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Original Research Article

Influence of Anaesthesia Management Parameters on the Occurrence of Severe Morbidity and Death

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Abstract

Background: There are few quantitative assessments of how anaesthesia management affects perioperative morbidity and mortality. The authors conducted a study to determine risk variables for anaesthetic care about severe morbidity and mortality within 24 hours of surgery.

Methods: In a case-control study conducted in 2021–2022, anaesthetized patients were evaluated. Within 24 hours of being put under anaesthesia, some patients in the cases passed away or went into a coma; in contrast, the controls did not experience any of these outcomes. The Anaesthesia and Recovery Form was used to gather data, and confounder-corrected odds ratios were the result.

Results: The cohort comprised 869,483 patients; 705 cases and 711 controls were studied. The frequency of 24-hour postoperative death was 8.8 per 10,000 anaesthetics, while the rate of unconsciousness was 0.5. Some significant anaesthetic management factors associated with decreased risk were using a checklist and protocol to check equipment (odds ratio: 0.64), recording equipment checks (odds ratio: 0.61), having a direct anaesthesiologist available (odds ratio: 0.46), having the same anaesthesiologist present during anaesthesia (odds ratio: 0.44); having a full-time working anaesthetic nurse (odds ratio: 0.41); having two people present at emergence (odds ratio: 0.69); and reversing anaesthesia (odds Postoperative pain medicine also carried a lower risk profile, mainly when administered intramuscularly or epidurally as opposed to intravenously.

Conclusions: Preoperative unconsciousness and death are associated, making postoperative mortality a severe problem. Anaesthetic management factors that impact this association include using medications during and after therapy, the type of anaesthetic care given during and after surgery, and the presence of anaesthesiologists throughout the procedure.

Keywords: Medical Error, Human Factors, Patient Safety, Critical Events.

Introduction

Since the middle of the nineteenth century, there has been an emphasis on assessing the mortality caused by anaesthetic. This group comprises individuals who passed away while receiving anaesthesia care. Regularly published studies provide an excellent way to gauge patient safety during anaesthesia. A review of anaesthesia-related deaths in Australia (1997–1999) is one of the noteworthy studies [1] ,the National Confidential Enquiry into Perioperative Death (NCEPOD) in the United Kingdom [2] , the examination of mortality and morbidity over five years in 2,363,038 patients in Japan [3], the Canadian four-centre study of anaesthetic outcomes [4-6] , the prospective survey of complications associated with anaesthesia in France [6], the study on mortality linked to anaesthesia in South Africa [7] , the analysis of deaths tied to anaesthesia in Finland [8] , the anaesthesia-related-mortality assessment in a study from New Zealand [9] , and the survey on preventing intraoperative anaesthetic accidents and related severe injuries through safety monitoring in the United States [10] .

These studies provide a convincing picture of the decline in anaesthesia-related mortality during the 20th century by drawing on observations from the nineteenth century. For instance, one in nine hundred patients had died from anaesthesia-related causes by the end of the eighteenth century [11]. In the late 1950s, a significant decrease occurred, with anaesthesia-related mortality ranging from 3.1 to 6.4 per 10,000 following anaesthesia administration [12-15] .Over the last thirty years, the fatality rate connected with anaesthesia has reduced to 0.04-7 per 10,000 patients undergoing anaesthetic [16], representing a tenfold decrease in anaesthesia-related mortality since the 1980s. As a result, anaesthesiology is widely regarded as the only medical speciality with a six-sigma defect rate. According to a six-sigma approach, 99.99966% of

the "end-products" or 3.4 faults per million are statistically error-free [17].

Anaesthesia-related death rates are a finite resource; hence, assessing anaesthesia safety necessitates a comprehensive analysis of the data. The primary barrier is the absence of a clear definition for mortality associated with anaesthesia. Some authors focus primarily on perioperative deaths if the anaesthetic provider is at fault [18–20], while others encompass all potential causes of death during or following anaesthesia, including both anaesthetic and surgical factors [20,21]. Moreover, there is disagreement over the window of time following anaesthesia that defines anaesthesia-related death. Depending on the study, this time frame can range from 24 to 30 days after an anaesthetic treatment [22–24]. This variation significantly affects the prevalence estimates of death linked to anaesthesia. To agree on a definition, experts in an International Symposium held in Vancouver in 1985 defined anaesthetic mortality as “death occurring before recovery from the effects of a drug or drugs given to relieve the pain of a condition or arising from an incident that occurred while the drug was effective” [25].

