Original Article

Prospective analysis of intraoperative critical incidents relevant to anaesthesia in a tertiary care teaching hospital in India

Saloni K. Shah, Aarti D. Kulkarni

Department of Anaesthesiology, Seth G. S. Medical College and KEM Hospital, Mumbai, Maharashtra, India

Abstract

Background and Aims: Critical incidents associated with anesthesia can affect the patient's outcome, may cause transient damage, and contribute to mortality. We aimed at recording anesthesia-related critical incidents in patients undergoing general surgical, ear, nose, and throat (ENT) and orthopedic surgical procedures in our institution. The critical incidents data were analyzed regarding the cause to establish protocols to prevent recurrences.

Material and Methods: We conducted a prospective analysis of voluntarily reported perioperative critical incidents occurring in patients subjected to anesthesia over 1 year. Critical incidents were noted in terms of time (while inducing/intraoperative/while extubating), location (operating theater/recovery room) of the incident, anesthesia-related or surgery-related complications. Data collected were expressed as numbers and proportions to calculate incidence.

Results: Anesthesia was administered to 5,645 patients of which 131 (2.32%) patients had critical incidents. Of these 131, 46 (35.11%) patients had more than one critical incident. A total of 216 (3.82%) critical incidents were noted. A majority of the patients were in the age range of 51–60 years. The maximum incidents occurred during the intraoperative period (35.11%) and in the operating theater (86.25%). Of the 216 incidents, 154 (71.30%) were anesthesia-related, 18 (8.33%) were surgery-related, 1 (0.46%) was patient-related and 43 (19.91%) were recovery-related. Of the 216 incidents, cardiovascular-related incidents accounted for the maximum incidents (18.05%, $n = 39$). Most of the events were preventable.

Conclusion: The critical incident reporting system should be encouraged and protocols established to reduce the frequency and severity of these occurrences.

Keywords: Critical incidents reporting, human error, morbidity and mortality, patient safety

Introduction

A critical event was defined as "An event under anesthesia care which had the potential to lead to substantial negative outcome (ranging from increased length of hospital stay to death or permanent disability or cancelled operative procedure) if left to progress".[1] Flanagan, in the 1940s, had first used critical incident reporting as a technique for the safety and work performance of military pilots. Cooper JB and colleagues applied this technique to anesthesia in the year 1978.[1]

Critical incident reporting has been widely accepted as an effective way to improve patient safety during anesthesia. The Australian incident monitoring system (AIMS) was the first to be introduced in the year 1987 and has been adopted in various countries as part of quality control. The United Kingdom introduced the National Reporting and Learning System (NRLS) in 2006 to mitigate liability and enhance patient safety for life-saving problems.[2] The German Society for Anaesthesiology and Intensive Care and the Association of German Anaesthetists in 2010 formed an online nationwide critical incident reporting system (CIRS).

Address for correspondence: Dr. Aarti D. Kulkarni, Andheri, Mumbai, Maharashtra, India.
E-mail: aartidk752000@yahoo.com

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Many studies on critical incident reporting are on record analysis, but a lot of underreporting occurs. India presently does not have an established reporting system for critical incidents.

Critical incidents due to patient factors, surgical factors and anesthesia factors contribute significantly to mortality and morbidity in anesthesia. Anesthesia for patients undergoing orthopedic, ear, nose, and throat (ENT) and general surgeries is challenging. Challenges include the various positions for surgery, prolonged operative time, geriatric patients who usually present for orthopedic procedures, bleeding, and sharing of the airway in ENT procedures. Our primary objective was to record anesthesia-related critical incidents in patients undergoing these surgical procedures as it had not been done previously in our institution and the secondary objective was to analyze these critical incidents (with regard to probable cause) and establish protocols to prevent recurrences, and thus, improve the quality of anesthesia.

