



OUTCOME OF PERI-OPERATIVE CRITICAL INCIDENTS IN ANAESTHESIA-A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Since the advent of its modern history, the administration of anaesthesia has been identified as a perilous endeavour with distinct risks to the patient. Perioperative risk is multifactorial and depends on the interaction of anaesthesia, patient and surgery specific factors. An incident reporting system which would improve patient safety and allow front-end clinicians to have easy access for reporting an incident is the need of the hour. The present study aimed to evaluate the critical incidents attributable to anaesthesia and analyze factors or events leading to anaesthetic mortality in perioperative period. A one year prospective observational study was conducted in the tertiary care hospital. Anaesthesiologists, working in operation theatres, post operative wards, Intensive Care Units and High Dependency Units, were asked to report critical incidents in an anonymous and voluntary basis on an indigenously prepared "Critical Incident Reporting Form". A total of 101 critical incidents were reported out of which 62.37% were attributed to anaesthesia related factors and 37.62% to surgical factors. Mortality was found in 10 cases among the reported critical incidents in which 6 mortalities were due to anaesthesia related factors again out of which 5 patients had pre-existing illness. Hence, anaesthesia factor was responsible for 10% (n=1) mortalities. Thus it was found that anaesthesia was not solely related to perioperative mortality and it could be concluded that critical incident reporting system is an integral part of quality assurance where clinicians should be encouraged to report critical incidents without the fear of a punitive action.

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INTRODUCTION

Anaesthesia is a complex and dynamic system in which there is interaction between man (anaesthesiologist, patient), machine (anaesthesia machine and monitors) and the environment (surgeons, nurses, the operating room and hospital).¹ Failures or errors can occur in any of the components of this system which could be harmful to the patient, therefore giving rise to critical incident. Since its early adoption in the field of aviation² and later in the field of anaesthesia,^{3,4} the collection of data on critical incidents is gaining acceptance in anaesthesia. However there are still sporadic studies⁵⁻⁷ from the developing countries. The frequency of incidents reported from different institutions have varied from 0.46% to 1.58%^{8,9} while higher incidence of 13.2%¹⁰ and 24.8%¹¹ have also been reported. An incident reporting system which would improve patient safety would allow front-end clinicians to have easy access for reporting an incident with an understanding that their report will be handled in a non-punitive manner, and that it will lead to enhanced

learning regarding the causation of the incident and systemic changes which will prevent it from recurring. At present, significant problems remain with local and national incident reporting systems. These include fear of punitive action, poor safety culture in an organization, lack of understanding among clinicians about what should be reported, lack of awareness of how the reported incidents will be analysed, and how will the reports ultimately lead to changes which will improve patient safety. Incident reports form an integral part of quality assurance activity in many departments of anaesthesia indifferent parts of the world.

Several sources of information are available, including the United States National Centre for Health Statistics and articles in the medical literature. Neither of these encompasses more than a fraction of the total experience; in addition, the population upon which most reports are based and the number of anaesthetics involved are usually not available as a denominator in determining the incidence of mishaps and the magnitude of the problem. We thus must recognize that anaesthesia is an iatrogenic disease that deserves serious attention as a public health problem. The aim of the study was

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to evaluate the critical incidents attributable to anaesthesia and analyze factors or events leading to anaesthetic mortality in perioperative period.

MATERIALS AND METHODS

A one-year (2013-2014) prospective observational study was conducted in the department of anaesthesia of VMMC and Safdarjung hospital. Ethical clearance was obtained from the hospital ethical committee.

A critical incident is defined as “An event under anaesthesia care which will have the potential to lead to substantial negative outcome (ranging from admission to intensive care, increased length of hospital stay to death or permanent disability or cancelled operative procedure) if left to progress”^{3,8}

Indigenous “Critical Incident Reporting Form” was developed and made available in all the operation theatres, post operative wards, Intensive Care Units and High Dependency Units. In these forms, detailed contextual information during recording of an event which would enhance the subsequent review of the incident was included. Only reported critical incidents were included in the study.

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

Inclusion criteria: General surgery, Obstetrics & Gynaecology, Orthopaedic, Plastic, ENT, Eye, and Paediatric surgery.

Exclusion criteria: Cardiovascular surgery, Burns, Neurosurgery.

Parameters studied: The Critical incidents were assigned to factors attributable to patient, anaesthesia, or surgery. Anaesthesia related critical incidents were further analyzed for factors responsible like- Equipment error- Failure/ non functional/unavailable/ Malfunction, Pharmacological error- Wrong drug/Wrong dose/route/look alike/sound alike, Human error as per report- Skill/Stress/Knowledge/Fearfulness/Lack of sleep/Lack of good assistant/No human error.

All completed Critical incident reporting forms were reviewed and analyzed.