However, neither this criterion nor those that came after have received enough endorsement or consensus to be recognized as industry standards in mortality reporting and research about anaesthesia. Another limitation relates to the peer-review process. Expert review panels often look at specific instances to see whether anaesthesia has a role in mortality. At the same time, there is a lot of disagreement among reviewers about what constitutes an adverse outcome. Certain research indicates that there were times when reviewers' agreement on the standard of care was only marginally better than chance [26-27]. As such, the precise numbers of mortality associated with anaesthesia remain unknown. The equation's denominator's measurement is the subject of the fourth restriction. Most of the research uses questionnaires, volunteer reports, coroners' registries, and malpractice lawsuits as their primary sources of information regarding preoperative deaths. Because of this, it is uncertain how many patients were anaesthetized overall, which is the denominator of the mortality equation; estimations of the total number of patients undergoing a surgical operation where anaesthesia is probably going to be required, as well as estimates of patients being released from both public and private hospitals, are frequently employed. This reliance on approximations has given rise to several debates in the literature on anaesthesia [28,29].

Finally, the Anaesthesia Patient Safety Foundation's definition of patient safety during anaesthesia ensuring that "no patient should be affected by anaesthesia" does not accurately correspond with anaesthesia-related mortality. In addition, harm encompasses anaesthesia-related morbidity, which ought to be investigated in conjunction with anaesthesia-related mortality to determine the actual degree of patient safety during anaesthesia [28,29].

Materials and Methods

The cohort included all patients in India [Balasore, Odisha] who underwent anaesthesia between January 2021 and December 2022. The study sought to identify a 5–15% risk increase with 90% power and a 5% significance level, assuming a prevalence of anaesthesia management risk factors at 5% and a preoperative death incidence of 1:10,000. However, the study was limited to selecting Indian hospitals [Balasore, Odisha] for logistical and practical reasons.

Study Design

A case-control design was selected since the goal of the study was to perform a quantitative, systematic analysis and because unintended comas connected to anaesthesia-related deaths are uncommon. This method is more effective than a full-cohort study since it selects controls for comparison and finds all cases with the desired result. It also allows for establishing the etiologic connection between the result and additional risk variables. As the entire cohort's data is available, absolute incident rates can also be determined [30–33]. The preoperative outcomes of particular interest to this investigation were severe morbidity and mortality. Mortality was defined as passing away during or within 24 hours of anaesthesia, whereas unintended coma lasting 24 hours following anaesthesia was indicative of severe morbidity. Patients in comas or who passed away, regardless of the apparent cause, were included in the cases. Patients who were randomly chosen from the cohort, matched for sex, and in the same 5-year age range but who neither died nor remained unconscious following anaesthesia served as controls.

Data Collection

The hospitals selected between January 2021 and December 2022 received a research protocol. Anaesthesiologists and the medical staff committee must approve each institution. It was suggested that the anaesthesiologists contact a medical staff member ideally not another anaesthesiologist to function as a "correspondent" or a point of communication between the investigators and the anaesthesiologists. Every hospital, control group, and case in the research centre had a unique number accessible only by the principal investigator. The anaesthesiologist and the patient can maintain anonymity if they communicate through the same person in all correspondence. The procedure questionnaire, the hospital characteristics questionnaire, and the anaesthesia and recovery

forms were the two structured questionnaires used to collect the data. At the beginning and end of the experiment, each participating institution submitted a questionnaire about hospital characteristics that included information on anaesthetic practises and hospital qualities. This allowed for assessing the prevalence of severe morbidity and mortality within 24 hours and accounting for notable modifications in anaesthetic practice within the data analysis.

Statistical Analysis

Since there were too few comatose patients to analyse separately and because every one of the initial comatose patients passed away in the hospital, the analysis was conducted jointly on all cases (n = 705) and controls (n = 711). Depending on the circumstance, the student t-test, chi-square test or Mann-Whitney U test and SPSS were used to compare anaesthesia, hospital, procedure and patient variables. The determinants were revaluated if the variable seemed significant or if the two-sided p-values in the univariate analysis were less than 0.25. Multivariable logistic regression was used to adjust the determinants' risk estimates for covariates. Hosmer's approach was used to investigate potential confounders for each significant predictor in the univariate research using multivariable logistic regression [34].

