

Analysis of Adverse Events in the Perioperative Period in a Tertiary Care Hospital.

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Abstract

Background and Aim

The state of anaesthesia is considered to be intrinsically unsafe. Patients are subjected to administration of drugs whose side-effects, particularly on the cardiovascular and respiratory systems may be detrimental to life. Preventable critical incidents occur in all anaesthesia departments despite the best intentions of involved professionals, adherence to institutional protocols and delivering standards of care. This study aims at identifying the incidence, potential risk factors and outcome of adverse events that occur during the perioperative period in a tertiary care hospital by encouraging safe and comprehensive reporting of adverse events through a simple, easily understandable and anonymous adverse event reporting form which was accessible in all OTs, ICUs, HDUs and Post-Operative wards of the hospital.

Methodology

A departmental meeting was held prior to commencing this study where all members of the Anaesthesiology team including the Residents were requested to report peri-operative adverse events occurring under their care, anonymously in an "Adverse Event Reporting Form". It did not contain the patient and the anaesthesiologist's name. However, it comprised of detailed information regarding patient's disease profile, nature and circumstance of event, consequent management strategy employed to handle the event and its outcome.

Results

A total of 15370 surgical procedures were performed during the study period, of which 13501 were elective and 1869 were emergency in nature. A total of 127 adverse events were reported with an incidence of 0.82. It amounted to 6% of the total procedures carried out, of which 106 were during elective procedures and 21 were during emergency procedures; constituting 83% and 17% of all adverse events reported peri-operatively, respectively.

Conclusion

Human error is the most important factor in the majority of these incidents. We emphasize that strategies and protocols that may be developed to enhance patient safety and to update knowledge base to avoid errors of judgment contributing to peri-operative adverse events.

Keywords

Adverse Events, Critical Incidents, Hypotension, Bradycardia, Aspiration, Perioperative Period

Introduction

The state of anaesthesia is considered to be intrinsically unsafe. Patients are subjected to administration of drugs whose side-effects, particularly on the cardiovascular and

respiratory systems may be detrimental to life [1].

Unconsciousness rendered by general anaesthesia carries with it the risks of airway obstruction, pulmonary aspiration of gastric contents, and the relative inability to detect injury during the course of the anaesthetic.

Pharmacological muscle paralysis necessitates the use of artificial ventilation, making the patient dependent on the anaesthetist and his equipment for the fundamental functions of oxygenation and for the elimination of carbon dioxide (Co₂).

The anaesthetist may deliberately alter physiological

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functions, for example - by inducing hypotension or ventilating only one lung - if the surgery necessitates it. Anaesthesiologists have a unique opportunity and bound duty to ensure the safety and quality of patient care.[1,2]

Maintaining patient safety has always been a critical element of anaesthetic practice and adverse incident reporting is one of the most important factors in realizing this aim [3].

Several European countries have their own national critical incident reporting systems. For Instance, Switzerland has an online anaesthesia-specific reporting system which was initiated in the mid 1990s and more recently, the German Society of Anaesthesiology and Intensive Care set up its own Patient Safety Optimization System [3].

The UK National Patient Safety Agency (NPSA), established in 2001, set up a Reporting and Learning System (RLS) to collect and learn from adverse incidents and near misses reported throughout the National Health Service in England and Wales [4].

Developing countries are yet to implement Critical Care Reporting Systems and adopt a culture where incident reporting is a routine occurrence [5,6].

Preventable critical incidents occur in all anaesthesia departments despite the best intentions [7,8] and the need to identify and prevent them has grown partly as a result of the dramatic increase in medical malpractice claims and suits [9].

Despite the known benefits of the incident reporting systems, under-reporting remains a significant problem. There may be various reasons for under reporting including that the incidents are just not recognized, or are that they are not documented properly [10], unfamiliarity with the process of reporting [11], administrative issues such as fear of punitive action [12,13], legal ramifications, and the fear of discrimination at the workplace [10].

Many staff do not consider near misses to be reportable incidents, which could also serve as a rich source for learning [14]. Also, many doctors do not consider omission of medication to be reportable, which again, indicates lack of essential knowledge about what should be reported.