Material and Methods

The study was conducted in a tertiary care teaching hospital patient population for 1 year and included patients above 18 years of age undergoing surgery under anesthesia in general surgery, ENT, and orthopedic surgery. It was a prospective observational study approved by the institutional ethics committee (IEC-I ref no. EC/23/2017, dated August 16, 2017). Since it was an observational study without any intervention, consent from the patient was not required. An appropriate case record form was developed after considering all the critical incidents relevant to anesthesia and was distributed to the anesthesiologists in general surgery, ENT, and orthopedic surgery. The anesthetic team that consisted of a senior anesthetist (with an experience of more than 5 years) and a junior resident (1st year, 2nd year, or 3rd year) involved in the case, reported and analyzed the critical incidents. The anesthesiologists were regularly motivated and reminded to report critical incidents on an anonymous and voluntary basis. In these forms, the detailed contextual information of the incident was also required to enhance the subsequent review of the incident. The collected data was confidential. Documentation was divided into descriptive and specific areas.

Descriptive area

It included general instructions to a reporter like

1) Details of patients: Name, age, sex, weight, diagnosis, name of the procedure, elective/emergency, abnormal preoperative investigations, medical history, surgical history, medications, addictions, American society of anesthesiologists (ASA) status of the patient.
2) Anesthetic technique
   -General anesthesia (GA) with an endotracheal tube (ETT) or laryngeal mask airway (LMA),
   -Regional anesthesia (RA): spinal, epidural, peripheral nerve block
   -Combined GA and RA,
   -Local anesthesia (LA) with intravenous sedation (IVS)
   -Monitored anesthesia care (MAC)
3) Place of incident: Waiting room, operating theater, during patient's transfer, recovery room (within 1 hour).
4) Time of incident: Before taking the patient to the theater, pre-induction, during induction, during patient's positioning, intra-operatively, during extubation, and immediately postoperatively.

Specific areas

A) Anesthesia related
   1) Airway: trauma to the airway, dental injuries, difficult intubation, esophageal intubation, endobronchial intubation, ETT displacement, obstruction, kinking or disconnection, accidental extubation, reintubation or inadvertently retained throat packs
   2) Respiration: bronchospasm, laryngospasm, aspiration of gastric contents, desaturation, and pneumothorax
   3) Cardiovascular: arrhythmias, pulmonary edema, cardiac arrest, myocardial ischemia, myocardial infarction, hypertension, pulmonary embolism, and hypotension
   4) Neurological: stroke, seizures, and neurological deficits
   5) Metabolic: electrolyte imbalance, acidosis, alkalosis, hypoglycemia, and hyperglycemia
   6) Medication: wrong route of administration, wrong drug administration, overdose, allergic reaction, use of an expired drug, and wrong labeling
   7) Equipment: laryngoscope malfunction, gas supply problem, dislodgement of LMA, power outage, non-functional suction machine, and non-availability of suction apparatus
   8) Position: vision loss, nerve palsy, nerve compression injuries, facial swelling, and tongue swelling
   9) Physical hazards: breathing system disconnection, tangled intravenous (IV) line/arterial lines, and electric shock
   10) Miscellaneous: mismatched blood transfusion, non-availability of blood/blood products, hypothermia, lost venous access, and needle-stick injury
   11) Regional: inadequate sensory and/or motor blockade after RA requiring additional analgesic and GA, high spinal, migration of epidural catheter, local anesthesia systemic toxicity (LAST), and dural puncture

B) Surgery-related: hemorrhage—Class one (0–750 mL), Class two (750–1500 mL), Class three (1500–2000 mL), Class four (2000 or more), wrong operation site
C) Patient-related: inadequate fasting (adequate starvation of 6–8 hours for elective procedure),[3] unreported allergies
D) Recovery-related: delayed recovery, postponement of surgery, postoperative ventilator requirement, ICU requirement.

Statistical analysis

The principal and co-investigators did the compilation and analysis of the data. A database was created on Microsoft Office Excel spreadsheet. The number of incidents and percentage incidence of critical events were calculated.

The result was graded based on the outcome and preventability of critical incidents as per the definition of good practice by the Royal College of Anaesthetists (RCOA) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI).[4]

Outcome

1. No eventuality—critical incident reported, but patient not affected by it
2. Temporary abnormality not noticed by a patient—critical incident reported and the patient is affected but not aware of it
3. Temporary abnormality with full recovery—a patient is affected by the critical incident and the problem is rectified with full recovery of the patient
4. Possibly permanent, but not incapacitating—a patient may suffer permanent damage, but there is no morbidity
5. Possibly permanent, but incapacitating—a patient may suffer permanent damage with morbidity
6. Death.