Ethical Approval

Patients were told, verbally, in writing, or both, that the hospital was doing a study to raise the standard of care for every patient getting anaesthesia. Patients were informed about the trial and granted their consent consequently.

Results

The study had 705 cases and 711 controls, all sedated for a surgical procedure, except five pers. The attributes of the patients, the surgical process, the anaesthetic approach, and the hospital details are delineated (Fig. 1 & Table 1). As anticipated, in contrast to controls, a greater percentage of cases exhibited a severe classification, according to the American Society of Anaesthesiologists. As expected, despite the study being structured to impartially select controls without favouring specific criteria such as time, type, complexity, or urgency of operation, controls tended to undergo minor, elective procedures more frequently, particularly during regular working hours. The average duration of the procedures differed significantly between cases and controls (mean difference, 1.18 h; SE, 0.10; $p<0.01$). This discrepancy was linked to the nature of surgical interventions, with cases more commonly undergoing cardiac and major vascular procedures. At the same time, controls opted for orthopaedic, urologic, and ophthalmologic procedures more often.

1. There was a total of 705 reported cases. Among them, 609 succumbed within 24 hours, while 49 remained in an unconscious state, ultimately meeting the same fate within the confines of the hospital. Across the study area and duration, the recorded count of administered anaesthetics reached 869,483. The projected incidence of 24-hour postoperative mortality stood at 8.8 (95% CI, 8.2–9.5) per 10,000 anaesthetics, with a parallel estimated incidence of 24-hour postoperative coma at 0.5 (95% CI, 0.3–0.6)