Organizational factors which make reporting difficult (long forms, insufficient time, and no feedback) have also been identified as major barriers to reporting [15].

This study envisaged to identify the incidence, potential risk factors and outcome of adverse events occurring during the perioperative period in a tertiary care hospital by encouraging safe, anonymous and comprehensive reporting of adverse events through a simple and easily understandable adverse event reporting form which was

accessible in all OTs, ICUs, HDUs and post op wards.

Aims & Objectives

The aim of this study was to analyze the adverse events in perioperative period in a tertiary care hospital.

Specific objectives of this study included:

- To identify the adverse events and their outcome in perioperative period.
- To evaluate the potential risk factors leading to critical incidents in perioperative period.
- To formulate recommendations on basis of above findings.
- To evolve new polices to prevent recurrences by sharing and discussing these adverse incidents.

Material and Methods

The Hospital Ethical Committee approval was duly obtained and a prospective study to analyze the adverse events in perioperative period was conducted over a period of one year viz. between May 2016 through Apr 2017 in a tertiary care hospital (ACMS & Base Hospital - Delhi Cantt., New Delhi, India, PIN 110 010).

Since it was an observational study not involving specific interventions, written informed patient consent was forgone.

All surgical procedures conducted at the tertiary care hospital Operation Theatre - Elective as well as Emergency in nature - were included for analysis of occurrence(s) of any Adverse Event (s) anytime during the peri-operative period . However, surgical cases that were listed but were cancelled prior to shifting to the OT were excluded.

A departmental meeting was held where all members of the anaesthesiology team including Residents, were requested to report peri-operative adverse events occurring under their care, anonymously in an "Adverse Event Reporting Form" that was made available in all OT's, post-op wards and ICUs / HDUs.

Anaesthesiologists were regularly motivated and reminded to report critical incidents on an anonymous and voluntary basis and care was taken to maintain complete confidentiality.

An Adverse Event was defined as unintended injury or complication that was caused by health care personnel, rather than by patients' underlying disease(s) and that had lead to death or disability at the time of discharge or that had resulted in a prolonged hospital stay.

The "Perioperative Adverse Event Reporting" form was anonymous and did not contain the patient's nor the anaesthesiologist's name. However, it comprised of

detailed information regarding patient's disease profile, nature and circumstance of event, consequent management strategy employed to handle the event and its outcome.

The Form had two components, the Descriptive and the Analysis Portions.

The Descriptive Portion contained detailed information regarding:

- (a) Patient profile (Age, Sex, Weight, OPD/IPD Status, ASA Physical Status Grade)
- (b) Disease profile (Diagnosis, Co-Morbidities, Surgery, Elective/Emergency)
- (c) Anaesthesia details (ASA Grade, Technique Of Anaesthesia Administered, Experience of the Anaesthesiologist, Adequacy of the Staff Available in the OT, Availability of Emergency Trained Help and Any Deviation from Institutional Protocol)
- (d) Adverse Event details (Time, Place, Phase of Care (Pre/Intra/Post-Operative Period) and the Duration of Anaesthesia)
- (e) The Type of Adverse Event - Broadly grouped into 6 categories as under :
 - (i) Patient Identity related (Wrong patient, Surgery on wrong side)
 - (ii) Airway Related (CVCI, Airway spasm, Aspiration, Oesophageal intubation, inadvertent Extubation)
 - (iii) Vascular access related (Inadvertent arterial puncture, Pneumothorax, Limb ischemia, Misc.,)
 - (iv) Drug related (Wrong drug, Wrong dose, Expired drug, Wrong route of administration, Defective batch of drug, Drug interaction, Transfusion reaction, Drug allergy, Contact allergy, Misc)
 - (v) Equipment / Monitoring Related
 - (vi) Injuries (Dental injuries, Eye injuries, Fracture / dislocations, Nerve injuries, Airway injuries, Diathermy burns, Misc)

Detailed description including the circumstances of the Adverse Events and how it was managed, along with any additional information that can help in preventing such incidents in future were endorsed.