Preventability

1) Likely to be preventable with existing resources
2) Likely to be preventable with extra resources
3) Cannot be prevented with any resources.

Results

In our study, 131 (2.32%) patients had critical incidents of the total 5,645 patients who were administered anesthesia during the study period. Out of 131 patients, 46 (35.11%) patients had more than one critical incident. A total of 216 (3.82%) critical incidents occurred in total [Table 1]. The mean age of the study subjects was 45.81 ± 15.69 years [Figure 1], with 77 (58.8%) females and 54 (41.2%) males. Majority of the incidents occurred in the operating theater (86.25%) and 38 (29%) incidents occurred while inducing the patient [Table 2]. Critical incidents were slightly more in the emergency procedures (52.68%, n = 69) than the elective procedures (47.32%, n = 62). Majority of critical incidents occurred in ASA II patients (49.6%) followed by ASA I (43.5%), ASA III (5.4%), and ASA IV (1.5%). Maximum critical incidents were seen in patients undergoing general surgical (n = 59, 45.03%) procedure followed by orthopedic (n = 57, 43.51%), and ENT (n = 15, 11.45%) procedures. Out of 131 patients, 57 (43.5%) were given GA and 51 (38.93%) were given RA. Combined GA and RA were given to 19 (14.5%) patients and LA with IVS was given to 4 (3.06%) patients.

Airway-related critical incidents accounted for 24 (11.11%) out of 216 incidents [Figure 2]. Among the 39 (18.05%) cardiovascular critical incidents, hypotension (11.11%, n = 24) was the most common followed by cardiac arrest (3.24%, n = 7), myocardial ischemia (1.39%, n = 3), and pulmonary embolism (1.39%, n = 3) [Figure 3]. Hypotension was associated with blood loss in 11 (47.2%) cases, high spinal in 3 (13.04%)

Table 1: Total critical incidents (n=216)

	Number	Percentage (%)
a) Anesthesia related		
Airway	24	11.11
Cardiovascular	39	18.05
Respiratory	26	12.03
Neurological	3	1.39
Physical hazards	10	4.62
Equipment	3	1.39
Medication	9	4.16
Miscellaneous	11	5.1
Regional	17	7.90
Position	5	2.31
Metabolic	7	3.24
b) Recovery related	43	19.91
c) Patient related	1	0.46
d) Surgery related	18	8.33
Total	216	100