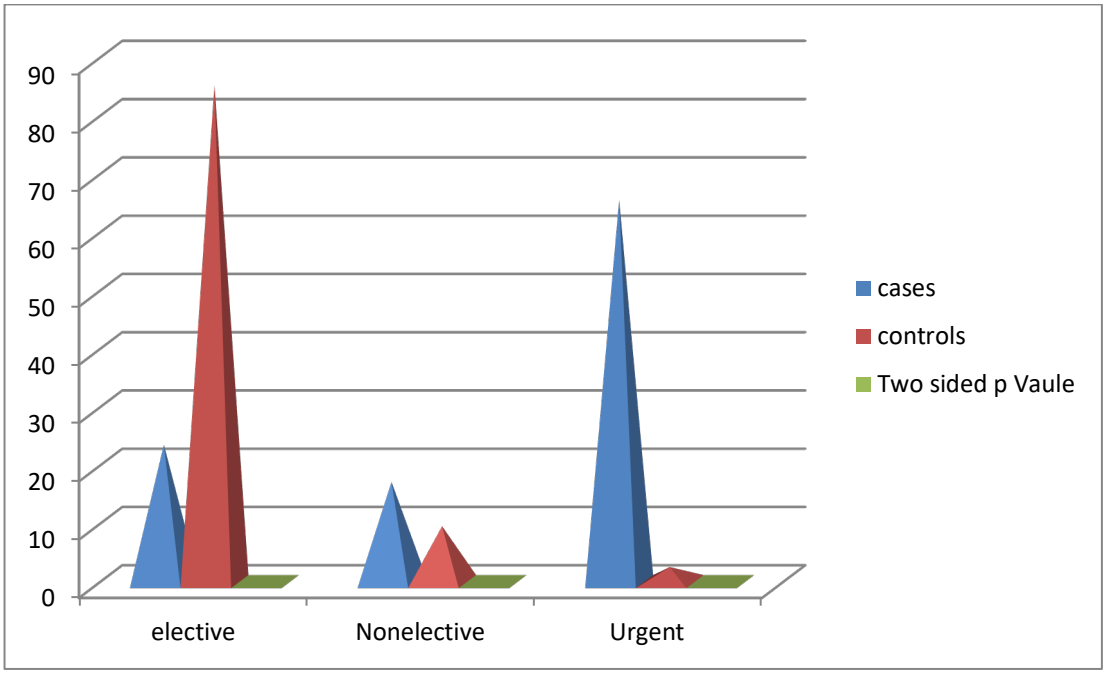

Figure A: Urgency of procedure

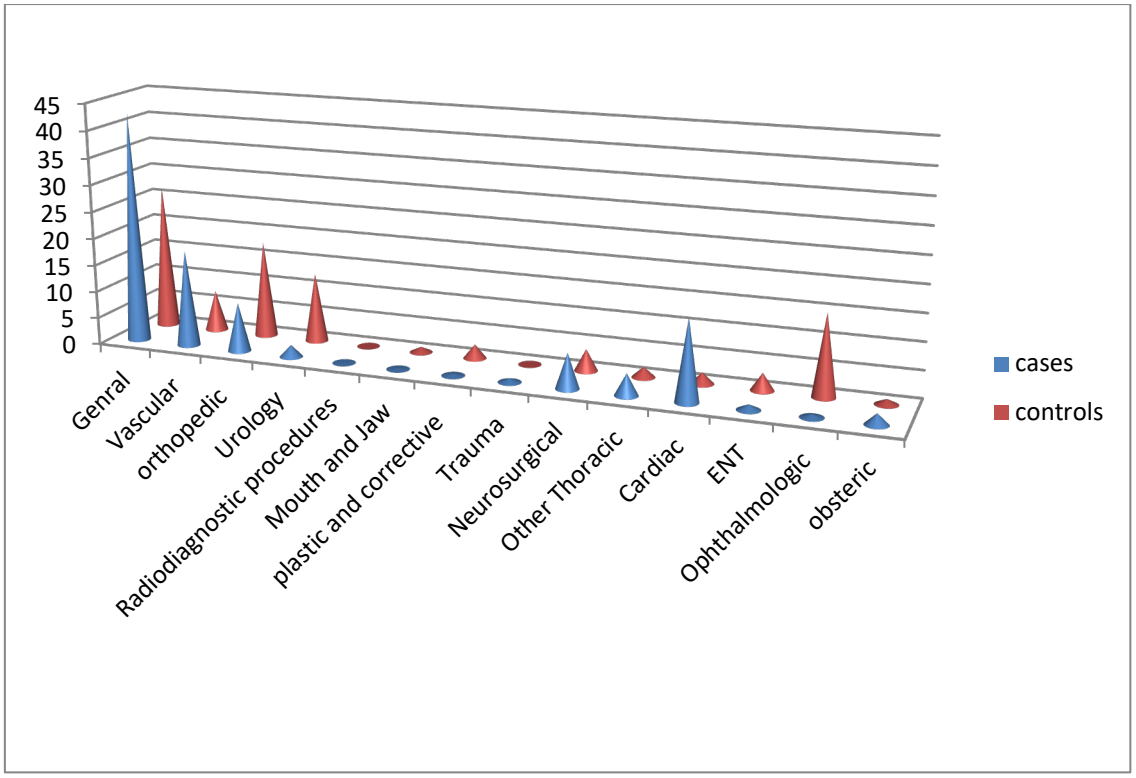

Figure B: Type of surgery

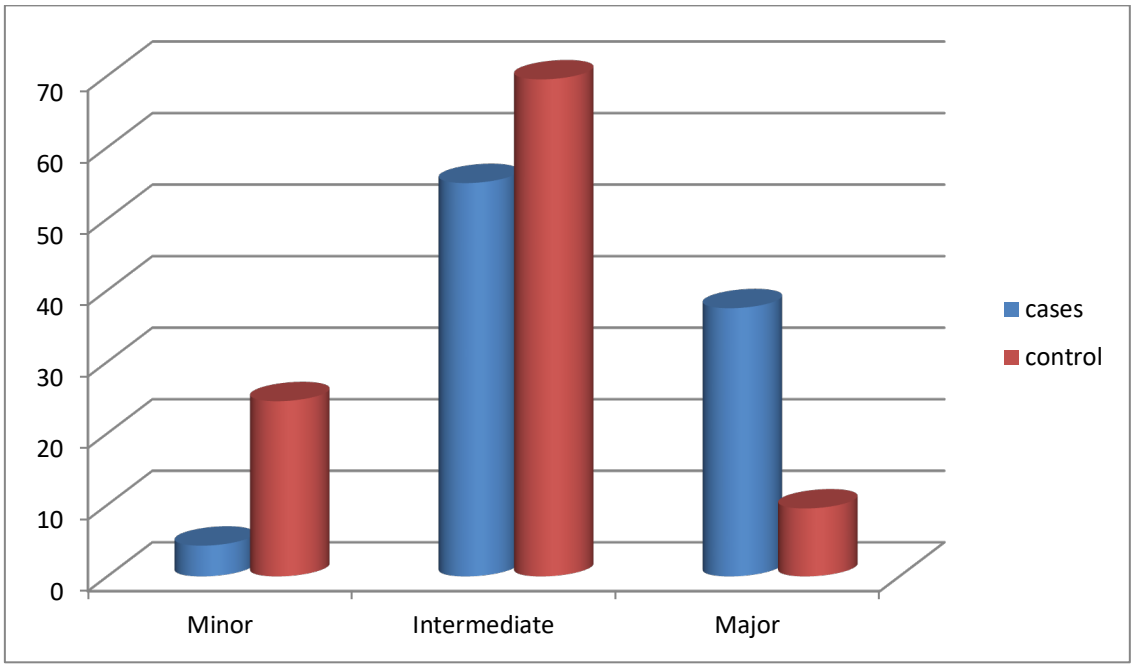

Figure C: Anaesthetic techniques

Figure 1 Characteristics of the Surgical Procedure

Preoperative, Intra-operative and Postoperative Anaesthesia Management Risk Factors

Performing equipment checks with a checklist and protocol reduced the risk of preoperative morbidity and mortality (odds ratio, 0.67; 95% CI, 0.43–0.95). Documenting the check odds and having direct intercom availability for the anaesthesiologist during maintenance (odds ratio, 0.49; 95% CI, 0.32–0.55) were associated with lower risk. No intraoperative change of anaesthesiologist (odds ratio, 0.44; 95% CI, 0.20–0.99) also decreased risk. In postoperative care, intramuscular opiates (odds ratio, 0.13; 95% CI, 0.07–0.34) and epidural pain medication (odds ratio, 0.23; 95% CI, 0.06–0.89) significantly lowered the risk of coma or death compared to intravenous administration.

Table: 1 Anaesthetic techniques, cases, and controls

Anaesthetic techniques	cases	Controls
Regional	3.7	19.5
Regional with sedation	3.5	16.8
Inhalational	8.5	11.1
Inhalational with sedation	1	2.1
Sedation	0.1	0.3
Regional with combined technique	0.7	1.5
Regional with total intravenous	4.5	7.6
Regional with inhalational	1.4	2.8
Combined intravenous and inhalational	48.5	31.5
Total intravenous	27.2	11.3

Discussion

This study demonstrated a correlation between several parameters, such as the availability of anaesthesiologists, the use of medications before, during, and following surgery, the quality of anaesthetic treatment provided, and preoperative coma and death. This case-control study is noteworthy for being the first to statistically evaluate several perioperative death risk factors linked to anaesthetic medication. The validity of the case-control approach is jeopardized despite its benefits by issues with locating the source population and selecting cases and controls. It is critical to guarantee that case ascertainment maintains objectivity about the parameters being examined in this case, the risk factors related to anaesthesia treatment.