Patients were followed up till they recover and outcomes endorsed in the proforma.

In the Analysis portion, a team of senior consultants of the department analyzed these events at the end of every month and the analysis report along with suggested preventive measures were endorsed in the per forma.

Table 1: Frequency of Adverse Events

Type of Adverse Event	Frequency	Percentage (%)
Patient Identity	1	0.8
Airway	30	23.6
Vascular	18	14.2
Drug	25	19.7
Equipment/Monitor	14	11
Injury	24	18.9
Modification of Plan	15	11.8
Total	127	100

The data so collected was subjected to statistical analysis at the end of 12 months.

Results & Statistical Analysis

Adverse events were reported under 7 broad categories.

- Among the 127 total Adverse Events reported, the most common adverse events were related to Airway (23.6%), followed by Drug related (19.7%) and Injury (18.9%).
- Least common was Patient Identity related adverse events. (0.8%).
- Vascular events constituted 14.2% and Equipment and Monitoring related events was 11% of the reported Adverse Events.
- A total of 15,370 surgical procedures were performed during the study period, of which 13,501 were elective and 1869 were emergency in nature.

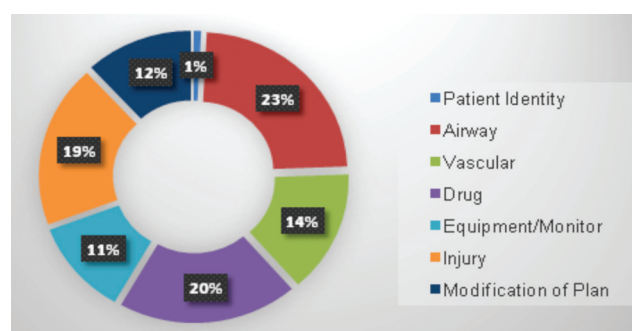


Figure 1: Frequency of Adverse Events

A total of 127 Adverse Events were reported with an incidence of 0.826%, of which 106 were during elective surgery and 21 were during emergency surgery constituting 83% and 17% of all adverse events, respectively.

Airway related adverse events and Injuries were more common in both the groups.

However, Emergency cases showed higher incidence of airway related adverse events 33.3% (7) and Injuries 20% (4) as compared to 21.7% (23) and 18.9% (20) respectively among Elective cases.

Elective cases demonstrated a higher percentage of vascular related adverse events 20.7% (22) as compared to 14.3% (3) among Emergency cases.

There was only One Patient Identity Related Adverse event among Elective cases.

Table 2: Nature of Surgery & Type of Anaesthesia Administered

Nature of Surgery	Frequency	Type of Anesthesia Administered (% of Nature of Surgery)	
		GA	RA
Elective	106 (83%)	50 (47%)	56 (53%)
Emergency	21 (17%)	17 (81%)	04 (09%)
Total	127 (100%)	67 (53%)	60 (47%)

Incidence of adverse events was slightly higher among Emergency cases (1.123%) as compared to Elective (0.785%).

This might be due to:

- Inadequate Optimization of Patients requiring Emergency Surgeries;
- Non Availability of Emergency Instruments (Bougie, Video-Laryngoscope Etc.);
- Non-Availability of Emergency Drugs;
- Non-Availability Expert & Experienced Personnel Help;
- Incomplete Work-Up of the Patient;
- Delayed Blood Investigation Reports and / or
- Sub-Optimum Blood Bank Support.

However, it was not statistically significant.

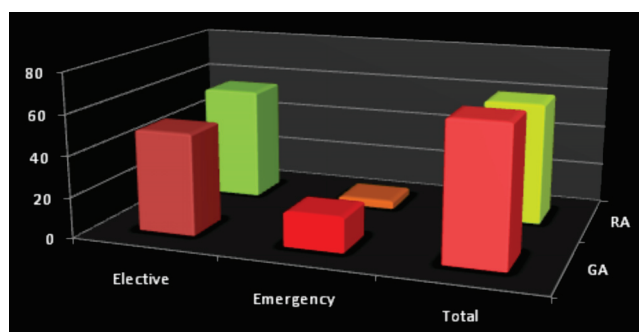


Figure 2: Nature of Surgery & Type of Anaesthesia Administered

Out of a total of 127 adverse events reported, 52.7% (67) cases were done under general anaesthesia (GA) and 47.3% (60) were done under regional anaesthesia (RA) technique.

