 0.9
Age (years)	0.95	0.76 to 1.19	0.7
Body weight (kg)	0.96	0.88 to 1.02	0.2
Surgical discipline			
Ear, nose, and throat	—	—	
Dental	1.09	0.47 to 2.50	0.8
Gastroenterology	1.30	0.33 to 5.17	0.7
Orthopaedic	0.43	0.16 to 1.07	0.078
Plastic surgery	0.40	0.12 to 1.18	0.11
Urology	1.54	0.43 to 5.48	0.5
Log-likelihood = -124.362 (df = 10) *n* = 205			
Logistic regression summary for the respiratory events			
Age (years)	0.63	0.40 to 1.00	0.049
Weight (kg)	0.99	0.83 to 1.11	0.9
ASA classification			
I	—	—	
II	0.23	0.01 to 1.29	0.2
III	2.52	0.57 to 10.6	0.2
Airway management method			
ETT	—	—	
Facemask	0.07	0.00 to 0.42	0.016
Supraglottic	0.18	0.03 to 0.77	0.041
Log-likelihood = -54.468 (df = 7) *n* = 206			

ASA – American Society of Anesthesiologists, CI – confidence interval, ETT – endotracheal tube, OR – odds ratio

The patient, surgical, and anaesthetic factors associated with critical events

Patient factors

When analysing all the critical events, lower weight was significantly associated with critical events ($p < 0.05$). However, when a multivariable logistic regression (including ASA status, surgical discipline, weight, and age) was performed, this relationship between critical events and weight was no longer statistically significant (odds ratio [OR] = 0.96; 95% CI 0.88 to 1.02; $p = 0.2$).

Surgical factors

There were no statistically significant differences between the critical event and no critical event groups for the timing of surgery ($p = 0.7$) or the distribution of surgeries across the various disciplines ($p = 0.3$).

Anaesthetic factors

The results relating to factors associated with critical and respiratory events are presented in Table V. Although no anaesthetic factors were found to be significantly associated with critical event occurrence, a multivariable logistic regression performed to assess respiratory events alone showed a significant association between age and the incidence of a critical respiratory event ($p < 0.05$), such that increasing age was associated with lower odds of having an event compared to younger ages.

In addition, there was a significant association between the airway management method and the occurrence of respiratory critical events, such that there were lower odds of having an event when using a facemask ($p < 0.05$) or supraglottic device ($p < 0.05$) compared to using an ETT. However, the CIs for the OR were very wide, indicating a lack of precision in the estimate (this may be attributed to the low frequency of use of the two methods), making it difficult to interpret the importance of this finding.

The immediate postoperative outcomes

All patients were either discharged home directly from the theatre or to the ward. None of the patients were admitted to high-care facilities or an intensive care unit. No mortalities were reported during the study period. There was no statistically significant difference between the critical event and no critical event groups for being discharged home versus discharged to the ward ($p = 0.8$).

Discussion

A prospective observational cross-sectional study was conducted at RMMCH in Johannesburg. The cumulative incidence of critical events was 34% (95% CI, 27–4 0). The incidence of hypoglycaemia was the highest with an incidence of 21% (95% CI,16–27). The incidence of respiratory critical events was 11% (95% CI, 7–16), emergence delirium 2.4% (95% CI, 0.90–5.9), cardiovascular events 1.9% (95% CI, 0.62–5.2) and temperature abnormalities was 0.5% (95% CI, 0.03–3.1).

In the hypoglycaemic group, the majority (72%) had a low haemoglucose level (2.6–3.5 mmol/L) and 28% a very low haemoglucose level of < 2.6 mmol.

Management of the events varied according to physician preferences. Patients with haemoglucose levels > 3.5 mmol/l (median [SE] dextrose dose = 0% [0.00]) received significantly lower doses of dextrose compared to the patients in the low (2.6–3.5 mmol/l; median [SE] dextrose dose = 2% [0.33]; $p < 0.001$) and very low (< 2.6 mmol/l; median [SE] dextrose dose = 2% [0.02]; $p < 0.001$) haemoglucose concentration categories. Of the patients included, 87% were discharged to the ward.