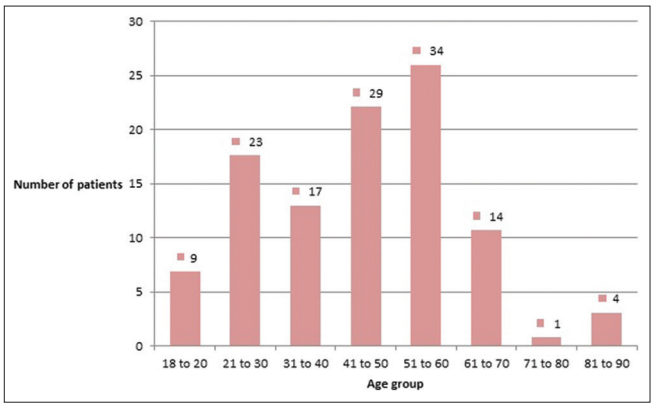

Figure 1: Age distribution

cases, and myocardial ischemia in 2 (8.71%) cases, and pulmonary embolism and cardiac arrest in 1 (4.35%) case each. The cause of hypotension was not specified in 6 (21.73%) cases. Twenty-six (12.03%) respiratory-related critical incidents were observed. Desaturation accounted for 13 (6.01%) patients. Desaturation was associated with reintubation after extubation in 6 (46.17%) cases followed by 1 (7.69%) case each of bronchospasm, laryngospasm, tube disconnection, weak suction, wrong drug administration, hypotension, and endobronchial intubation. Two (0.92%) incidents of pneumothorax were seen after central line insertion in the internal jugular vein [Table 3]. Seventeen (7.87%) critical incidents occurred due to RA. Drug-related critical incidents contributed to 4.16% ($n = 9$) [Table 3]. Among the neurological critical incidents, seizures were seen in 3 (1.39%) patients. Position-related critical incidents accounted for 2.31% ($n = 5$). Fracture of the opposite upper limb (0.46%) was seen in a patient given lateral position and facial swelling was seen in 4 (1.85%) patients because of the prone position. Hypothermia contributed to 1.39% ($n = 3$) of incidents due to prolonged procedures with non-availability of warming devices which led to delayed recovery. Postoperative ventilation was required in 20 (9.25%) cases because of delayed recovery due to inadequate reversal of muscle relaxant in 2 (10%) cases, 3 (15%) cases each of intraoperative cardiac arrest, intraoperative myocardial ischemia and hypotension on noradrenaline support followed by 1 (5%) case each of intraoperative seizure, major blood loss, and aspiration. Post-extubation desaturation was seen in 6 (30%) cases requiring reintubation and postoperative ventilation. Blood loss was seen in 18 (8.33%) cases out of which Class 2 hemorrhage was seen in 8 (3.7%) patients, Class 3 in 7 (3.24%) patients, and Class 4 in 3 (1.39) patients.

Human error was the most common responsible factor for anesthesia-related critical incidents. Of the 154 anesthesia-related critical incidents, 145 (94.16%) incidents were seen due to human error and 9 (5.84%) were seen due to equipment error. Human error was divided into lack of vigilance that accounted for 94 (61.03%) cases, lack of expertise that accounted for 32 (20.8%) cases, and lack of communication that accounted for 19 (12.33%) cases. It was also found that the experience of senior anesthetists conducting the procedure was more than 5 years in 81 (61.83%) cases and more than 10 years in 50 (38.17%) cases.

Table 4 shows the outcome of patients. Mortality was seen in 5 (3.81%, 8.8 per 10,000 anesthetics) patients. Cardiovascular events were responsible for most of the mortalities [Table 5]. About 39% ($n = 104$) patients had critical incidents that were likely to be preventable with existing resources, 13.74% ($n = 18$) were likely to be preventable with extra resources, and 6.87% ($n = 9$) could not be prevented with any resources.

Discussion

Anesthesia continues to be associated with morbidity and mortality despite improvements in drugs and equipment.[5] An audit of critical incident reporting in anesthesia will help in preventing potential disasters and reduce patients' morbidity and mortality. Orthopedic procedures are common in geriatric patients with co-morbidities leading to complications if patients are not well optimized prior to surgery. Major surgeries, such as spine procedures, are prolonged, can lead to major blood loss and hypothermia due to low ambient