To achieve this, we decided to include all cases of perioperative mortality and coma in the research area, avoiding selection bias at the hospital level. By doing this, we could verify that the controls were chosen from the same study population as the cases, enabling us to estimate the risk exposure in the community accurately. Our study population was limited to a certain region and time frame, and we only examined extreme outcomes. This approach raises the likelihood of comprehensive data collection and reduces the possibility of a muddled link between risk factors and outcomes.

To obtain an average similarity in the age and sex distributions, controls and cases were closely matched. It is important to remember that multivariate regression analysis was utilized to adjust for confounding; the primary goal of the matching was to improve statistical efficiency. The age and sex of the patients were the only factors matched; matching based on other patient characteristics or the type of procedure was purposefully avoided as it may enhance bias rather than decrease it. Furthermore, reaching by the physical state classification system of the American Society of Anaesthesiologists would complicate the examination of the matching factor as a possible risk factor [30–33].

This study employed a voluntary reporting system to address potential selection bias and underreporting. To discourage preferred reporting, preoperative coma and death instances had to be fully reported, and anonymity-protecting measures had to be put in place. About 27% of the institutions implemented a check procedure to estimate underreporting. The study extensively analysed the potential implications of underreporting on relationships between anaesthesia management characteristics and outcomes to assure the findings' reliability. It found no evidence of selective underreporting in committee inspections conducted at several universities.

Anaesthesiologists' recollections can differ between cases and controls. By limiting the postoperative stay to 24 hours and maintaining comparability between the two groups, we could minimize this. We used unique identifying numbers and cross-referenced the questionnaire with the anaesthetic and recovery form, completed upon admission to the study centre, to gather more data. Errors in form documentation can still happen in circumstances where memories are limited. Through a stringent introductory period, frequent meetings, and newsletters, we hoped to improve compliance, increase enthusiasm, and lessen fear of legal implications—all of which would help to eliminate selectivity in preoperative recording.