The relatively higher incidence might be due to the preference of general anaesthesia technique in High-Risk patients.

As one may expect, Cases done under GA had an overall majority of Adverse Events related to the Airway constituting 44.8% (30) than other categories of Adverse Events in that group.

A majority of Adverse Events in the RA group was related to Drug or Injury - constituting 35% (21) and 25% (15) - respectively of all the Adverse Events in that group.

Discussion

Internal audits based on recording of critical incidents in institutions are imperative in the specialty of Anaesthesiology, firstly, to study the changes in patient outcome which underline the improvement in standards of anaesthesia care and secondly, for sharing and discussing these critical incidents to evolve new policies to prevent recurrences [16-19].

A prospective reporting system avoids the problems of inaccurate recall and allows warnings and advice to be issued if necessary, soon after the occurrence [8].

We conducted a prospective study to analyze perioperative adverse events over a one year period from May 2016 to April 2017 and recorded 127 adverse events with an overall incidence of 0.826%.

The frequency of incidents reported from different institutions have varied from 0.28% to 2.8% [12,13], while higher incidence of 12.1% [20] and 10.6% have also been reported.

The vast difference in these figures lies in the fact that interpretation of critical events in anaesthesia varies according to individual perception of an incident and to an ambiguity in how these are applied in practice.

There is reluctance to report seemingly minor events while some major events go unreported for fear of retribution, lack of motivation and lack of acceptance of the fact that it could be beneficial as an educational tool [21].

In this study, most common adverse events were related to Airway (23.6%), mainly due to Laryngospasm, Hypoxia, Bronchial And Esophageal Intubation, Bronchospasm and Pulmonary Aspiration.

This is consistent with the previous literature that Critical incidents related to Airway Management was found to be 17-34% of incidents and Airway Management has been shown to contribute to approximately one quarter of anaesthesia related deaths [22].

The incidence of other Adverse Events were:

- **Drug Related (19.7%)** - Defective Batch of Medicine, Wrong Route of Administration, Delayed Awakening, Drug Allergy, Wrong Look

- Alike Drug, Anaphylaxis, Cement Reaction and Transfusion Reaction;
- **Injury (18.9%)** - Accidental Dural Puncture in Attempted Epidural Anaesthesia, Dental Trauma And Airway Injury, Diathermy Burns;
- **Vascular events (14.2%)** - Loss of Vascular Access, Inadvertent Arterial Puncture, Hematoma And Pneumothorax During Attempted Central Venous Access;
- **Equipment And Monitoring Related Events (11%)** - Unmonitored Hypoglycemia, Equipment Not Working etc.

Least common was patient identity related adverse event (0.8%).

We found in common with the other studies that the frequency of adverse events and mortality was higher with general anaesthesia (53%) than Regional anaesthesia (47%) [5,6,9].

Likewise, there may be a bias towards general anaesthesia in emergency settings or in patients with co-existing medical conditions.

Sub analysis of the data revealed that General Anesthesia cases had majority of airway related adverse events constituting 44.8% of all adverse events in that group.

Whereas, Majority of the adverse events in Regional Anaesthesia group had Drug and Injury related adverse event constituting 35% and 25% of all adverse events in that group respectively.

The most comprehensive recent survey of cardiac arrest incidence during neuraxial anaesthesia reported as 2.7 per 10,000 anaesthetics [23] is nearly similar to our study (3.4 per 10,000).

Improved knowledge of neuraxial block physiology and the use of new local anaesthetics with fewer side effects, associated with more routinely used pulse oximetry has substantially decreased the possibility of major complications during neuraxial anaesthesia [23].