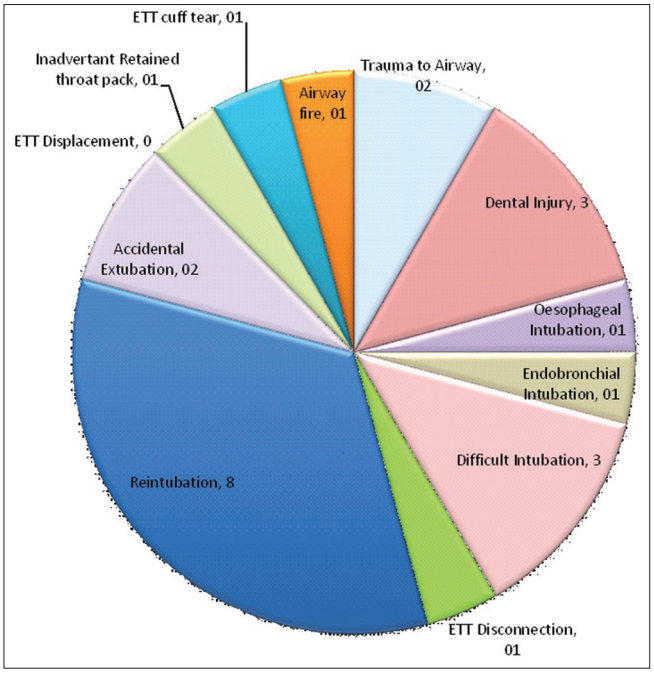

Figure 2: Distribution of airway-related critical incidents

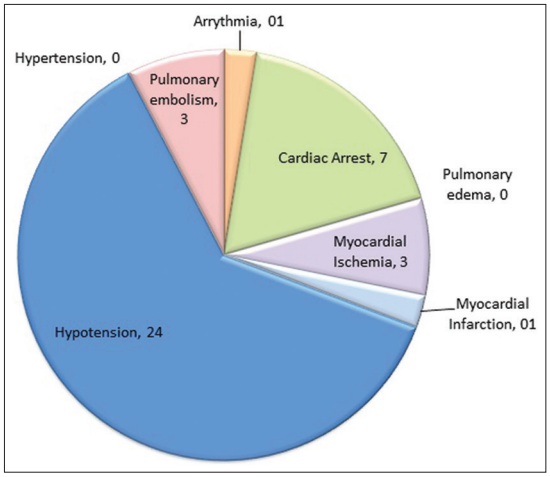

Figure 3: Distribution of cardiovascular-related critical incidents

Table 2: Factors leading to critical incidents

Factors		Number of occurrences (n=131)	Percentages
Schedule of procedures	Emergency	69	52.68
	Elective	62	47.32
Routine investigation availability	Yes	131	100.00
	No	0	
ASA status of the patient	ASA I	57	43.5
	ASA II	65	49.6
	ASA III	7	5.4
	ASA IV	2	1.5
Place of incidence	Waiting room	4	3.05
	Operation theater	113	86.25
	While shifting patient	8	6.10
	Recovery room (within 1 h)	6	4.6
Time of incident	Before taking patient to OT	4	3.05
	Pre-induction	4	3.05
	During induction	38	29.00
	While giving position	15	11.45
	Intraoperative	46	35.12
	During extubation	3	2.30
	Immediate postoperative	21	16.03

Table 3: Respiratory, regional, and drugs related critical incidents

Type of incident	Number (out of 216)	Percentage
1) Respiratory related		
Apnea	1	0.46
Bronchospasm	6	2.77
Laryngospasm	1	0.46
Aspiration	1	0.46
Desaturation	13	6.01
Pneumothorax	2	0.92
Subcutaneous emphysema	2	0.92
Total	26	12.00
2) Regional related		
Inadequate RA converted to GA	3	1.39
High spinal	4	1.85
Migration of epidural catheter	4	1.85
LAST	2	0.92
Dural puncture	4	1.85
Total	17	7.86
3) Drug related		
Wrong route	0	0
Wrong drug	2	0.92
Wrong label	1	0.46
Allergic reaction	3	1.39
Overdose	1	0.46
Expired drug	2	0.92
Total	9	4.15

temperature in the operation theater. Orthopedic procedures are also performed in prone and lateral positions, which may make access to the airway difficult and position-related complications can occur. There can be ETT disconnections as well as kinking during ENT surgeries because of sharing of the airway between the surgeon and anesthetist. Blood loss, electrolyte abnormalities, and pneumoperitoneum in laparoscopic procedures can lead to complications in general surgery patients.

We undertook this prospective audit to determine the incidence of perioperative critical incidents, types of critical incidents, the severity of the outcome, and preventability in orthopedic, ENT, general surgery OT of a tertiary care teaching hospital. Many retrospective studies have been carried out to establish the risk factors.[6] But a prospective audit avoids the problems of missing data and following up with the patients. Disease outcomes and prevalence are easy to calculate and allow precautionary measures to be taken soon after the occurrence of the critical incident. In our institute, 5,645 anesthetics were administered and 216 (3.82%) critical incidents were reported. The incidence of critical incidents in an audit by PK Manghnani[7] was 0.46% and Sunanda Gupta[8] was 0.79%, and up to 6.1% in an audit by PO Agbamu *et al*.[9] A wide range was noted because of the confounding variables such as surgical procedures and surgical expertise. The difference in figures may be due to the variation in definitions of critical incidents and lack of accepted nomenclature as well as individual perception and ambiguity in the application.[10] Delayed reporting of the incident can lead to alteration of the actual event in the report. Reporting bias could lead to underreporting. A possible reason for underreporting by junior resident could also be due to fear of blame by the senior anesthetist, lack of motivation, and lack of acceptance of the fact that it could be beneficial as an educational tool.[11]