On the other hand, this bias would probably underestimate impacts if selectivity existed. Our main area of interest was the connection between preoperative coma or death and risk variables associated with anaesthesia management. To provide a cross-check, the 200-question survey on anaesthetic management included repeated questions for about 10% of risk factors. Furthermore, the anaesthetic and recovery form validated a significant percentage of the questionnaire components.

Our etiologic study relied heavily on the biological and practical plausibility of an anaesthetic risk factor in routine anaesthetic practise and its interplay with confounders. According to our research, there was less danger when equipment was inspected using a

checklist and methodology. Since establishing a list for these tests, there has been concern over the frequent neglect to perform appropriate preoperative checks of anaesthetic equipment. This is the case despite most anaesthesiologists knowing the guidelines and how important it is to check anaesthesia equipment before using it. Kendall et al. found that 60–82.5% of the machines they looked at had at least one problem, with 11–18% categorized as severe. [30] According to several academics, the primary cause of noncompliance with the rules is that they are too time-consuming [35].

Thus, the anaesthetic care team's expertise, training, and composition may influence this risk factor. We were dependent on a system of voluntary reporting. Therefore, bias might have been introduced. First, per the literature, one would anticipate that there would not have been enough time to properly conduct and record an equipment check in the non-elective and urgent operations. Secondly, there might have been a propensity to provide the "right" replies, particularly in the case of the anaesthesia-related deaths of patients. But in such a scenario, there would no longer be a risk difference between the patients and the controls. Investigators of catastrophic incidents also commonly mentioned neglecting to do an equipment check as a risk factor [36,37]. This likely relates to overall treatment quality and the real equipment failure that occurs in 15–20% of procedures, as stated.

Conclusion

In conclusion, perioperative mortality and morbidity continue to present significant challenges within the medical landscape. There is a pressing need for enhanced etiologic insight into the intricacies of anaesthetic management to identify better and address potential preventive measures. As certain aspects of anaesthetic management play a pivotal role in adverse events, further research and concerted efforts toward refining preventive strategies are essential to advance patient safety and optimize perioperative outcomes.

References

1. Australian New Zealand College of Anaesthetists Safety of anaesthesia in Australia. In Mackay P (Ed.). A review of Anaesthesia related mortality 1997–1999. Melbourne: Australian and New Zealand College of Anaesthetists, 2002.
2. Lunn JN. The National confidential enquiry into perioperative deaths. Journal of clinical monitoring 1994; 10: 426–428.
3. Kawashima Y, Takahashi S, Suzuki M et al. Anaesthesia-related mortality and morbidity over a 5-year period in 2,363,038 patients in Japan. Acta Anaesthesiologica Scandinavica 2003; 47: 809–817.
4. Cohen MM, Duncan PG, Tweed WA et al. The Canadian four-centre study of anaesthetic outcomes: I. Description of methods and populations. Canadian Journal of Anaesthesia 1992; 39: 420–429.
5. Cohen MM, Duncan PG, Pope WD et al. The Canadian four-centre study of anaesthetic outcomes: II. Can outcomes be used to assess the quality of anaesthesia care? Canadian Journal of Anaesthesia 1992; 39: 430–439.
6. Tiret L, Desmonts JM, Hatton F & Vourc'h G. Complications associated with anaesthesia–a prospective survey in France. Canadian Anaesthesia Society Journal 1986; 33: 336–344.
7. Coetzee A. Mortality associated with anaesthesia. South African Medical Journal 1996; 86: 973–976.
8. Tikkanen J & Hovi-Viander M. Death associated with anaesthesia and surgery in Finland in 1986 compared to 1975. Acta Anaesthesiologica Scandinavica 1995; 39: 262–267.
9. Gibbs JM. The anaesthetic mortality assessment committee 1979–1984. N Z Med J 1986; 99:55–59.
10. Eichhorn JH. Prevention of intraoperative anaesthesia accidents and related severe injury through safety monitoring. Anaesthesiology 1989; 70: 572–577.
11. Brown DL. Risk and outcome in anaesthesia. 2nd ed. Philadelphia: Lippincott, 1992
12. Beecher HK & Todd DP. A study of the deaths associated with anaesthesia and surgery: based on a study of 599,548 anaesthesias in ten institutions 1948-1952, inclusive. Annals of Surgery 1954; 140: 2–35.
13. Memery HN. Anaesthesia mortality in private practice. A ten-year study. Journal of the American Medical Association 1965; 194: 1185–1188.
14. Arbous MS, Meursing AE, van Kleef JW et al. Impact of anaesthesia management characteristics on severe morbidity and mortality. Anaesthesiology 2005; 102: 257–268. quiz 491–2.
15. Varkey P, Reller MK & Resar RK. Basics of quality improvement in health care. Mayo Clinic Proceedings 2007; 82: 735–739.
16. Arbous MS, Grobbee DE, van Kleef JW et al. Mortality associated with anaesthesia: a qualitative analysis to identify risk factors. Anaesthesia 2001; 56: 1141–1153.
17. Lagasse RS, Steinberg ES, Katz RI & Saubermann AJ. Defining quality of perioperative care by statistical process control of adverse outcomes. Anaesthesiology 1995; 82: 1181–1188.
18. Chopra V, Bovill JG & Spierdijk J. Accidents, near accidents and complications during