Emergency cases had a higher incidence of airway related adverse events (33.3%) and Injuries (20%) as compared to (21.7% and 18.9% respectively) in the elective group.

Elective cases had a higher incidence of vascular related adverse events (20.7%) as compared to (14.3%) in emergency group. This difference is consistent with recent Airway Adverse Events Audits [31].

Emergency cases had a slightly higher overall incidence of adverse events at 1.123% as compared to 0.785% in elective surgeries.

This slightly higher incidence of adverse incidents and

mortality in emergency surgery as compared to elective surgery is possibly because of poor optimization of patient's pre-operative status, non-availability of emergency drugs, investigation facilities and poor operating conditions [24,25].

Significant number of patients who suffered an Adverse Event had an uneventful recovery (79%) and a substantial margin of patients (15.7%) required ICU admission for subsequent management following the Adverse Event.

One third of all Airway Adverse Events required ICU admission and they constituted 50% of all the ICU admissions following an Adverse Event.

Emergency cases with adverse events had higher ICU admission rate (28.6%) as compared to (13.2%) in elective cases with Adverse Events.

Only one death reported was due to inadvertent intravascular injection of local anesthetic drug during a Brachial Plexus Block. It has been suggested that anaesthesia related mortality has decreased in the last three decades and currently ranges from 0.05 to 10 per 10,000 [22,26-28] and in most developed countries lies between 0.12-1.4 per 10,000 anaesthetics [25,28].

In this study, Crude Anaesthetic Mortality was 0.65 per 10,000 anaesthetics, which is comparable with the rest of the world and was significantly better than that compared to anaesthetics reported from developing countries viz. 22.6 per 10000 [24,28].

The reasons for lower Crude Anaesthetic Mortality Rate in our department as compared with those from other developing countries, in spite of having sicker patients and despite of Residents as the major work force than Consultants, may be due to the fact that we have clearly defined the role of every team member and his check lists, well rehearsed emergency maneuvers, better standardized OT practices, periodic checking of equipments and drugs and regular departmental audits to evaluate the lacunae in health care and fix them in time.

Risk factors of adverse peri-operative events

Based on the results of this study, We identify the following Risk Factors to be significant in contributing to the Incidence of Peri-Operative Adverse Events:

- 1.) **Emergency Nature of Surgery:** Likely due to relative deficiency & inattention in manpower during off - working hours, inadequate optimization of patient condition and inadequate time to assess and plan airway, drugs, monitoring etc.
- 2.) **General Anaesthetic Modality:** Possibly due to obvious contribution by airway - related adverse

events, more drugs required to be administered, underlying co-morbidities necessitating GA over RA and most of the emergency cases being performed under GA.

- 3.) **Therapeutic Mis-Adventure:** Inadvertent intravascular injection of local anesthetic agent, unmonitored hypoglycaemia, anaphylaxis to drug(s)/cement etc. are some of the well-known adverse events with undoubted disastrous consequences and increased mortality.
- 4.) **Inadequate Vigilance:** Dental trauma, loss of vascular access, airway device misplacement, diathermy burns etc, represent a significant chunk of adverse events that can be clearly prevented by exercising greater caution and improving standards of vigilance especially intra-operatively.

Recommendations

The following set of broad recommendations may be made by analyzing the results of this study to minimize Peri-Operative Adverse Events:

1.) Preventing Life-Threatening Events:

- 1a) Ultrasound (USG) Guided Regional Anaesthesia [29] in all circumstances if USG available at Anaesthesiologist's disposal has been proven to reduce the incidence of intravascular injection of LA and is effective in reducing the incidence of LAST (Local Anaesthetic Systemic Toxicity).
- 1b) Difficult Airway Trolley [30] designated place within each OT, complete in all aspects, exhaustive range of airway & related equipment, checked before every case, maintained periodically & sufficient spares made available enhances the team's ability to handle airway management crises & minimizes airway related morbidity.
- 1c) A Robust Drug Related Policy [32]:
 - i.) Customized drug crash carts
 - ii.) Periodically maintained drug replenishment
 - iii.) Scheduled & random inspections to audit the compliance on drugs management
 - iv.) Centralized display of expiry dates & batch no.s'
 - v.) Ensuring vigilance before each drug administration by anaesthesiologist or OT assistant
 - vi.) Compliance to universal color coded

labels on drug syringes with dose and name clearly mentioned in indelible ink on EVERY syringe