The incidence of intraoperative hypoglycaemia in children has been reported globally to range from 1% to 26%.[8,13-15] The incidence of critical events in this study was more than double the number reported in a large South African multicentre study published by Cronjé et al. in 2021, where the overall incidence of critical events was reported to be 16%.[8] This difference is mainly attributed to the high incidence of hypoglycaemia in this study (21% compared to 1%).

The questionnaire in this study specifically evaluated the HGT in every case and required details concerning the treatment implemented. At RMMCH, it is routine for glucose levels to be tested for every paediatric patient undergoing a procedure in theatre. In the study by Cronjé et al., the operating room case record form did not specify HGT levels but instead only recorded if the patient had hypoglycaemia.[8] Therefore, it is not known if the HGT levels were routinely performed for all cases included in the study.[8] It is a possibility that some of the hypoglycaemic events could have been missed in the study by Cronjé et al. if the HGT levels, especially those of children undergoing short procedures, were not routinely performed.[8]

Prevention and adequate management of hypoglycaemia is important as it can have numerous physiological consequences. This include and is not limited to ketosis, hypotension, discomfort due to thirst and hunger, seizures with subsequent brain damage, developmental delay with learning challenges as well as physical disabilities and even death.[16,17-19]

The reason for the high incidence of hypoglycaemia at RMMCH is likely multifactorial. RMMCH has a large patient burden.[20] RMMCH is an academic hospital where the procedural times are often longer or unpredictable due to teaching. The order of theatre lists is constantly changing. This may be attributed to problems with equipment failure or shortages, patients not arriving, and invalid consent according to the departmental statistics.[21,22] Prolonged and unpredictable transport to the hospital, administrative delays, long waiting times to obtain files, and delays relating to children having different surnames to parents and requirements for police affidavits to confirm guardianship may be contributing factors. High patient-to-nursing staff ratios may result in difficulties in implementing guidelines.[20,21] Poor

communication and a lack of education among nursing staff and surgeons may result in incorrect preoperative fasting orders.

Understanding the reasons for poor guideline uptake is complex. Saluja et al. published a review article to establish the challenges influencing guideline uptake in low- to middle-income countries.[23] The findings were summarised in four broad categories. This included inadequate infrastructure, limited funding, the lack of experience and training of healthcare workers, and the lack of national regulations or legislation. Fasting guidelines can be implemented without additional infrastructure or funding. A large tertiary paediatric teaching hospital in the United Kingdom reduced patient fasting times using quality improvement programmes and education only.[24]

The latest guidelines for preoperative fasting in children published in 2022 by the European Society of Anaesthesiology and Intensive Care recommend the intake of clear fluid in healthy individuals up to one hour before elective procedures. Breastmilk is recommended for up to three hours, and formula milk and a light meal are allowed up to four hours before anaesthesia.[16] RMMCH does not currently have a protocol where clear fluids are administered to patients two hours prior to surgery, this results in prolonged fasting times.

Poor or non-adherence to protocols may adversely affect patient outcomes as seen at other hospitals.[25] CME is a way to improve clinicians' performance by changing their behaviour in the clinical setting.[26,27] It is also a way of keeping up with the latest evidence-based knowledge, anaesthetic skills, emerging technology, and safety practices to decrease the risk of adverse events, deliver quality anaesthetic care to patients, and minimise critical events.

The results of this study emphasises the importance of the development and implementation of departmental-specific guidelines, CME initiatives, and evaluating such interventions is recommended.

Study limitation

This study didn't record fasting times to determine an association between fasting times and hypoglycaemia. This study was contextual; consequently, the results cannot be extrapolated to other healthcare settings regionally or globally. There may also have been an overestimation of critical events due to the subjectivity of the interpretation of the critical event definitions.

Future Research

These results can be used as a baseline for future studies that could possibly examine interventions to improve patient care and the quality of anaesthetic practices.

Conclusion

The cumulative incidence of critical events was more than double the number previously reported in a large South African multicentre study. Hypoglycaemia continues to be the biggest contributor. To improve patient outcomes, attention should be given to improving in-service training and CME.

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Conflict of interest

The authors declare no conflict of interest.

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Ethical approval

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee (M220813). All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Consent for participation in the study was obtained for children under the age of seven years, and assent was obtained from children older than seven years.

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