General surgery patients were found more vulnerable to the occurrence of critical incidents followed by orthopedic surgery patients, which may be due to a greater number of patients operated under general surgery, more chance of electrolyte imbalance, and sepsis in these patients.[12]

AO Amucheazi carried out a retrospective audit in which he found that critical incidents are seen more in the 4th and 5th decade of life.[6] In our institute, maximum incidents were seen in the 5th and 6th decade of life. This shows that the middle age group is more vulnerable to critical incidents most likely because of co-morbidities. In our audit, maximum surgeries took place in ASA II and I patients, and therefore, maximum critical incidents belonged to this physical status. But, Maaloe R *et al.*[13] found a relationship between the increasing ASA grade and the risk of critical incidents and mortality.

Incidence of critical incidents was slightly higher in emergency than elective procedures because of poor preoperative optimization of the patient, non-availability of investigation facilities, and poor operating conditions. Sunanda Gupta[8] and Maaloe R *et al.*[13] have also reported a higher incidence of critical incidents and mortalities in emergency surgery as compared to elective surgery. Majority of the incidents occurred during induction. This shows that the 10-minute period surrounding the induction of anesthesia is a high critical incident zone.

In an audit by Short TG *et al.*,[11] critical incidents related to airway management have been found in 17–34% of incidents and have been shown to contribute to approximately a quarter of anesthesia-related deaths. In our audit, airway-related incidents accounted for 11.11% (n = 24) and did not contribute to any deaths. This could have been because of the direct supervision by the senior anesthetist for most of the cases. It is difficult to assess the post-extubation airway problems when the ETT is in place. Prior to extubation, a thorough airway assessment should be done and neuromuscular monitoring devices should be used to assess for any residual neuromuscular blockade. Endobronchial migration of ETT with desaturation was observed after positioning in one patient which improved after adjusting the tube. Air entry should be confirmed on both lung fields after the patient is placed in the final position for surgery.

In our audit, the maximum number of anesthesia-related critical incidents were cardiovascular-related (18.05%). PK Manghnani also reported maximum cardiac-related incidents in her audit.[7] There were 24 (11.11%) incidents of hypotension out of which 11 were due to hemorrhage, and among them, 7 required inotropic support. The anesthesiologist must anticipate and be prepared for potential massive blood loss. Adequate blood and blood products must be available.

Aspiration of gastric contents was seen in 1 (0.46%) patient. The patient was a 32-year-old male scheduled for laparoscopic

Table 4: Outcome of 131 patients

Outcome	Number	Percentage
No eventuality	62	47.32
Temporary abnormality not noticed by patient	24	18.32
Temporary abnormality with full recovery	31	23.66
Possibly permanent but not incapacitating	3	2.3
Possibly permanent but incapacitating	6	4.59
Death	5	3.81

Table 5: Analysis of anesthesia-related mortality (n=5/131)

Variable	No. of Patients (n=5)	
ASA status	I (1, 20%)	
	II (3, 40%)	
	IV (1, 20%)	
Emergency/elective	Emergency (1, 20%)	
	Elective (4, 80%)	
Pre-existing system involvement	No system involved (1, 20%)	
	Cardiovascular system (4, 80%)	
Place of occurrence	Operation theater (2, 40%)	
	Recovery room (2, 40%)	
	While shifting (1, 20%)	
Time of incident	Induction (1, 20%)	
	Intraoperative (1, 20%)	
	Postoperative (3, 60%)	
Technique of anesthesia	General anesthesia (3, 60%)	
	Combined spinal epidural (2, 40%)	
	Type of event	**Description**
Type and description of incident	Cardiac (5,100%)	Cardiac arrest (3, 60%) Cardiac arrest after pulmonary embolism (2, 40%)

necrosectomy for acute pancreatitis. The patient did not have a Ryles tube *in situ* and aspirated at the time of induction. Patients with acute pancreatitis are considered full stomach. Preoperative insertion of a Ryles tube and a rapid sequence induction could have prevented the incident. The patient required postoperative ventilation. While no death occurred due to aspiration in our study, death rates in patients who aspirated range from 3.8% in the AIMS[14] to 4.6% in the Swedish study.[15]