- vii.) Requisite training on LASA drugs
- viii.) Mock drills on managing anaphylaxis and other drug mishaps.
- 1d. Dedicated Post-Anaesthesia ICU & Care Units [33]
Adequate staffing, availability of monitoring devices, mechanical ventilators, emergency drugs & equipment enable safer handling of patients who suffer adverse events & enable better vigilance by anaesthesia personnel during their recovery.

2.) Human Factors & Preventable Errors of Judgment [34]

- 2a.) Establish and maintain a non-punitive [34] & anonymous adverse event reporting system and constitute a dedicated board of dept. members for periodic audit and re-formulation of patient safety policies.
- 2b.) Use of simulation [34] in training residents & paramedical staff to handle real - life crises better.
- 2c.) Train & encourage closed-loop communication [34]
 - i.) Repeating verbal orders followed by clear communication of concurrence,
 - ii.) Structured patient handover between colleagues
 - iii.) Clear documentation of all relevant peri-operative data
 - iv.) Rehearsal of management plans before complex & extensive cases .
- 2d.) Work Culture & Ethics [34]
 - i.) Avoiding any factor causing operator fatigue, carelessness, hurry or neglect
 - ii.) Adequate Turn-Over time
 - iii.) Unburdening Resident Working Hours
 - iv.) Clear Role Attributes of Team Members
 - v.) Empowering Nursing & Para -Medical staff to enable early & better recognition and management of adverse events.

3.) Quality Improvement & Patient Safety Dynamics [35]

- a.) Meticulous adherence [35] to mandatory WHO Surgical Safety Checklist &

anaesthesia pre- checks.

- b.) Patient safety initiatives [35] like boot camps, monthly charter of key improvement areas, motivational speaking & group learning activities.
- c.) Infrastructure & logistics [35] periodically checked spares and additional monitoring equipment over and above the working number, accredited service & quality control updates, eliminating faulty & unserviceable equipment.
- d.) Team Dynamics & Group Strategy [35]:
 - i.) Cordial interpersonal relationships
 - ii.) Sub-specialty training of paramedics' & retaining the same team for the specific OTs.
 - iii.) Discretion of reward & punishment for annual performance
 - iv.) Non-dominating hierarchical system that encourages unbiased and undeterred exchange of constructive criticism & inter-departmental co-operation in patient safety efforts.

4.) Administrative & Managerial Aspects [36]:

- a.) Choice of quality products & brands
- b.) Human resource allocation & planning
- c.) Stringent drug & equipment procurement strategies
- d.) Willful participation of all types of OT staff in decision making processes
- e.) Innovative information systems & alarm devices
- f.) Incorporating artificial intelligence in monitoring & vigilance processes.

Limitations of the Study

There may have been some methodological weakness associated with our study.

Firstly, under-reporting could be significant - since it was based on voluntary reporting of Adverse Events by faculty and residents.

Secondly, it seems that the anaesthesiologists' report major adverse events more accurately and frequently rather than minor events. Hence, a large chunk of Adverse Events might have gone un-reported.

Thirdly, critical incidents reported in this study over a one year period represent a very small sample size to calculate statistical significance of risk factors.

Conclusions

Anaesthesia continues to be associated with mortality and morbidity despite improvements in drugs and equipments. Human error is the most important factor in the majority of these incidents.

We emphasize that strategies to update knowledge base and protocols to avoid errors of judgment should be developed and followed meticulously.

There is evidence that the use of checklists, protocols and improved awareness of the relevance of critical incidents can improve safety.

Thus, we conclude, that critical incident reporting should be introduced in all Departments of Anaesthesiology as part of quality assurance programs to ensure improved patient care.

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