Statistical analysis: The data were entered in terms of percentage of different values and were analysed by SPSS statistical software version 16.0.

RESULTS AND OBSERVATIONS

Out of a total 25,144 patients, who were administered anaesthesia during the period of one year study in the tertiary care centre, 101 (0.40%) critical incidents were reported.

Critical incidents were found mostly in 15-60 year age group (n=75, 74.25%) with a maximum incidence in males (n=65,64.35%).

The incidents occurred more under the supervision of senior residents with experience of 3-6 years (n=60, 59.40%) then under consultants with experience of >6 years. All the reported incidents took place when the workload of the anaesthetist was presumed to be less than 12 hours, without any report of contributing factors like haste, distraction or inadequate help.

Majority of critical incidents occurred in ASA grade I patients (n=63,62.37%) and also mostly in patients with no pre-existing systemic involvement (n=62,61.38%).

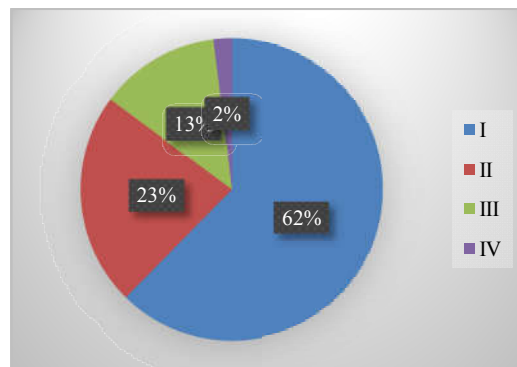


Fig 1 ASA grading

Most of the critical incidents were due to events involving either cardiovascular system (n=78,77.22%), or respiratory system (airway + pulmonary) (n=70,69.30%) or both (n=14,13.86%) or both cardiovascular & central nervous system events were 12 events (11.88%), both respiratory & central nervous system were 7 events (6.93%).

In multiple organ dysfunctions heart failure were found in 8 patients (7.92%), septic shock in 7 patients (6.93%), renal failure in 2 patients (1.98%).

Miscellaneous events were found in 4 patients (3.96%) where pruritus and surgical emphysema were found in 2 patients respectively.

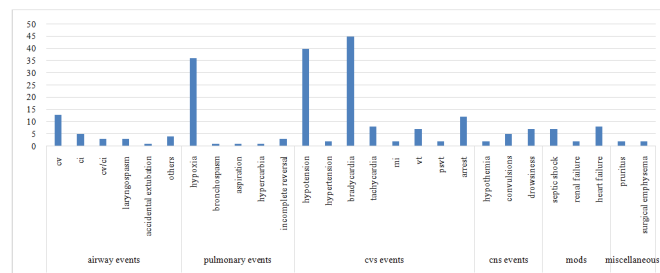


Fig 2 Critical incidents due to Systemic Events

In the present study, out of 101 critical incidents, 38 cases (37.62%) were due to surgical related critical incidents, rest 63 cases (62.37%) were due to anaesthesia related critical incidents, out of which 24 cases were due to patient's pre-existing condition, equipment error accounted for 7 cases (6.93%), drugs error accounted for 10 cases (9.90%) and 6 cases were due to human error (5.94%).

From a total of 101 reported critical incidents, cardiac arrest occurred in 13 patients (12.87%) at operation theatre, out of which 12 patients revived and 1 patient not revived.

Out of 53 patients, 19 patients stayed in ICU for <48 hrs (35.84%), whereas 25 patients had an ICU stay of >48 hrs (47.16%) and 9 patients (16.98%) had cardiac arrest.

Out of 101 reported critical incidents, morbidities were seen in 31 cases (30.69%) and of them 18 were due to patient's pre-existing condition, mortality seen in 10 cases (9.90%) and of them 7 were due to patient's pre-existing condition. Mortality were found in 10 cases (9.90%). 4 mortalities (40%) were due to surgical related factors 6 mortalities (60%) were due to anaesthesia related factors.

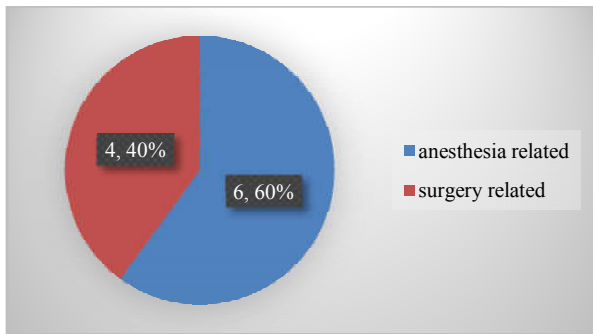


Fig 3 Mortality due to Anaesthesia related or Surgery related

DISCUSSION

The difference in the number of critical incidents reported in the studies conducted by Manghnani *et al*⁶ (0.46%) and Webb RK *et al*¹² (1.58%) with the present study can be explained by the fact that interpretation of the term “critical incidence” in anaesthesia varies according to individual perception of an incident and vague application of the same. Moreover there might be reluctance to report minor events or fear of retribution in reporting major events.