FA Khan *et al.*[16] in their study found that 21% of critical incidents were drug-related. In our audit, a lower incidence of drug-related critical incidents was found. Two incidents were due to wrong drug administration. The first was the fixation of a proximal humeral fracture under GA. Suxamethonium was given to the patient IV instead of lignocaine as they had both been drawn in 2 mL syringes and not labeled. On observation of fasciculation and apnea, the anesthetist immediately administered propofol and intubated the patient. Earlier studies have also highlighted drug-related critical incidents, the majority being attributable to failing to read or misreading the label, mislabeling, confusion with labels, or drugs being present in wrong boxes.[17] The incident could be avoided by drawing drugs only required for a procedure and clearly labeling them. The second patient scheduled for laparoscopic hernia repair received rocuronium instead of normal saline. The patient was immediately ventilated and then intubated. Lack of vigilance on the part of the anesthetist was a common factor in all these incidents.

Surgical procedures are done in various positions due to which peripheral nerve injuries can occur. Precautions must be taken to cushion all pressure points especially in extreme positions such as prone, lateral, lithotomy. Other complications like airway edema, facial edema, and visual loss can also occur due to prone position. In our audit, it was difficult to assess the position-related injuries like nerve palsy as the patients were observed only for 1-hour post-op in the recovery room.

Critical incidents were more frequent under general anesthesia than regional anesthesia and this was in common with the other published studies,[12] possibly due to the high-risk surgeries are done under general anesthesia.

The operation theater temperatures should be maintained at 21°C ± 3°C with corresponding relative humidity between 20 and 60%.[18] Hypothermia adversely impacts blood loss, infection risk, and cardiac events, potentially increasing the length of hospital stay. It also slows anesthetic drug metabolism and may alter pharmacodynamics, thus contributing to increased recovery time.[19]

LAST is seen commonly during upper limb blocks because of proximity to vascular structures. Two (0.92%) cases of LAST were seen. Both patients had complaints of slurred speech and an inability to breathe. They were immediately intubated and Intralipid emulsion was given at a bolus dose of 1.5 mL/kg and the infusion was started at 0.25 mL/kg/min.[20] Dural puncture was seen in four (1.85%) cases while instituting lumbar epidural anesthesia. All four cases were done by 1st-year junior residents under the supervision of senior anesthetists. It was observed that these incidents occurred as a part of training since it is a teaching institute.

Warden JC considered mortality associated with anesthesia as death within 24 hours of an anesthetic.[21] The mortality rate in his study was 4.4 per 10,000 anesthetics. Anesthesia-related mortality in most developed countries lies between 0.12 and 1.4 per 10,000 anesthetics.[22] Anesthesia-related mortality has decreased in the last three decades and currently ranges from 0.05 to 10 per 10,000.[8] In our audit, the mortality rate was 8.8 per 10,000 which was higher than in the developed countries. Anesthesia-related mortality may be different in developing countries where only a limited trained workforce, monitoring, and training facilities are available.[23]

Critical incidents are reducible. Critical incidents mostly occur because of human error, equipment failure, and surgical error.[24] Short TG *et al.*[11] reported that 80% of the anesthesia-related critical incidents were caused by human error. In our audit, 94% of the anesthesia-related incidents were due to human error. Human error can be reduced by being more vigilant, not working for long hours, working under the supervision of seniors, and learning from mistakes. Surgical errors like blood loss are difficult to prevent at times. Therefore, the anticipation of blood loss should be done and adequate blood and blood products should be reserved beforehand. Anticipating difficult intubation and using a fiberoptic bronchoscope or a videolaryngoscope can help prevent airway-related critical incidents. Use of an equipment checklist prior to surgery and proper maintenance of the equipment could help reduce equipment-related critical incidents.

Conclusion

Most of the patients recovered fully and most of the events were preventable. This audit will help in increasing the voluntary reporting of critical incidents and continued training for such incidents can reduce the severity and frequency in the anesthesiology department of our institution. It will help in formulating protocols, thus, ensuring patients' safety.

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Conflicts of interest
There are no conflicts of interest.

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