anaesthesia. A retrospective analysis of a 10-year period in a teaching hospital. Anaesthesia 1990;45: 3–6.
19. Pedersen T & Johansen SH. Serious morbidity attributable to anaesthesia. Considerations for prevention. Anaesthesia 1989; 44: 504–508.
20. Devlin HB & Lunn JN. Confidential inquiry into perioperative deaths. British Medical Journal (Clin Res Ed) 1986; 292: 1622–1623.
21. Warden JC & Horan BF. Deaths attributed to anaesthesia in New South Wales, 1984–1990. Anaesthesia & Intensive Care 1996; 24: 66–73.
22. Eagle CJ & Davies JM. Current models of "quality"–an introduction for anaesthetists. Canadian Journal of Anaesthesia 1993; 40: 851 –862.
23. Lagasse RS. Anaesthesia safety: model or myth? A review of the published literature and analysis of current original data. Anaesthesiology 2002; 97: 1609–1617.
24. Walker JS. Quality and safety in anaesthesia. London: BMJ Pub. Group, 1994.
25. Goldman RL. The reliability of peer assessments of quality of care. Journal of the American Medical Association 1992; 267: 958–960.
26. Cooper JB & Gaba D. No myth: anaesthesia is a model for addressing patient safety. Anaesthesiology 2002; 97: 1335–1337.
27. Anaesthesia Patient Safety Foundation (APS). Available at: http://www.apsf.org/about_ history.php. [accessed 14.11.23].
28. Kent M. The Oxford dictionary of sports science and medicine. Oxford; New York: Oxford University Press, 1994.
29. Derrington MC & Smith G. A review of studies of anaesthetic risk, morbidity and mortality. British Journal of Anaesthesia 1987; 59: 815–833
30. Miettinen OS: Design of sampling of the base, Theoretical Epidemiology. Edited by Miettinen OSM. New York, John Wiley & Sons, 1985, pp 69–83
31. Miettinen OS: The "case-control" study: Valid selection of subjects. J Chronic Dis 1985; 38: 543–8
32. Wacholder S, McLaughlin JK, Silverman DT, Mandel JS: Selection of controls in case-control studies: I. Principles. Am J Epidemiol 1992; 135:1019–28
33. . Rothman KJ, Greenland S: Case-control studies, Modern Epidemiology, 2nd edition. By Rothman KJ, Greenland S. Philadelphia, Lippincott–Raven, 1998, pp 93–114
34. Hosmer DW, Lemeshow S: Model building strategies, Applied Logistic Regression, 2nd edition. By Hosmer DW, Lemeshow S. New York, John Wiley & Sons, 2000, pp 91–142
35. Zorab JSM: Anaesthetic machine checking practices (letter). Anaesthesia 1993; 48:267
36. Kumar V, Barcellos WA, Mehta MP, Carter JG: An analysis of critical incidents in a teaching department for quality assurance: A survey of mishaps during anaesthesia. Anaesthesia 19 88; 43:879–83
37. Chopra V, Bovill JG, Spierdijk J: Accidents, near accidents, and complications during anaesthesia: A retrospective analysis of a 10-year period in a teaching hospital. Anaesthesia 19 90; 45:3–6.