The maximum number of critical incidents reported by Manghnani *et al*⁶ (age group 41-50 yr and male sex) and Gupta *et al*¹³ (age group 0-10 yr and equal among both sexes) varied with the present study probably because of more number of surgeries being performed in that particular age group and sex. The present study reported more number of critical incidents when conducted by resident doctors under the supervision of senior residents with 3-6 years experience which comparable to studies conducted by Gupta *et al*¹³ and Amucheazi *et al*¹⁴.

Gupta *et al*¹³ and Manghnani *et al*⁶ in their study, reported that critical incidents occurred more in ASA grade I (61.61% and 51% respectively). The above findings were comparable to the present study. This could possibly be because of the presence of senior faculty, more intensive monitoring and vigilance undertaken during the conduct of anaesthesia of higher ASA grade patients and also may be due to the more number of patients undergoing surgery were ASA I and II.

Manghnani *et al*⁶ found maximum critical incidents in patients (51%) with no contributing medical illness. Amucheazi *et al*¹⁴ reported that the frequency of critical incidents was maximum in patients with no pre-existing systemic involvement (n=69, 61.61%), followed by those with cardiovascular (n=19, 16.96%) and respiratory (n=8, 7.14%) system involvement. Gupta *et al*¹³ also found that the incidence was maximum in patients with no pre-existing systemic involvement (n=69, 61.61%) followed by those with cardiovascular (n=19, 16.96%) and respiratory (n=8, 7.14%) system involvements.

In the present study showed that number of critical incidents was maximum in patients with no pre-existing systemic involvement (n=62, 61.38) followed by cardiovascular (n=22, 21.78%) and respiratory (n=6, 5.94%) system which were comparable with above studies and the reason could be because most of the patients who got operated (during which most of critical incidents were reported) did not have pre-existing systemic involvement.

Amucheazi *et al*¹⁴ found that cardiovascular causes were more frequently responsible for anaesthesia related critical incidents and morbidity was mainly due to hypotension (63%) and bradycardia (7.4%). This was followed by respiratory incidents

which included failed intubation (5.6%), failed intubation with failed ventilation (1.9%), hypoxia (7.4%). Gupta *et al*¹³ also found most of the critical incidents were due to events involving either respiratory system (39.29%), or cardiovascular system (32.14%). Manghnani *et al*⁶ noted in their study, cardiac events (like bradycardia, hypotension, ventricular tachycardia) in 28.5% patients, followed by respiratory events (like laryngospasm, apnoea) in 14.6%. Similar findings in the present study could be due to close monitoring of heart rate, blood pressure and oxygen saturation to assess cardiovascular and respiratory system homeostasis in every patients respectively.

Gupta *et al*¹³ found that maximum critical incidents occurred due to factors related to anaesthesia (42.85%) as compared to surgery related factors (16.96%) and out of 32 mortalities, 19 patients had pre-existing illness (59.38%). Thus anaesthesia factor was responsible for 25% (n=8) mortalities.

In the present study, maximum critical incidents occurred due to factors related to anaesthesia (62.37%) as compared to those related to surgical factors (37.62%) and mortality were found in 10 cases among the total critical incidents in which 7 patients had pre-existing illness (70%). Out of 10 mortalities, 6 mortalities were due to anaesthesia related factors in which 5 patients had pre-existing illness. Hence, anaesthesia factor was responsible for 10% (n=1) mortalities.

CONCLUSION

In this prospective observational study, an effort was made to find out perioperative critical incidents related to perioperative mortality over one year period and find possible critical incidents attributable to anaesthesia or events leading to anaesthetic mishaps. The present study showed that anaesthesia was not solely related to perioperative mortality.

In conclusion, this study has helped to introduce the concept of voluntary reporting of critical incidents in the department of anaesthesiology of our institution. Furthermore, because it is a proactive activity (not a mortality review), it is more attractive, forward looking and should be encouraged. There might be some degree of methodological weakness in the present study because of under reporting, as the basis of the study was voluntary reporting of adverse events by attending anaesthetists. Opinions might vary on what is termed adverse events and fear of punitive measures might have undermined incident reporting. The use of checklists, protocols and improved awareness of the relevance of critical incidents can improve the safety of anaesthetic practice¹⁵.

Thus, critical incident reporting should be introduced in all anaesthesia departments as part of quality assurance programme to ensure improved patient care, as an educational tool but never as a punitive measure.

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